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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 March 31, 2023

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 **(State or other jurisdiction of incorporation or organization)**	**76-0837053** **(IRS Employer Identification No.)**
355 Alhambra Circle **Suite 801** **Coral Gables, Florida** **(Address of principal executive offices)**	**33134** **(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 106,076,959 shares of common stock, $0.001 par value per share, were outstanding as of May 8, 2023.

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CATALYST PHARMACEUTICALS, INC.

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

	March 31, 2023 (unaudited)	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 148,247	$ 298,395
Accounts receivable, net	33,402	10,439
Inventory	10,328	6,805
Prepaid expenses and other current assets	6,934	5,167
Total current assets	198,911	320,806
Operating lease right-of-use asset	2,706	2,770
Property and equipment, net	1,285	847
License and acquired intangibles, net	184,083	32,471
Deferred tax assets, net	20,242	18,736
Total assets	$ 407,227	$ 375,630
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,391	$ 3,975
Accrued expenses and other liabilities	53,318	53,613
Total current liabilities	56,709	57,588
Operating lease liability, net of current portion	3,468	3,557
Other non-current liabilities	13,389	14,064
Total liabilities	73,566	75,209
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized: none issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized; 105,938,292 shares and 105,263,031 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	106	105
Additional paid-in capital	254,114	250,430
Retained earnings	79,430	49,862
Accumulated other comprehensive income	11	24
Total stockholders' equity	333,661	300,421
Total liabilities and stockholders' equity	$ 407,227	$ 375,630

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

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

	For the Three Months Ended March 31, 2023	For the Three Months Ended March 31, 2022
Revenues:		
Product revenue, net	$ 85,304	$ 43,033
License and other revenue	62	56
Total revenues	85,366	43,089
Operating costs and expenses:		
Cost of sales (a)	9,946	5,890
Research and development	3,562	3,403
Selling, general and administrative (a)	29,718	16,430
Amortization of intangible assets	6,531	—
Total operating costs and expenses	49,757	25,723
Operating income	35,609	17,366
Other income, net	1,704	93
Net income before income taxes	37,313	17,459
Income tax provision	7,745	4,218
Net income	$ 29,568	$ 13,241
Net income per share:		
Basic	$ 0.28	$ 0.13
Diluted	$ 0.26	$ 0.12
Weighted average shares outstanding:		
Basic	105,561,229	102,781,771
Diluted	113,986,129	109,041,096
Net income	$ 29,568	$ 13,241
Other comprehensive income:		
Unrealized gain (loss) on available-for-sale securities, net of tax of $5 and $94, respectively	(13)	(305)
Comprehensive income	$ 29,555	$ 12,936

(a) exclusive of amortization of intangible assets

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 months ended March 31, 2023 and 2022
(in thousands)

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Gain (Loss)	Total
Balance at December 31, 2022	$ —	105,263	$ 105	$250,430	$ 49,862	$ 24	$300,421
Issuance of stock options for services	—	—	—	2,177	—	—	2,177
Exercise of stock options for common stock	—	548	1	1,269	—	—	1,270
Amortization of restricted stock for services	—	—	—	715	—	—	715
Issuance of common stock upon vesting of restricted stock units, net	—	127	—	(477)	—	—	(477)
Other comprehensive gain (loss)	—	—	—	—	—	(13)	(13)
Net income	—	—	—	—	29,568	—	29,568
Balance at March 31, 2023	$ —	105,938	$ 106	$254,114	$ 79,430	$ 11	$333,661

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total
Balance at December 31, 2021	$ —	102,993	$ 103	$233,186	$ (26,310)	$ (148)	$206,831
Issuance of stock options for services	—	—	—	1,623	—	—	1,623
Exercise of stock options for common stock	—	364	—	1,102	—	—	1,102
Amortization of restricted stock for services	—	—	—	280	—	—	280
Repurchase of common stock	—	(400)	—	—	(2,551)	—	(2,551)
Other comprehensive gain (loss)	—	—	—	—	—	(305)	(305)
Net income	—	—	—	—	13,241	—	13,241
Balance at March 31, 2022	$ —	102,957	$ 103	$236,191	$ (15,620)	$ (453)	$220,221

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 Three Months Ended March 31, 2023	2022
Operating Activities:		
Net income	$ 29,568	$ 13,241
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation	69	34
Stock-based compensation	2,892	1,903
Amortization of intangible assets	6,531	—
Deferred taxes	(1,519)	1,901
Change in accrued interest and accretion of discount on investments	—	(2)
Reduction in the carrying amount of right-of-use asset	64	60
Acquired inventory samples expensed from asset acquisition	130	—
(Increase) decrease in:		
Accounts receivable, net	(22,963)	(3,933)
Inventory	577	43
Prepaid expenses and other current assets	(191)	(563)
Increase (decrease) in:		
Accounts payable	(584)	2,371
Accrued expenses and other liabilities	(2,422)	(6,504)
Operating lease liability	(82)	(73)
Net cash provided by (used in) operating activities	12,070	8,478
Investing Activities:		
Purchases of property and equipment	(74)	—
Payment in connection with asset acquisition	(162,293)	—
Net cash provided by (used in) investing activities	(162,367)	—
Financing Activities:		
Payment of employee withholding tax related to stock-based compensation	(477)	—
Proceeds from exercise of stock options	1,270	1,000
Repurchase of common stock	—	(2,551)
Payment of liabilities arising from asset acquisition	(644)	—
Net cash provided by (used in) financing activities	149	(1,551)
Net increase (decrease) in cash and cash equivalents	(150,148)	6,927
Cash and cash equivalents – beginning of period	298,395	171,445
Cash and cash equivalents – end of period	$ 148,247	$178,372
Supplemental disclosures of cash flow information:		
Cash paid for income taxes	$ —	$ 41
Non-cash investing and financing activities:		
Proceeds from exercise of stock options not yet settled at end of period	$ —	$ 102
Liabilities arising from asset acquisition	$ 1,915	$ —

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 biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases and diseases that are difficult to treat. With exceptional patient focus, is committed to developing and commercializing innovative first-in-class medicines that address rare neurological and epileptic diseases.

Catalyst's New Drug Application for FIRDAPSE® (amifampridine) Tablets 10 mg for the treatment of adults with Lambert-Eaton myasthenic syndrome (LEMS) was approved in 2018 by the U.S. Food & Drug Administration (FDA), and FIRDAPSE® is commercially available in the United States as a treatment for adults with LEMS. Further, Canada's national healthcare regulatory agency, Health Canada, approved the use of FIRDAPSE® for the treatment of adult patients in Canada with LEMS in 2020 and FIRDAPSE® is commercially available in Canada for the treatment of patients with LEMS through a license and supply agreement with KYE Pharmaceuticals. Finally, in the third quarter of 2022, the FDA approved the Company's sNDA approving an expansion of the FIRDAPSE® label to include pediatric patients (ages six and older).

On December 17, 2022, the Company entered into an asset purchase agreement with Eisai Co., Ltd. (Eisai) for the acquisition of the United States rights to FYCOMPA® (perampanel) CIII, a prescription medication used alone or in combination with other medicines to treat focal onset seizures with or without secondarily generalized seizures in people with epilepsy aged four and older and with other medicines to treat primary generalized tonic-clonic seizures in people with epilepsy aged 12 and older. The Company closed the acquisition of FYCOMPA® on January 24, 2023 and the Company is marketing FYCOMPA® in the United States.

Since inception, the Company has devoted substantially all its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, raising capital, and selling its products. The Company incurred operating losses in each period from inception and started reporting operating income during the year ended December 31, 2019. The Company has been able to fund its cash needs to date through offerings of its securities and from revenues from sales of its products. See Note 15 (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 operations for at least the next 12 months from the issuance date of this report.

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 business development activities, 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 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, 2022 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, 2022 included in the 2022 Annual Report on Form 10-K filed by the Company with the SEC. The results of operations for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for any future period or for the full 2023 fiscal year.

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 consolidated 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 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 March 31, 2023 and December 31, 2022, investments consisted of U.S. Treasuries. Such investments are not insured by the Federal Deposit Insurance Corporation.

The U.S. Treasuries held at March 31, 2023 are classified as available-for-sale securities. 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 its consolidated balance sheets. There are no short-term or non-current investments as of March 31, 2023 and December 31, 2022.

The Company records available-for-sale securities at fair value with unrealized gains and losses reported in accumulated other comprehensive income (in stockholders' equity). Realized gains and losses are included in other income, net in the consolidated statements of operations and comprehensive income, 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 losses based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. At March 31, 2023 and December 31, 2022, the Company determined that an allowance for expected credit losses was not required. No accounts were written off during the periods presented.

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

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. 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.

Products that have been approved by the FDA or other regulatory authorities, such as FIRDAPSE® and FYCOMPA®, 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 forms of FIRDAPSE® and FYCOMPA® 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”.

