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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 September 30, 2024

OR

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

Commission File No. 001-33057

CATALYST PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date 119,273,436 shares of common stock, $0.001 par value per share, were outstanding as of November 4, 2024.

CATALYST PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

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

	September 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 442,331	$ 137,636
Accounts receivable, net	58,266	53,514
Inventory	20,017	15,644
Prepaid expenses and other current assets	18,384	12,535
Total current assets	538,998	219,329
Operating lease right-of-use asset, net	2,301	2,508
Property and equipment, net	1,380	1,195
License and acquired intangibles, net	166,016	194,049
Deferred tax assets, net	48,473	36,544
Investment in equity securities	14,842	16,489
Total assets	$ 772,010	$ 470,114
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 11,563	$ 14,795
Accrued expenses and other liabilities	93,832	61,268
Total current liabilities	105,395	76,063
Operating lease liability, net of current portion	2,889	3,188
Other non-current liabilities	2,785	2,982
Total liabilities	111,069	82,233
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized: none issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized; 119,266,561 shares and 107,121,549 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	119	107
Additional paid-in capital	431,597	266,488
Retained earnings	229,225	121,272
Accumulated other comprehensive income (Note 4)	—	14
Total stockholders' equity	660,941	387,881
Total liabilities and stockholders' equity	$ 772,010	$ 470,114

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

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	$ 126,424	$ 102,617	$ 347,518	$ 287,398
License and other revenue	2,271	71	2,396	238
Total revenues	128,695	102,688	349,914	287,636
Operating costs and expenses:				
Cost of sales (a)	19,277	14,167	47,202	36,158
Research and development	3,284	83,662	8,850	91,178
Selling, general and administrative (a)	45,880	33,560	133,548	91,674
Amortization of intangible assets	9,345	8,487	28,033	23,506
Total operating costs and expenses	77,786	139,876	217,633	242,516
Operating income (loss)	50,909	(37,188)	132,281	45,120
Other income (expense), net	6,296	(833)	9,801	2,684
Net income (loss) before income taxes	57,205	(38,021)	142,082	47,804
Income tax provision (benefit)	13,321	(7,257)	34,129	11,238
Net income (loss)	$ 43,884	$ (30,764)	$ 107,953	$ 36,566
Net income (loss) per share:				
Basic	$ 0.37	$ (0.29)	$ 0.92	$ 0.34
Diluted	$ 0.35	$ (0.29)	$ 0.87	$ 0.32
Weighted average shares outstanding:				
Basic	118,931,153	106,568,137	117,976,056	106,133,077
Diluted	125,407,279	106,568,137	124,519,838	113,751,370
Net income (loss)	$ 43,884	$ (30,764)	$ 107,953	$ 36,566
Other comprehensive income (loss) (Note 4):				
Unrealized gain (loss) on available-for-sale securities, net of tax of $0, $1, $4 and $3, respectively	—	(4)	(14)	(9)
Comprehensive income (loss)	$ 43,884	$ (30,768)	$ 107,939	$ 36,557

(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 and nine months ended September 30, 2024
(in thousands)

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total
Balance at December 31, 2023	$ —	107,122	$ 107	$ 266,488	$ 121,272	$ 14	$ 387,881
Issuance of common stock, net	—	10,000	10	140,694	—	—	140,704
Stock-based compensation	—	—	—	8,248	—	—	8,248
Exercise of stock options for common stock	—	664	1	1,521	—	—	1,522
Issuance of common stock upon vesting of restricted stock units, net	—	244	—	(204)	—	—	(204)
Other comprehensive gain (loss)	—	—	—	—	—	(14)	(14)
Net income (loss)	—	—	—	—	23,275	—	23,275
Balance at March 31, 2024	—	118,030	118	416,747	144,547	—	561,412
Issuance of common stock, net	—	—	—	10	—	—	10
Stock-based compensation	—	—	—	4,408	—	—	4,408
Exercise of stock options for common stock	—	491	1	2,030	—	—	2,031
Net income (loss)	—	—	—	—	40,794	—	40,794
Balance at June 30, 2024	—	118,521	119	423,195	185,341	—	608,655
Stock-based compensation	—	—	—	4,424	—	—	4,424
Exercise of stock options for common stock	—	746	—	3,978	—	—	3,978
Net income (loss)	—	—	—	—	43,884	—	43,884
Balance at September 30, 2024	$ —	119,267	$ 119	$ 431,597	$ 229,225	$ —	$ 660,941

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

CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (unaudited)
For the three and nine months ended September 30, 2023
(in thousands)

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total
Balance at December 31, 2022	$ —	105,263	$ 105	$ 250,430	$ 49,862	$ 24	$ 300,421
Stock-based compensation	—	—	—	2,892	—	—	2,892
Exercise of stock options for common stock	—	548	1	1,269	—	—	1,270
Issuance of common stock upon vesting of restricted stock units, net	—	127	—	(477)	—	—	(477)
Other comprehensive gain (loss)	—	—	—	—	—	(13)	(13)
Net income (loss)	—	—	—	—	29,568	—	29,568
Balance at March 31, 2023	—	105,938	106	254,114	79,430	11	333,661
Stock-based compensation	—	—	—	3,298	—	—	3,298
Exercise of stock options for common stock	—	557	1	616	—	—	617
Issuance of common stock upon vesting of restricted stock units, net	—	6	—	(52)	—	—	(52)
Other comprehensive gain (loss)	—	—	—	—	—	8	8
Net income (loss)	—	—	—	—	37,762	—	37,762
Balance at June 30, 2023	—	106,501	107	257,976	117,192	19	375,294
Stock-based compensation	—	—	—	3,810	—	—	3,810
Exercise of stock options for common stock	—	92	—	212	—	—	212
Issuance of common stock upon vesting of restricted stock units, net	—	12	—	—	—	—	—
Other comprehensive gain (loss)	—	—	—	—	—	(4)	(4)
Net income (loss)	—	—	—	—	(30,764)	—	(30,764)
Balance at September 30, 2023	$ —	106,605	$ 107	$ 261,998	$ 86,428	$ 15	$ 348,548

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

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

	For the Nine Months Ended September 30,	
	2024	2023
Operating Activities:		
Net income (loss)	$ 107,953	$ 36,566
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	283	232
Stock-based compensation	17,080	10,000
Amortization of intangible assets	28,033	23,506
Deferred taxes	(11,943)	(18,701)
Accretion of discount	(796)	1,146
Reduction in the carrying amount of right-of-use asset	207	195
Acquired inventory samples expensed from asset acquisition	—	130
Acquired in-process research and development	—	79,288
Change in fair value of equity securities	1,647	568
(Increase) decrease in:		
Accounts receivable, net	(4,752)	(37,610)
Inventory	(4,373)	1,870
Prepaid expenses and other current assets	(5,849)	(7,219)
Increase (decrease) in:		
Accounts payable	(3,232)	623
Accrued expenses and other liabilities	44,948	(2,390)
Operating lease liability	(275)	(252)
Net cash provided by (used in) operating activities	168,931	87,952
Investing Activities:		
Purchases of property and equipment	(468)	(138)
Payment in connection with asset acquisition	—	(162,293)
Acquisition of in-process research and development	—	(79,288)
Purchase of equity securities	—	(13,465)
Net cash provided by (used in) investing activities	(468)	(255,184)
Financing Activities:		
Payment of employee withholding tax related to stock-based compensation	(204)	(529)
Proceeds from exercise of stock options	7,531	2,099
Payment of liabilities arising