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. **PROPERTY AND EQUIPMENT, NET.** Property and equipment are recorded at cost less accumulated depreciation. Depreciation is calculated to amortize the depreciable assets over their useful lives using the straight-line method and commences when the asset is placed in service. Leasehold improvements are amortized on a straight-line basis over the term of the lease or the estimated life of the improvement, whichever is shorter. Useful lives generally range from three to five years for computer equipment and software, from five to seven years for furniture and equipment, and from five to ten years for leasehold improvements. Expenditures for repairs and maintenance are charged to expenses as incurred.

j. **BUSINESS COMBINATIONS AND ASSET ACQUISITIONS**. The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet the requirements of a business. If determined to be an asset acquisition, the Company accounts for the transaction under ASC 805-50, which requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes transaction costs in addition to consideration given. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values. Contingent consideration payments in asset acquisitions are recognized when the contingency is resolved and the consideration is paid or becomes payable.

Refer to Notes 12 (Commitments and Contingencies) and 13 (Agreements) for further discussion on the Company’s exclusive license agreement with Jacobus Pharmaceutical Company, Inc (Jacobus), for the rights to develop and commercialize RUZURGI® in the United States and Mexico, which the Company accounted for as an asset acquisition under ASC 805-50. Refer to Note 13 (Agreements) for further discussion on the Company’s acquisition of the U.S. rights of FYCOMPA® from Eisai Co., Ltd, which the Company accounted for as an asset acquisition under ASC 805-50.

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

k. **INTANGIBLE ASSETS, NET.** Identifiable intangible assets with a finite life are comprised of licensed rights and other acquired intangible assets and are amortized on a straight-line basis over the respective estimated useful life.

The Company reviews intangible assets with finite lives for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment exist, an impairment test is performed to assess the recoverability of the affected assets by determining whether the carrying amount of such assets exceeds the undiscounted expected future cash flows. If the affected assets are deemed not recoverable, the Company would estimate the fair value of the assets and record an impairment loss.

l. **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 March 31, 2023 and December 31, 2022, the fair value of these instruments approximated their carrying value.

m. **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 March 31, 2023	**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	$ 12,373	$ 12,373	$ —	$ —
U.S. Treasuries	$ 115,785	$ 115,785	$ —	$ —

	Balances as of December 31, 2022	**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	$ 168,853	$ 168,853	$ —	$ —
U.S. Treasuries	$ 105,442	$ 105,442	$ —	$ —

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

n. 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.

o. 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 retained earnings (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.

p. REVENUE RECOGNITION.

Product Revenues:

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 assesses the goods or services promised within each contract and determines those that are performance obligations by assessing 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.

The Company recognizes revenue when its customer and FYCOMPA® customers 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. For FIRDAPSE®, 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®. The Company sells FYCOMPA®, through a Transition Service Agreement with Eisai, directly to major wholesalers, specialty pharmaceutical distributors, managed care organizations, and government agencies. FYCOMPA® customer contracts generally consist of both a master agreement, which is signed by the Company and its customer, and a customer submitted purchase order, which is governed by the terms and conditions of the master agreement. These customers purchase FYCOMPA® product by direct channel sales from the Company or by indirect channel sales through various distribution channels.

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

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. The Company sells FYCOMPA® directly to customers subject to both master agreements and purchase orders. In addition to the distribution agreement with its Customer and FYCOMPA® customer contracts, 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.

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 months ended March 31, 2023 and 2022.

During the three months ended March 31, 2023 and 2022, substantially all of the Company's product revenues were from sales to customers in the United States.

The following table summarizes the Company's net product revenue disaggregated by product (in thousands):

	For the Three Months Ended March 31,	
	2023	2022
FIRDAPSE®	$ 57,526	$ 43,033
FYCOMPA®	27,778	—
Total product revenue, net	$ 85,304	$ 43,033

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, FYCOMPA® customers, 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 FYCOMPA® customers) or a current liability (if the amount is payable to a party other than a Customer or FYCOMPA® customers).

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.

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

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 March 31, 2023 and, therefore, the transaction price was not reduced further during the three months ended March 31, 2023 and 2022. 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, Allowances and Wholesaler Fees: The Company provides its Customer and FYCOMPA® customers 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 its Customer and the sale of FYCOMPA® to its customers, 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 are not distinct from the Company's sale of products to the Customer or FYCOMPA® customers, these payments have been recorded as a reduction of revenue within the consolidated statements of operations and comprehensive income through March 31, 2023 and 2022, as well as a reduction to accounts receivable, net on the consolidated balance sheets.

Prompt Payment Discounts: The Company provides its Customer and FYCOMPA® customers 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.

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 its products, that have 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, its distributor, and FYCOMPA® customers 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 or master agreement. The Company estimates the amount of its product sales that may be returned by its Customer or FYCOMPA® customers 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.

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

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 paid for the product and the ultimate selling price to the qualified healthcare providers. The Company also participates in programs with government entities and other parties, including covered entities under the 340B Drug Pricing Program, whereby pricing on FYCOMPA® is extended below wholesaler list price to participating entities (the FYCOMPA® Participants). These entities purchase FYCOMPA® through wholesalers at the lower program price and the wholesalers then charge the Company the difference between their acquisition cost and the lower program price.

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 or at the time of a resale to a FYCOMPA® Participant by a wholesaler, and the Company generally issues credits for such amounts within a few weeks of the Customer's or wholesalers' notification to the Company of the resale. Reserves for chargebacks consist primarily of chargebacks that the Customer or wholesalers have 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® or FYCOMPA® free of charge for longer periods of time for those who are uninsured or functionally uninsured with respect to FIRDAPSE® or FYCOMPA® because they are unable to obtain coverage from their payor despite having health insurance, to the extent allowed by applicable law.

The Company provides FYCOMPA® free of charge to uninsured patients who satisfy pre-established criteria through a Patient Assistance Program. In addition, Catalyst provides programs to assist patients through the process for obtaining reimbursement approval for their FYCOMPA® prescriptions from their insurers. Catalyst also provides support for patients using FYCOMPA® through an Instant Savings Card Program.

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.

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

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.

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.

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.

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 11 (Collaborative and Licensing Arrangements), for further discussion on the Company’s collaborative and licensing arrangements.

q. **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.

r. **ADVERTISING EXPENSE.** Advertising costs are expensed as incurred. The Company incurred $1.7 million and $0.7 million in advertising costs during the three months ended March 31, 2023 and 2022, respectively, which are included in selling, general and administrative expenses in the Company’s consolidated statements of operations and comprehensive income.

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

s. STOCK-BASED COMPENSATION. The Company recognizes expense in the consolidated statements of operations for the grant date 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.

t. 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, FIRDAPSE®, 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.

As of March 31, 2023, the Company had two products, which makes it difficult to evaluate its current business, predict its future prospects, and forecast financial performance and growth. The Company had invested a significant portion of its efforts and financial resources in the development and commercialization of its lead product, FIRDAPSE®. The Company expects FIRDAPSE® and the recently acquired product FYCOMPA® to constitute virtually all of the Company’s product revenue for the foreseeable future.

The Company relies exclusively on third parties to formulate and manufacture FIRDAPSE®, FYCOMPA® and any future drug candidates. The commercialization of FIRDAPSE®, FYCOMPA®, 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.

u. ROYALTIES. Royalties incurred in connection with the Company’s license agreement for FIRDAPSE®, as disclosed in Note 13 (Agreements), are expensed to cost of sales as revenue from product sales is recognized.

Royalties incurred in connection with the Company’s license agreement for RUZURGI®, as disclosed in Note 13 (Agreements), are expensed to cost of sales as revenue from product sales is recognized for any royalties in excess of the minimum annual royalty payment from the effective date of the agreement through 2025. The minimum royalty payment that exists annually for calendar years from the Effective Date through 2025 of $3 million are included in the purchase price of the agreement.

v. 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 2019. 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.

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

w. **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 months ended March 31, 2023 and 2022, and is comprised of net unrealized gains (losses) on the Company's available-for-sale securities.

x. **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.

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

	For the Three Months Ended March 31, 2023	For the Three Months Ended March 31, 2022
Basic weighted average common shares outstanding	105,561,229	102,781,771
Effect of dilutive securities	8,424,900	6,259,325
Diluted weighted average common shares outstanding	113,986,129	109,041,096

Outstanding common stock equivalents totaling approximately 1.3 million and 2.3 million, were excluded from the calculation of diluted net income per common share for the three months ended March 31, 2023 and 2022, respectively, as their effect would be anti-dilutive.

y. **SEGMENT INFORMATION.** Management has determined that the Company operates in one reportable segment, which is the development and commercialization of drug products.

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

aa. **RECENTLY ISSUED ACCOUNTING STANDARDS.** The Company did not adopt any accounting standards during the three-month period ending March 31, 2023.

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 March 31, 2023:				
U.S. Treasuries - Cash equivalents	$115,785	$ 14	$ —	$115,771
Total	$115,785	$ 14	$ —	$115,771
At December 31, 2022:				
U.S. Treasuries - Cash equivalents	$105,442	$ 32	$ —	$105,410
Total	$105,442	$ 32	$ —	$105,410

There were no realized gains or losses from available-for-sale securities for the three months ended March 31, 2023 or 2022.

The estimated fair values of available-for-sale securities at March 31, 2023, by contractual maturity, are summarized as follows (in thousands):

	March 31, 2023
Due in one year or less	$115,785

4. Accumulated Other Comprehensive Income.

The following table summarizes the changes in accumulated other comprehensive income, net of tax from unrealized gains (losses) on available-for-sale securities (in thousands), the Company's only component of accumulated other comprehensive income for the three months ended March 31, 2023 and 2022.

There were no reclassifications out of accumulated other comprehensive income during the three months ended March 31, 2023 or 2022.

	Total Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2022	$ 24
Other comprehensive gain (loss) before reclassifications	(13)
Amount reclassified from accumulated other comprehensive income	—
Net current period other comprehensive gain (loss)	(13)
Balance at March 31, 2023	$ 11

5. Inventory.

Inventory consists of the following (in thousands):

	March 31, 2023	December 31, 2022
Raw materials	$ —	$ —
Work-in-process	5,642	5,543
Finished goods	4,686	1,262
Total inventory	$ 10,328	$ 6,805

6. Prepaid Expenses and Other Current Assets.

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

	March 31, 2023	December 31, 2022
Prepaid manufacturing costs	$ 1,147	$ 1,147
Prepaid tax	44	44
Prepaid insurance	871	1,224
Prepaid subscriptions fees	1,057	808
Prepaid research fees	157	178
Prepaid commercialization expenses	2,585	592
Due from collaborative and licensing arrangements	213	354
Prepaid conference and travel expenses	525	234
Other	335	586
Total prepaid expenses and other current assets	$ 6,934	$ 5,167

7. Operating Leases.

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 the first quarter of 2021.

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

	For the Three Months Ended March 31, 2023	For the Three Months Ended March 31, 2022
Operating lease cost	$ 108	$ 108

Supplemental cash flow information related to lease was as follows (in thousands):

	For the Three Months Ended March 31, 2023	For the Three Months Ended March 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows	$ 125	$ 121
Right-of-use assets obtained in exchange for lease obligations:		
Operating lease	$ 22	$ 22

Supplemental balance sheet information related to lease was as follows (in thousands):

	March 31, 2023	December 31, 2022
Operating lease right-of-use assets	$ 2,706	$ 2,770
Other current liabilities	$ 345	$ 337
Operating lease liabilities, net of current portion	3,468	3,557
Total operating lease liabilities	$ 3,813	$ 3,894

As of March 31, 2023 and December 31, 2022, the weighted average remaining lease term was 8.1 years and 8.3 years, respectively. The weighted average discount rate used to determine the operating lease liabilities was 4.51% as of March 31, 2023 and December 31, 2022.

Remaining payments of lease liabilities as of March 31, 2023 were as follows (in thousands):

2023 (remaining nine months)	$ 382
2024	522
2025	537
2026	553
2027	570
Thereafter	2,027
Total lease payments	4,591
Less: imputed interest	(778)
Total	$3,813

Rent expense was approximately $0.1 million for each of the three-month periods ended March 31, 2023 and 2022.

8. Property and Equipment, Net.

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

	March 31, 2023	December 31, 2022
Computer equipment	$ 51	$ 51
Furniture and equipment	296	222
Leasehold improvements	980	980
Software	433	—
Less: Accumulated depreciation	(475)	(406)
Total property and equipment, net	$ 1,285	$ 847

9. License and Acquired Intangibles, Net.

The following table presents the Company's intangible assets at March 31, 2023 (in thousands):

	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Intangible assets:			
License and acquired intangibles for RUZURGI®	$ 33,569	$ 1,678	$ 31,891
License and acquired intangibles for FYCOMPA®	158,143	5,951	152,192
Total	$ 191,712	$ 7,629	$ 184,083

The following table presents the Company's intangible assets at December 31, 2022 (in thousands):

	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Intangible assets:			
License and acquired intangibles for RUZURGI®	$ 33,569	$ 1,098	$ 32,471
Total	$ 33,569	$ 1,098	$ 32,471

The Company amortizes its definite-lived intangible assets using the straight-line method, which is considered the best estimate of economic benefit, over its estimated useful life. The useful life for RUZURGI® and FYCOMPA® is approximately 14.5 years and 5 years, respectively. The Company recorded approximately $0.6 million and $0 in amortization expense related to the licensed and acquired intangibles for RUZURGI® during the three months ended March 31, 2023 and 2022 within selling, general and administrative expenses in the consolidated statements of operations and comprehensive income. The Company recorded approximately $6.0 million and $0 in amortization expense related to the licensed and acquired intangibles for FYCOMPA® during the three months ended March 31, 2023 and 2022 within cost of sales. Amortization of both the FYCOMPA® and RUZURGI® intangible assets are reported together as amortization of intangible assets in the consolidated statements of operations and comprehensive income.

The following table presents future amortization expense the Company expects for its intangible assets (in thousands):

2023 (remaining nine months)	$ 25,462
2024	33,949
2025	33,949
2026	33,949
2027	33,949
Thereafter	22,825
Total	$184,083

At March 31, 2023 and December 31, 2022, the weighted average amortization period remaining for intangible assets was 6.7 years and 14.0 years, respectively.

If all or a portion of the intangible assets are deemed not recoverable, the Company would estimate the fair value of the assets and record an impairment loss. There were no impairment charges recognized on definite-lived intangibles for the three months ended March 31, 2023 or 2022.

10. Accrued Expenses and Other Liabilities.

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

	March 31, 2023	December 31, 2022
Accrued preclinical and clinical trial expenses	$ 290	$ 479
Accrued professional fees	5,626	1,619
Accrued compensation and benefits	2,043	5,132
Accrued license fees	7,614	20,444
Accrued purchases	146	154
Operating lease liability	345	337
Accrued variable consideration	4,748	3,381
Accrued contributions	1,350	—
Accrued income tax	17,949	8,702
Due to licensor	12,928	13,127
Other	279	238
Current accrued expenses and other liabilities	53,318	53,613
Lease liability – non-current	3,468	3,557
Due to licensor – non-current	13,389	14,064
Non-current accrued expenses and other liabilities	16,857	17,621
Total accrued expenses and other liabilities	$ 70,175	$ 71,234

11. Collaborative 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 (Par). 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 Endo/Par. As of March 31, 2023 and 2022, no milestone payments have been earned.

There were no revenues from this collaborative arrangement for the three months ended March 31, 2023 or 2022. There were no expenses incurred, net, in connection with the collaborative arrangement for the three months ended March 31, 2023 or 2022.

11. Collaborative and Licensing Arrangements (continued).

KYE Pharmaceuticals Inc.

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.

This agreement is in form identified as a collaborative agreement and the Company has concluded for accounting purposes that it also 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 KYE. Revenue from sales of FIRDAPSE® by KYE is recognized in the quarter in which the sales occurred.

Revenues from the arrangement with KYE for the three months ended March 31, 2023 and 2022 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.

11. Collaborative and Licensing Arrangements (continued).

The agreement includes milestones that are considered a sales-based royalty 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. Additionally, the agreement includes regulatory milestone payments which represent variable consideration, and due to uncertainty are 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.

There was $0.2 million and $0 in revenue from the arrangement with DyDo for the three months ended March 31, 2023 and 2022, respectively, which is included in product revenue, net in the accompanying consolidated statements of operations and comprehensive income. As of March 31, 2023, no milestone payments have been earned.

12. Commitments and Contingencies.

In May 2019, the FDA approved a New Drug Application (NDA) for RUZURGI®, Jacobus Pharmaceuticals' version of amifampridine (3,4-DAP), for the treatment of pediatric LEMS patients (ages 6 to under 17). In June 2019 the Company filed suit against the FDA and several related parties challenging this approval and related drug labeling. Jacobus later 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 the Company's 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 this lawsuit 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' motions for summary judgment, and dismissed the Company's case. The Company appealed the District Court's decision to the U.S. Court of Appeals for the 11th Circuit. The case was fully briefed in early 2021, and oral argument was held in March 2021.

On September 30, 2021, a three-judge panel of 11th Circuit judges issued a unanimous decision overturning the District Court's decision. The appellate 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. In November 2021, Jacobus filed a motion seeking rehearing of the case from the full 11th Circuit, which motion was denied in January 2022. Further, in January 2022, Jacobus filed motions with both the 11th Circuit and the U.S. Supreme Court seeking a stay of the 11th Circuit's ruling indicating that it would seek a review of the 11th Circuit's decision from the U.S. Supreme Court. Both stay motions were denied, and on January 28, 2022, the 11th Circuit issued a mandate directing the District Court to enter summary judgment in the Company's favor. The District Court entered that order on January 31, 2022. On February 1, 2022, the FDA informed Jacobus that, consistent with the Court of Appeals for the Eleventh Circuit's September 30, 2021, decision in favor of Catalyst, the final approval of the RUZURGI® NDA was switched to a tentative approval until the 7-year orphan-drug exclusivity (ODE) for FIRDAPSE® has expired.

On July 11, 2022, the Company settled certain of its disputes with Jacobus. In connection with the settlement, the Company licensed the rights to develop and commercialize RUZURGI® in the United States and Mexico (the Territory). Simultaneously, the Company purchased, among other intellectual property rights, Jacobus' U.S. patents related to RUZURGI®, its new drug applications in the United States for RUZURGI®, and certain RUZURGI® inventory previously manufactured by Jacobus. At the same time, the Company received a license from Jacobus for use of its know-how related to the manufacture of RUZURGI®. Further, the Company settled the patent case, which has been dismissed without prejudice. Finally, Jacobus agreed that until the later of (i) the expiration of the royalty term or (ii) December 31, 2034, Jacobus and its affiliates, will not, directly or indirectly, research, develop, manufacture, commercialize, distribute, use or otherwise exploit any product competitive to FIRDAPSE® or RUZURGI® in the Territory, and Laura Jacobus, the sole shareholder of Jacobus, and two of Jacobus' other officers, also signed individual non-competition agreements containing the same terms.

12. Commitments and Contingencies (continued).

In connection with the settlement with Jacobus, the Company agreed to pay the following consideration to Jacobus:

- $30 million of cash, of which $10 million was paid at the closing of the settlement on July 11, 2022 and the balance of which will be paid over the next two years, on the first and second anniversary of closing;
- An annual royalty on our net sales (as defined in the License and Asset Purchase Agreement between Catalyst and Jacobus) of amifampridine products in the United States equal to: (a) for calendar years 2022 through 2025, 1.5% (with a minimum annual royalty of $3.0 million per year), and (b) for calendar years 2026 through the expiration of the last to expire of Catalyst's FIRDAPSE® patents in the United States, 2.5% (with a minimum annual royalty of $5 million per year); provided, however, that the royalty rate may be reduced and the minimum annual royalty may be eliminated under certain circumstances; and
- If Catalyst were to receive a priority review voucher for FIRDAPSE® or RUZURGI® in the future, 50% of the consideration paid by a third party to acquire that voucher will be paid to Jacobus.

Royalties will be trued up at the end of the year to the extent that royalties on net sales are below the minimum royalty.

The Company's New Drug Submission filing for FIRDAPSE® for the symptomatic treatment of LEMS was approved when Health Canada issued a Notice of Compliance, or NOC, on July 31, 2020. In August 2020, the Company entered into a license agreement with KYE Pharmaceuticals, or KYE, pursuant to which the Company licensed to KYE the Canadian rights for FIRDAPSE® for the treatment of LEMS. On August 10, 2020, Health Canada issued a NOC to Medunik (Jacobus' licensee in Canada for RUZURGI®) for the treatment of LEMS. Shortly thereafter, the Company 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 an 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 an NOC for RUZURGI®, once again allowing the product to be marketed in Canada for patients with LEMS. As a result, in July 2021 the Company, along with its partner in Canada, KYE, filed a second suit against Health Canada to overturn this decision.

On March 11, 2022, the Company announced that the Company had received a favorable decision from the Canadian court setting aside, for the second time, the decision of Health Canada approving RUZURGI® for the treatment of LEMS patients. In its ruling, the court determined that the Minister of Health's approach to evaluating whether FIRDAPSE®'s data deserved protection based on FIRDAPSE®'s status as an innovative drug, which protects by regulation the use of such data as part of a submission seeking an NOC for eight years from approval of the innovative drug, was legally flawed and not supported by the evidence. The Minister of Health appealed that decision, and, in January 2023, the Canadian Appellate Court overturned the trial court's decision. Thereafter, the Minister of Health reissued an NOC for RUZURGI® in Canada and, as a result, RUZURGI® is once again available for sale in Canada.

In January 2023, the Company received Paragraph IV Certification Notice Letters from three generic drug manufacturers advising that they had each submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking authorization from the FDA to manufacture, use or sell a generic version of FIRDAPSE® in the United States. The notice letters each alleged that the six patents listed in the FDA Orange Book covering FIRDAPSE® are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in these ANDA submissions. Under the FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, the Company had 45 days from receipt of the notice letters to commence patent infringement lawsuits against these generic drug manufacturers in a federal district court to trigger a stay precluding the FDA from approving any ANDA until May 2026 or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first. In that regard, after conducting the necessary due diligence, the Company filed lawsuits on March 1, 2023 in the U.S. District Court for the District of New Jersey against each of the three generic drug manufacturers who notified the Company of their ANDA submissions, thus triggering the stay.

12. Commitments and Contingencies (continued).

On February 20, 2023, the Company received a Paragraph IV Certification Notice Letter from a company that appears to have filed the first ANDA for the oral suspension formulation for FYCOMPA®. The same company sent a similar letter to the Company later in February with a similar certification for the tablet formulation for FYCOMPA®, the fourth such certification for this formulation. Both of these letters were paragraph IV certifications of non-infringement, non-validity, and unenforceability to the '497 patent for FYCOMPA® but each application, like the previous Paragraph IV notices from ANDA filers, for FYCOMPA® tablets does not challenge the '571 patent. Similar to the actions with the FIRDAPSE® Paragraph IV Certifications described above, after due diligence the Company filed lawsuits on April 5, 2023 in the U.S. District Court for the District of New Jersey against the drug manufacturer who notified the Company of their ANDA submissions for both FYCOMPA® formulations, thus triggering the 30 month stay for each application.

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.

13. 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 to our licensor 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. LICENSE AGREEMENT FOR RUZURGI®. On July 11, 2022 (the Effective Date), the Company entered into an exclusive license agreement with Jacobus Pharmaceutical Company, Inc. (Jacobus), for the rights to develop and commercialize RUZURGI® in the United States and Mexico.

Pursuant to the terms of the license agreement, the Company paid Jacobus a $10 million up-front payment on the Effective Date and will pay an additional $10 million on the first annual anniversary of the Effective Date (July 11, 2023), another $10 million on the second annual anniversary of the Effective Date (July 11, 2024) and tiered royalty payments on net sales (as defined in the license agreement) of all of the Company's products in the United States that range from 1.25% to 2.5% based on whether there is a competing product or generic version of FIRDAPSE® being marketed or sold in the United States. A minimum royalty payment exists annually for calendar years from the Effective Date through 2025 of $3 million, provided that such minimum annual royalty payment shall be prorated in the first calendar year of the agreement. As these minimum payments are both probable and estimable, they are included in the purchase price of the agreement and any royalties in excess of this amount will be charged to cost of sales as revenue from product sales is recognized. A minimum royalty payment exists annually for calendar years from 2026 through the expiration of the royalty term (which ends when there is no valid claim under the Company's FIRDAPSE® patents in the United States) of $5 million unless a competing product or generic version of FIRDAPSE® is being marketed or sold in the United States. If these minimum payments become probable in the future, the Company would recognize a contingent liability at that time with an offset to the value of the intangible asset acquired. Any royalties in excess of this amount will be charged to cost of sales as revenue from product sales is recognized. Royalties over the minimum, if any, will be paid based on the agreement terms on a quarterly basis.

13. Agreements (continued).

Assets acquired as part of the license agreement include among other intellectual property rights, Jacobus' U.S. patents related to RUZURGI®, its new drug applications in the United States for RUZURGI®, its Trademark for RUZURGI®, the Orphan Drug Designation for RUZURGI® and a license from Jacobus for use of its know-how related to the manufacture of RUZURGI®.

Additionally, the Company also purchased from Jacobus approximately $4.1 million of RUZURGI® inventory previously manufactured by Jacobus, which were recorded as an expense in research and development expenses in the consolidated statement of operations and comprehensive income for the third quarter of 2022.

Under business combination guidance, the screen test states that if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the set is not considered a business and is accounted for as an asset acquisition. The Company has determined that the screen test was not met. However, the Company determined that the acquisition did not meet the definition of a business under ASC 805, Business Combination. The Company believes that the licensing agreement and other assets acquired from Jacobus are similar and considered them all to be intangible assets with the exception of the inventory acquired. As the screen test was not met, further determination was required to determine that the Company had not acquired inputs and processes that have the ability to create outputs, which would meet the requirements of a business, and therefore, determined that this was an asset acquisition. The Company accounted for the Jacobus license agreement as an asset acquisition under ASC 805-50, which requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes consideration given.

The total purchase price was allocated to the acquired assets based on their relative fair values, as follows (in thousands):

License and acquired intangibles	$33,569
Acquired research and development inventory expensed from asset acquisition	4,130
Total purchase price	$37,699

The straight-line method is used to amortize the license and acquired intangibles, as disclosed in Note 9 (License and Acquired Intangibles, Net).

c. **ACQUISITION OF U.S. RIGHTS FOR FYCOMPA®.** On January 24, 2023, the Company acquired the U.S. Rights for FYCOMPA® (perampanel) CIII a commercial stage epilepsy asset, from Eisai Co., Ltd. (Eisai). The aggregate consideration for the acquisition was $164.2 million in cash and certain liabilities.

Eisai is also eligible to receive a contingent payment of $25 million if certain regulatory milestones are met. As the regulatory milestones are not probable, the Company did not recognize any amount related to the milestone payments in the purchase price. Additionally, after the loss of patent exclusivity for FYCOMPA®, the Company may be obligated to pay certain royalties to Eisai on net sales of FYCOMPA®. As the Transaction is accounted for as an asset acquisition under U.S. GAAP, the Company opted to recognize the royalty payments in cost of sales as revenue from product sales is recognized.

The following table summarizes the aggregate amount paid for the assets acquired by the Company in connection with the acquisition of FYCOMPA®:

Base cash payment	160,000
Cash paid for pro-rated prepaid expenses	1,576
Reimbursement on base purchase price[(i)]	(3,238)
Transaction costs[(ii)]	5,870
Total purchase consideration	$164,208

(i) Recorded in prepaid expenses and other current assets in the accompanying consolidated balance sheet as of March 31, 2023

(ii) $1.9 million of transaction expenses are recorded in accrued expenses and other liabilities in the accompanying consolidated balance sheet as of March 31, 2023, the remaining $4.0 million has been paid in cash

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13. Agreements (continued).

The acquisition of FYCOMPA® has been accounted for as an asset acquisition in accordance with FASB ASC 805-50. The Company accounted for the acquisition of FYCOMPA® as an asset acquisition because substantially all of the fair value of the assets acquired is concentrated in a single asset, the FYCOMPA® product rights. The FYCOMPA® products rights consist of certain patents and trademarks, at-market contracts and regulatory approvals, marketing assets, and other records, and are considered a single asset as they are inextricably linked. ASC 805-10-55-5A includes a screen test, which provides that if substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the assets acquired are not considered to be a business. ASC 805 requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes consideration given.

The total purchase price was allocated to the acquired assets based on their relative fair values, as follows (in thousands):

Inventory	4,100
Prepaid expenses and other current assets (samples)	130
Prepaid commercialization expenses	1,576
Property and equipment, net	433
License and acquired intangibles for FYCOMPA®	158,143
Accrued preclinical and clinical trial expenses	(174)
Total purchase consideration	$164,208

The straight-line method is used to amortize the license and acquired intangibles, as disclosed in Note 9 (License and Acquired Intangibles, Net).

d. 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.

14. Income Taxes.

The Company's effective income tax rate was 20.8% and 24.2% for the three months ended March 31, 2023 and 2022, respectively. 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 March 31, 2023 and December 31, 2022.

15. Stockholders' Equity.

Preferred Stock

The Company has 5,000,000 shares of authorized preferred stock, $0.001 par value per share, at March 31, 2023 and December 31, 2022. No shares of preferred stock were outstanding at March 31, 2023 and December 31, 2022.

Common Stock

The Company has 200,000,000 shares of authorized common stock, par value $0.001 per share. At March 31, 2023 and December 31, 2022, 105,938,292 and 105,263,031 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. During the three months ended March 31, 2023 and 2022, no shares and 400,000 shares were repurchased for an aggregate purchase price of approximately $0 and $2.6 million, respectively ($0 and $6.38 average price per share, respectively).

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.

16. Stock Compensation.

For the three months ended March 31, 2023 and 2022, the Company recorded stock-based compensation expense as follows (in thousands):

	2023	2022
Research and development	$ 339	$ 432
Selling, general and administrative	2,553	1,471
Total stock-based compensation	$2,892	$1,903

Stock Options

As of March 31, 2023, there were outstanding stock options to purchase 12,082,183 shares of common stock, of which stock options to purchase 8,442,955 shares of common stock were exercisable as of March 31, 2023.

During the three months ended March 31, 2023 and 2022, the Company granted seven-year term options to purchase an aggregate of 340,500 and 410,000 shares, respectively, of the Company's common stock to employees. The Company recorded stock-based compensation related to stock options totaling $2.2 million and $1.6 million, respectively, during the three months ended March 31, 2023 and 2022.

During the three months ended March 31, 2023 and 2022, options to purchase 547,957 shares and 363,772 shares, respectively, of the Company's common stock were exercised, with proceeds of $1.3 million and $1.1 million respectively, to the Company.

As of March 31, 2023, there was approximately $18.0 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 2.4 years.

16. Stock Compensation (continued).

Restricted Stock Units

The Company granted no restricted stock units and 474,500 restricted stock units during the three months ended March 31, 2023 and 2022, respectively. During the three months ended March 31, 2023 and 2022, the Company recorded non-cash stock-based compensation expense related to restricted stock units totaling $0.7 million and $0.3 million, respectively.

As of March 31, 2023, there was approximately $6.8 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 2.5 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 first quarter of fiscal 2023.
- 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 months ended March 31, 2023 as compared to the three months ended March 31, 2022.
- 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 and diseases that are difficult to treat. With exceptional patient focus, we are committed to developing a robust pipeline of cutting-edge, best-in-class medicines for treating rare and difficult to treat diseases. We are dedicated to making a meaningful impact on the lives of those suffering from rare and difficult to treat diseases, and we believe in putting patients first in everything we do.

Our flagship U.S. commercial product is FIRDAPSE® (amifampridine) Tablets 10 mg. approved for the treatment of Lambert-Eaton myasthenic syndrome, or LEMS, for adults and for children ages six and up. On December 17, 2022, we entered into an asset purchase agreement with Eisai Co., Ltd. (Eisai) for the acquisition of the United States rights to FYCOMPA® (perampanel) CIII, a prescription medication used alone or with other medicines to treat focal onset seizures with or without secondarily generalized seizures in people with epilepsy aged four and older and with other medicines to treat primary generalized tonic-clonic seizures in people with epilepsy aged 12 and older. We closed our acquisition of FYCOMPA® on January 24, 2023 and we are marketing FYCOMPA® in the United States.

Impact of the COVID-19 pandemic on our business

The COVID-19 pandemic affected our business operations in numerous ways. At various times during the pandemic, we had to make modifications to our normal operations, including allowing our employees to work remotely. Further, during the pandemic, national, state and local governments in affected regions implemented varying safety precautions, such as quarantines, border closures, increased border controls, travel restrictions, shelter-in-place orders and shutdowns, business closures, cancellations of public gatherings, mask mandates, and other measures. While most of these measures have since been relaxed or removed, a resurgence in cases as a result of one or more new variants could lead to some or all of these precautions being put back into place. At present, our operations have returned to mostly being in-person, with some contact with physicians by our commercial sales force still being done remotely. However, there can be no assurance that the COVID-19 pandemic will not in the future disrupt once again our normal business operations.

FIRDAPSE®

On November 28, 2018, we received approval from the United States Food and Drug Administration (FDA) of our new drug application (NDA) for FIRDAPSE® Tablets 10 mg for the treatment of adult patients (ages 17 and above) with LEMS, and in January 2019, we launched FIRDAPSE® in the United States. Further, on September 29, 2022, the FDA approved our supplemental NDA (sNDA) to expand the indicated age range for FIRDAPSE® Tablets 10 mg to include pediatric patients, six years of age and older for the treatment of LEMS.

We sell FIRDAPSE® through a field force experienced in neurologic, central nervous system or rare disease products consisting at this time of approximately 29 field personnel, including sales (Regional Account Managers), thought-leader liaisons, patient assistance and insurance navigation support (Patient Access Liaisons), and payor reimbursement (National Account Managers). We also have a field-based force of six medical science liaisons who are helping educate the medical communities and patients about LEMS and our programs supporting patients and access to FIRDAPSE®.

Additionally, 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 a LEMS patient who can benefit from FIRDAPSE®. We also use non-personal promotion to reach the 20,000 neurologists who are potential LEMS treaters and the 16,000 oncologists who might be treating a LEMS patient with small cell lung cancer. Further, we continue to make available at no-cost a LEMS voltage gated calcium channel 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 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 and the National Organization for Rare Disorders) 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 for patients who enroll in it. Catalyst Pathways® is a single source for personalized treatment support, education and guidance through the challenging dosing and titration regimen required to reach 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 drug 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 patients with LEMS 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. A co-pay assistance program designed to keep out-of-pocket costs to not more than $10.00 per month (currently less than $2.00 per month) is available for all LEMS patients with commercial coverage who are prescribed FIRDAPSE®. Our FIRDAPSE® co-pay assistance program is not available to patients enrolled in state or federal healthcare programs, including Medicare, Medicaid, VA, DoD, or TRICARE. However, we are donating, and committed to continuing 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 January 2023, we received Paragraph IV Certification Notice Letters from three generic drug manufacturers advising us that they had each submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking authorization from the FDA to manufacture, use or sell a generic version of FIRDAPSE® in the United States. The notice letters each alleged that our six patents listed in the FDA Orange Book covering FIRDAPSE® are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in these ANDA submissions. Under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, we had 45 days from receipt of the notice letters to commence patent infringement lawsuits against these generic drug manufacturers in a federal district court to trigger a stay precluding the FDA from approving any ANDA until May 2026 or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first. In that regard, after conducting the necessary due diligence, we filed lawsuits on March 1, 2023 in the U.S. District Court for the District of New Jersey against each of the three generic drug manufacturers who notified us of their ANDA submissions, thus triggering the stay.

We intend to vigorously protect and defend our intellectual property for FIRDAPSE® and, although there can be no assurance, we believe that our patent estate will protect FIRDAPSE® from generic competition for the life of our patents.

We are also working to prepare for the filing of an sNDA to increase the indicated maximum dose of FIRDAPSE® from 80 mg per day to 100 mg per day. In that regard, we recently sought guidance from the FDA on our proposed strategy for this supplementary NDA, and, based on the guidance received, we plan to file a sNDA early in the third quarter of 2023. There can be no assurance that any sNDA that we file to increase the indicated maximum dose of FIRDAPSE® from 80 mg per day to 100 mg per day will be approved.

FYCOMPA®

On December 17, 2022, we entered into an asset purchase agreement with Eisai for the acquisition of the U.S. rights to FYCOMPA® (perampanel) CIII. FYCOMPA® is a selective non-competitive antagonist of AMPA receptors, the major subtype of ionotropic glutamate receptors. It was the first, and still the only, drug of its class to be approved for epilepsy. Studies suggest that AMPA receptor antagonism can lead to reduced overstimulation and anticonvulsant effects, as well as inhibiting seizure generation and spread. FYCOMPA® is a controlled substance and is approved with a box warning label.

FYCOMPA® is used to treat partial onset seizures with or without secondarily generalized seizures in adults and children 4 years of age and older. It is also used in combination with other medications to treat primary generalized tonic-clonic seizures (also known as a "grand mal" seizure, a seizure that involves the entire body) in adults and children 12 years of age or older. Perampanel is in a class of medications called anticonvulsants. It works by decreasing abnormal electrical activity in the brain.

On January 24, 2023 we closed our acquisition of the U.S. rights to FYCOMPA®. In connection with the acquisition, we purchased Eisai's regulatory approvals and documentation, product records, intellectual property, inventory, and other matters relating to the U.S. rights for FYCOMPA®, in exchange for a cash upfront payment of $160 million, plus $1.6 million for reimbursement of certain prepayments. We also agreed to pay Eisai an additional cash payment of $25 million if a requested patent extension for FYCOMPA® is approved by the U.S. Patent and Trademark Office (USPTO). Finally, we agreed to pay Eisai royalty payments after patent protection for FYCOMPA® expires, which royalty payments will be reduced upon generic equivalents to FYCOMPA® entering the market.

In conjunction with the closing of our acquisition of FYCOMPA®, we entered into two additional agreements with Eisai; a Transition Services Agreement and a Supply Agreement. Under the Transition Services Agreement, a U.S. subsidiary of Eisai is providing us with certain transitional services, and under the Supply Agreement, Eisai has agreed to manufacture FYCOMPA® for us for at least seven years at prices listed in the Supply Agreement (to be updated on a yearly basis). Initially, following the closing of the acquisition, we began marketing FYCOMPA® in the U.S. through Eisai under the Transition Services Agreement as we built our FYCOMPA® marketing and sales team, and on May 1, 2023, we took over the marketing program for FYCOMPA®. In that regard, we have hired approximately 34 sales and marketing personnel to support FYCOMPA®, most of whom previously worked in Eisai's U.S. sales division marketing FYCOMPA®. We also are working to hire up to six medical science liaisons to help us educate the medical community who treat epilepsy and the patients who have epilepsy about their disease and the benefits of FYCOMPA®.

Catalyst is supporting patients using FYCOMPA® through an Instant Savings Card Program. Through the program, eligible commercially insured patients could pay as little as $10 for their FYCOMPA® co-pay (with a maximum savings of $1,300 per year). Eligible cash-paying patients receive up to $60 towards each prescription, up to a maximum of $720 per year. The FYCOMPA® instant savings card program is not available to patients enrolled in state or federal healthcare programs, including Medicare, Medicaid, VA, DoD, or TRICARE.

Patent protection for FYCOMPA® is primarily from two patents listed in the Orange Book. The first, U.S. Patent No. 6,949,571 (the '571 patent), will expire no earlier than May 23, 2025, which is the current expiration date for the '571 patent that includes the USPTO's current patent term extension calculation. A request for reconsideration of the agency's patent term extension calculation is currently pending. If successful, we would be entitled to patent term extension that would extend the '571 patent until June 8, 2026. There can be no assurance that our request for reconsideration of the '571 patent term extension will be granted by the U.S. Patent and Trademark Office. The second FYCOMPA® patent in the Orange Book is U.S Patent No. 8,772,497 (the '497 patent) that expires on July 1, 2026. The '497 patent is the one that has been the subject of previous Paragraph IV certifications from three ANDA filers.

On February 20, 2023, Catalyst received a Paragraph IV Certification Notice Letter from a company that appears to have filed the first ANDA for the oral suspension formulation for FYCOMPA®. The same company sent a similar letter to the Company later in February with a similar certification for the tablet formulation for FYCOMPA®, the fourth such certification for this formulation. Both of these letters were paragraph IV certifications of non-infringement, non-validity, and unenforceability to the '497 patent for FYCOMPA® but each application, like the previous Paragraph IV notices from ANDA filers, for FYCOMPA® tablets does not challenge the '571 patent. Similar to our actions with the FIRDAPSE® Paragraph IV Certifications described above, after due diligence Catalyst filed lawsuits on April 5, 2023 in the U.S. District Court for the District of New Jersey against the drug manufacturer who notified Catalyst of their ANDA submissions for both FYCOMPA® formulations, thus triggering the 30 month stay for each application.

Business Development

We are continuing our efforts to broaden and diversify our drug portfolio through acquisitions of early and/or late-stage products or companies or technology platforms in rare disease and CNS therapeutic categories. To accomplish these priorities, we are employing a disciplined approach to evaluating assets, and we believe that this strategic expansion will better position our company long term to build out a broader more diversified portfolio of drug candidates (which should add greater value to our company over the near and long-term). In that regard, we are currently exploring several additional opportunities to acquire companies with commercial drug products and/or drug products in development or to in-license or acquire commercialized drug products or drug products in development. However, no additional definitive agreements have been entered into to date, and there can be no assurance that our efforts to continue to broaden and diversify our product portfolio will be successful.

Capital Resources

At March 31, 2023, we had cash and cash equivalents of approximately $148 million. 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. There can be no assurance that we will continue to be successful in commercializing FIRDAPSE®, that our commercialization of FYCOMPA® will be successful, or that we 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 on acceptable terms. See “Liquidity and Capital Resources” below for further information on our liquidity and cash flow.

Basis of Presentation

Revenues.

During the fiscal quarter ended March 31, 2023, we generated revenues from product sales of FIRDAPSE® primarily in the U.S. and FYCOMPA® in the U.S. We expect these revenues to fluctuate in future periods based on our sales of FIRDAPSE® and FYCOMPA®. We received approval from Health Canada on July 31, 2020, for FIRDAPSE® for the symptomatic treatment of LEMS and as of December 31, 2020, we had launched FIRDAPSE® in Canada. During the three months ended March 31, 2023, revenues generated under our collaboration agreement with KYE Pharmaceuticals were immaterial. We expect our revenues from the KYE collaboration agreement to fluctuate in future periods based on our collaborator’s ability to sell FIRDAPSE® in Canada.

For the fiscal quarter ended March 31, 2023, 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 fiscal quarter ended March 31, 2023, we generated $0.2 million in revenues from our collaborative agreement with DyDo Pharma. We expect our revenue 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 our products. Cost of sales may also include period costs related to certain inventory manufacturing services, inventory adjustments charges, unabsorbed manufacturing and overhead costs, manufacturing variances and the amortization of FYCOMPA® product rights.

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. Prior to January 2023, 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 until we acquire or license new products we currently expect that our future development costs will be attributable principally to the continued development of FIRDAPSE® and FYCOMPA®.

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.

During 2019, we actively committed funds to developing our commercialization program for FIRDAPSE® and we have continued to incur substantial commercialization expenses, including sales, marketing, patient services, patient advocacy and other commercialization related expenses as we have continued our sales program for FIRDAPSE®. We are also now incurring substantial commercialization expenses for FYCOMPA®.

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, amortization of the RUZURGI® product rights, accounting, and consulting services.

Amortization of Intangible Assets.

Amortization of intangible assets consists of the amortization of the FYCOMPA® product rights, which are amortized using the straight-line method over its estimated useful life of 5 years, and the RUZURGI® product rights, which are amortized using the straight-line method over its estimated useful life of 14.5 years.

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 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 2022 Annual Report on Form 10-K that we filed with the SEC on March 15, 2023. Our most critical accounting policies and estimates include: accounting for revenue recognition, valuation of intangible assets, 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 2022 Annual Report on Form 10-K.

Results of Operations

Revenues.

For the three months ended March 31, 2023, we recognized $85.3 million in net revenue from product sales primarily in the U.S. compared to $43.0 million for the three months ended March 31, 2022. FIRDAPSE® sales were approximately $57.5 million for the 2023 period and FYCOMPA® sales were approximately $27.8 million for the period between January 24, 2023 (date of acquisition) and March 31, 2023. All net revenue for product sales of the 2022 first quarter were from sales of FIRDAPSE®.

The increase of approximately $42.3 million in net revenues between the first quarter of 2023 compared to 2022 was due to the acquisition of FYCOMPA® and related product sales and increases in sales volumes of approximately 21% (which included patients who were transferred to FIRDAPSE® in the first and second quarter of 2022 when RUZURGI® was removed from the market) and net price increases.

For the three months ended March 31, 2023 and 2022, we also recognized $0.1 million in license and other revenue.

Cost of Sales.

Cost of sales was approximately $9.9 million for the three months ended March 31, 2023, compared to $5.9 million for the three months ended March 31, 2022. Cost of sales in both periods consisted principally of royalty payments, which are based on net revenue as defined in the applicable license agreement. For FIRDAPSE®, royalties are payable on the terms set forth below in Liquidity and Capital Resources -*Contractual Obligations and Arrangements*, and increase by 3% when net sales (as defined in the applicable license agreement) exceed $100 million in any calendar year. Cost of sales for FYCOMPA® for the first quarter of 2023 consisted of product costs and excludes the amortization of the FYCOMPA® intangible assets. See Note 9 of the Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

Amortization of Intangible Assets.

Amortization of intangible assets was approximately $6.5 million for the three months ended March 31, 2023, compared to $0 million for the three months ended March 31, 2022. Amortization of intangible assets consists of the amortization of the FYCOMPA® rights, which are amortized using the straight-line method over its estimated useful life of 5 years, and the RUZURGI® rights, which are amortized using the straight-line method over its estimated useful life of 14.5 years.

Research and Development Expenses.

Research and development expenses for the three months ended March 31, 2023 and 2022 were approximately $3.6 million and $3.4 million, respectively, and represented approximately 7% and 13% of total operating costs and expenses, respectively. Research and development expenses for the three months ended March 31, 2023 and 2022 were as follows (in thousands):

	Three months ended March 31,		Change	
	2023	2022	$	%
Research and development expenses	$ 3,223	$ 2,971	252	8.5
Employee stock-based compensation	339	432	(93)	(21.5)
Total research and development expenses	$ 3,562	$ 3,403	159	4.7

For FIRDAPSE®, research and development expenses remained relatively consistent for the three months ended March 31, 2023, when compared to the same period in 2022. For the three months ended March 31, 2023 and 2022, research and development expenses included costs relating to closing out sites for both our MuSK-MG clinical trial and our previously operated expanded access program.

We expect that research and development expenses will continue to be substantial in 2023 and beyond as we execute on our strategic initiative to acquire or in-license innovative technology platforms and/or earlier stage programs in rare disease and difficult to treat categories.

Selling, General and Administrative Expenses.

Selling, general and administrative expenses for the three months ended March 31, 2023 and 2022 were approximately $29.7 million and $16.4 million, respectively, and represented approximately 60% and 64% of total operating costs and expenses for the three months ended

March 31, 2023 and 2022, respectively. Selling, general and administrative expenses for the three months ended March 31, 2023 and 2022 were as follows (in thousands):

	Three months ended March 31,		Change	
	2023	2022	$	%
Selling	$17,764	$ 6,790	10,974	161.6
General and administrative	9,401	8,169	1,232	15.1
Employee stock-based compensation	2,553	1,471	1,082	73.6
Total selling, general and administrative expenses	$29,718	$16,430	13,288	80.9

For the three months ended March 31, 2023, selling, general and administrative expenses increased approximately $13.3 million, compared to the same period in 2022, primarily attributable to the direct fees payable under the transition services agreement associated with the net product sales of FYCOMPA® of approximately $8.5 million, to the timing of our commitments to make contributions to 501(c)(3) organizations supporting LEMS patients of approximately $0.3 million, and an approximately $1.5 million increase in employee compensation related to annual merit increases and an increase in headcount resulting from the acquisition of FYCOMPA®.

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®, continue our efforts to market FYCOMPA®, and take steps to continue to expand our business.

Stock-Based Compensation.

Total stock-based compensation for the three months ended March 31, 2023 and 2022 was $2.9 million and $1.9 million, respectively. In the first quarter of 2023 and 2022, grants were principally for stock options relating to year-end bonus awards and grants to new employees.

Other Income, Net.

We reported other income, net in all periods, primarily relating to our investment of our cash and cash equivalents and investments of $1.7 million and $0.1 million for the three months ended March 31, 2023 and 2022, respectively. The increase in other income, net for the three months ended March 31, 2023 of approximately $1.6 million when compared to the same period in 2022 is primarily due to higher yields on investments as well as higher invested balances. Other income, net, consists primarily of interest and dividend income.

Income Taxes.

Our effective income tax rate was 20.8% and 24.2% for the three months ended March 31, 2023 and 2022, respectively. 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 effective tax rate is affected by many factors, including the number of stock options exercised in any period, and our effective tax rate is likely to fluctuate in future periods (and may be higher in future periods than it was in the first quarter of 2023).

We had no uncertain tax positions as of March 31, 2023 and December 31, 2022.

Net Income.

Our net income was $29.6 million for the three months ended March 31, 2023 ($0.28 per basic and $0.26 per diluted share) as compared to a net income of $13.2 million for the three months ended March 31, 2022 ($0.13 per basic and $0.12 per diluted share).

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through multiple offerings of our securities, since January 2019, from revenues from product sales of FIRDAPSE® and since January 2023, from revenues from product sales of FYCOMPA®. At March 31, 2023 we had cash and cash equivalents aggregating $148.2 million and working capital of $142.2 million. At December 31, 2022, we had cash and cash equivalents aggregating $298.4 million and working capital of $263.2 million. On January 24, 2023, we used approximately $162 million of our cash to acquire the U.S. rights to FYCOMPA®. At March 31, 2023, substantially all of our cash and cash equivalents were 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 and U.S. Treasuries.

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® and FYCOMPA® sales, or the products we acquire and continue to develop 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 cost of diligence in seeking a potential acquisition and of the completion of such acquisition, if an acquisition so occurs;
- future clinical trial results;
- the scope, rate of progress and cost of our clinical trials and other product development activities;
- 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® and FYCOMPA®;
- the effect of competition and market developments;
- the cost of filing and potentially prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in other products.

We may raise additional funds 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 business development activities, 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 $12.1 million and $8.5 million, respectively, for the three months ended March 31, 2023 and 2022. During the three months ended March 31, 2023, net cash provided by operating activities was primarily attributable to our net income of $29.6 million, a decrease of $0.6 million in inventory and $9.7 million of non-cash expenses. This was partially offset by increases of $23.0 million in accounts receivable, net, $0.2 million in prepaid expenses and other current assets and decreases of $0.6 million in accounts payable, $2.4 million in accrued expenses and other liabilities and $0.1 million in operating lease liability and $1.5 million in deferred taxes. The increase in accounts receivable, net, primarily relates to sales of FYCOMPA®, which has a longer cash collection cycle than FIRDAPSE®. During the three months ended March 31, 2022, net cash provided by operating activities was primarily attributable to our net income of $13.2 million, an increase of $2.4 million in accounts payable, $1.9 million in deferred taxes and $2.0 million of non-cash expenses. This was partially offset by increases of $3.9 million in accounts receivable, net and $0.6 million in prepaid expenses and other current assets and decreases of $6.5 million in accrued expenses and other liabilities and $0.1 million in operating lease liability.

Net cash used in investing activities was $162.4 million for the three months ended March 31, 2023, consisting primarily of payment in connection with the FYCOMPA® asset acquisition. There were no cash flows from investing activities for the three months ended March 31, 2022.

Net cash provided by financing activities during the three months ended March 31, 2023 was $0.1 million, consisting primarily of proceeds from the exercise of stock options, partially offset by the payment of liabilities arising from asset acquisition and payment of employee withholding tax related to stock-based compensation. Net cash used in financing activities during the three months ended March 31, 2022 was $1.6 million, consisting primarily of repurchases of common stock, partially offset by proceeds from the exercise of stock options.

Contractual Obligations and Arrangements.

We have entered into the following contractual arrangements with respect to sales of FIRDAPSE®:

- *Payments due under our license agreement for FIRDAPSE®.* We currently 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 months ended March 31, 2023, we recognized an aggregate of approximately $7.6 million of royalties payable under these license agreements, which is included in cost of sales in the accompanying consolidated statements of operations and comprehensive income.

  Further, if DyDo is successful in obtaining the right to commercialize FIRDAPSE® in Japan, we will pay royalties to our licensor on net sales in Japan equal to a similar percentage to the royalties that we are currently paying under our original license agreement for North America.

- *Payments due to Jacobus.* In connection with our July 2022 settlement with Jacobus, we agreed to pay the following consideration to Jacobus:
    - $30 million of cash, of which $10 million was paid at the closing of the settlement on July 11, 2022 and the balance of which will be paid over the next two years, on the first and second anniversary of closing;
    - An annual royalty on Catalyst's net sales (as defined in the License and Asset Purchase Agreement between Catalyst and Jacobus) of amifampridine products in the United States equal to: (a) for calendar years 2022 through 2025, 1.5% (with a minimum annual royalty of $3.0 million per year), and (b) for calendar years 2026 through the expiration of the last to expire of Catalyst's FIRDAPSE® patents in the United States, 2.5% (with a minimum annual royalty of $5 million per year); *provided, however*, that the royalty rate may be reduced and the minimum annual royalty may be eliminated under certain circumstances; and
    - If Catalyst were to receive a priority review voucher for FIRDAPSE® or RUZURGI® in the future, 50% of the consideration paid by a third party to acquire that voucher will be paid to Jacobus.

  Royalties will be trued up at the end of the year to the extent that royalties on net sales are below the minimum royalty.

  For the three months ended March 31, 2023, we recognized an aggregate of approximately $0.8 million of royalties payable to Jacobus.

We have entered into the following contractual arrangements with respect to sales of FYCOMPA®:

- *Payments due under our asset purchase agreement for FYCOMPA®*. In connection with its recent asset purchase agreement with Eisai Co., Ltd. (Eisai):
    - $160 million upfront cash payment plus $1.6 million for reimbursement of certain prepayments. Eisai is also eligible to receive a contingent payment of $25 million if a certain patent related milestone is met;
    - Royalties commencing on loss of exclusivity for each calendar year during the royalty term equal to 12% on net sales greater than $10 million and less than $100 million, 17% on net sales of greater than $100 million and less than $125 million and 22% on net sales greater than $125 million prior to the date of generic entry. Royalties equal to 6% on net sales greater than $10 million and less than $100 million, 8.5% on net sales of greater than $100 million and less than $125 million and 11% on net sales greater than $125 million after the date of generic entry.
    - Concurrently with the acquisition, the parties entered into two related agreements: (i) a short-term Transition Services Agreement for commercial and manufacturing services and (ii) a long-term Supply Agreement for the manufacturing of FYCOMPA®. Under the Transition Services Agreement, Eisai is providing commercial and manufacturing services to the Company for a transition period following the closing of the acquisition. Further, under the Supply Agreement, Eisai will manufacture FYCOMPA® for the Company for a period of seven years (or such longer period as is set forth in the Supply Agreement) following the closing of the acquisition.

We also have entered into the following contractual arrangements:

- *Employment agreements*. We have entered into an employment agreement with our Chief Executive Officer that required us to make base salary payments of approximately $0.7 million in 2023. The agreement expires in November 2024.
- *Purchase commitment*. We have entered into a purchase commitment with a contract manufacturing organization for approximately $0.5 million 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 office facilities. Under the amended lease, our leased space increased from approximately 7,800 square feet of office space to approximately 10,700 square feet of office space. We moved into the new space around March 1, 2021 when the space became available for use. We pay annual rent of approximately $0.5 million.

Off-Balance Sheet Arrangements.

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 report 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."

The continued successful commercialization of FIRDAPSE® and FYCOMPA® are highly uncertain. Factors that will affect our success include the uncertainty of:

- The impact of the COVID-19 pandemic, or any future pandemic, on our business or on the economy generally;
- Whether we will be able to continue to successfully market FIRDAPSE® and now successfully market FYCOMPA® 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 prove 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 FIRDAPSE® and FYCOMPA® at rates that are higher than historically experienced or are higher than we project;
- Whether the daily dose of FIRDAPSE® taken by patients changes over time and affects our results of operations;
- Whether new FIRDAPSE® patients and FYCOMPA® patients can be successfully titrated to stable therapy;
- Whether we can continue to market FIRDAPSE® and now market FYCOMPA® on a profitable and cash flow positive basis;
- Whether we can successfully integrate the team that we are hiring to market FYCOMPA® into our current business structure;
- Whether the acquisition of FYCOMPA® will prove to be accretive to EBITDA and EPS in 2023;
- Whether any revenue or earnings guidance that we provide to the public market will turn out to be accurate;
- Whether payors will reimburse for our products at the price that we charge for our products;
- The ability of our third-party suppliers and contract manufacturers to maintain compliance with current Good Manufacturing Practices (cGMP);
- The ability of those third parties that distribute our products to maintain compliance with applicable law;
- Our ability to maintain compliance with applicable rules relating to our patient assistance programs for FIRDAPSE® and FYCOMPA®;
- Our ability to maintain compliance with the applicable rules that relate to our contributions to 501(c)(3) organizations that support LEMS patients;
- The scope of our intellectual property and the outcome of any challenges to our intellectual property, and, conversely, whether any third-party intellectual property presents unanticipated obstacles for FIRDAPSE® or FYCOMPA®;
- Our ability to obtain a favorable decision on our pending request for reconsideration for an extension of the expiration date of patent protection for one of our patents listed in the Orange Book for FYCOMPA®;
- Whether there will be a post-closing review by antitrust regulators of our previous acquisition transactions, and the outcome of any such reviews if they occur;
- Whether we will be able to acquire additional drug products under development, complete the research and development required to commercialize such products, and thereafter, if such products are approved for commercialization, successfully market such products;
- Whether our patents will be sufficient to prevent generic competition for FIRDAPSE® after our orphan drug exclusivity for FIRDAPSE® expires;
- Whether we will be successful in our litigation to enforce our patents against the Paragraph IV challengers who have filed relating to FIRDAPSE® or FYCOMPA®;
- The impact on our profits and cash flow of adverse changes in 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 organizations, the federal government or the government of any state, including as a result of increased scrutiny over pharmaceutical pricing or otherwise;
- Changes in the healthcare industry and the effect of political pressure from and actions by the President, Congress and/or medical professionals seeking to reduce prescription drug costs, and changes to the healthcare industry occasioned by any future changes in laws relating to the pricing of drug products, including changes made in the Inflation Reduction Act of 2022, or changes in the healthcare industry generally;
- The state of the economy generally and its impact on our business;
- The potential impact of future healthcare reform in the United States, including the Inflation Reduction Act of 2022, and measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our product;
- 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 FIRDAPSE® can be successfully commercialized in Canada on a profitable basis through KYE Pharmaceuticals, our collaboration partner in Canada;
- 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 our collaboration partner in Japan, DyDo, will successfully complete the clinical trial in Japan that will be required to seek approval to commercialize FIRDAPSE® in Japan;
- Whether DyDo will be able to obtain approval to commercialize FIRDAPSE® in Japan; and
- Whether our version of vigabatrin tablets will ever be approved by the FDA and successfully marketed by Endo, whether we will earn milestone payments or royalties on sales of our version of generic vigabatrin tablets, and whether Endo's bankruptcy filing will impact these issues.

Our current plans and objectives are based on assumptions relating to the continued commercialization of FIRDAPSE® and FYCOMPA® and on our plans to seek to acquire or in-license additional products. Although we believe that our assumptions are reasonable, any of our assumptions could prove inaccurate. Considering 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 cash equivalents that are from time to time invested in highly liquid money market funds and U.S. Treasuries. 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 March 31, 2023, 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 March 31, 2023, 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

Paragraph IV Patent Litigation

In January 2023, we received Paragraph IV Certification Notice Letters from three generic drug manufacturers advising us that they had each submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking authorization from the FDA to manufacture, use or sell a generic version of FIRDAPSE® in the United States. The notice letters each allege that our six patents listed in the FDA Orange Book covering FIRDAPSE® are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in these ANDA submissions. Under the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, we had 45 days from receipt of the notice letters to commence patent infringement lawsuits against these generic drug manufacturers in a federal district court to trigger a stay precluding FDA from approving any ANDA until May 2026 or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first. In that regard, after conducting the necessary due diligence, we filed lawsuits on March 1, 2023 in the U.S. Federal District Court for the District of New Jersey against each of the three generic drug manufacturers who notified us of their ANDA filings.

We intend to vigorously protect and defend our intellectual property for FIRDAPSE® and, although there can be no assurance, we believe that our patents will protect FIRDAPSE® from generic competition for the life of our patents.

On February 20, 2023, Catalyst received a Paragraph IV Certification Notice Letter from a company that appears to have filed the first ANDA for the oral suspension formulation for FYCOMPA®. The same company sent a similar letter to the Company later in February with a similar certification for the tablet formulation for FYCOMPA®, the fourth such certification for this formulation. Both of these letters were paragraph IV certifications of non-infringement, non-validity, and unenforceability to the ‘497 patent for FYCOMPA® but each application, like the previous Paragraph IV notices from ANDA filers, for FYCOMPA® tablets does not challenge the ‘571 patent. Similar to our actions with the FIRDAPSE® Paragraph IV Certifications described above, after due diligence Catalyst filed lawsuits on April 5, 2023 in the U.S. District Court for the District of New Jersey against the drug manufacturer who notified Catalyst of their ANDA submissions for both FYCOMPA® formulations, thus triggering the 30 month stay for each application.

Canadian Litigation

On March 11, 2022, we announced that we had received a favorable decision from the Canadian court setting aside, for the second time, the decision of Health Canada approving RUZURGI® for the treatment of LEMS patients. In its ruling, the court determined that the Minister of Health’s approach to evaluating whether FIRDAPSE®’s data deserved protection based on FIRDAPSE®’s status as an innovative drug, which protects by regulation the use of such data as part of a submission seeking an NOC for eight years from approval of the innovative drug, was legally flawed and not supported by the evidence. The Minister of Health appealed that decision, and, in January 2023, the Canadian Appellate Court overturned the trial court’s decision. Thereafter, the Minister of Health reissued an NOC for RUZURGI® in Canada and, as a result, RUZURGI® is once again available for sale in Canada.

While there can be no assurance, we do not believe that the reissuance of an NOC for RUZURGI® in Canada will have a material adverse effect on our results of operations.

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 2022 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, our Board of Directors approved a share repurchase program that authorizes the repurchase of up to $40 million of our common stock, pursuant to a repurchase program under Rule 10b-18 of the Securities Act (the Share Repurchase Program). The Share Repurchase Program commenced on March 22, 2021.

At present, we are not purchasing shares under our share repurchase program, but rather we are retaining cash for use in our business development activities.

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The following table presents information regarding repurchases by us of our common stock under the Share Repurchase Program during the three months ended March 31, 2023:

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)*
January 1, 2023 – January 31, 2023	—	$ —	—	$ 21,003
February 1, 2023 – February 28, 2023	—	$ —	—	$ 21,003
March 1, 2023 – March 31, 2023	—	$ —	—	$ 21,003

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable

ITEM 5. OTHER INFORMATION

None

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: May 10, 2023

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: May 10, 2023

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

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: May 10, 2023

/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 March 31, 2023 (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: May 10, 2023

/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 March 31, 2023 (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: May 10, 2023

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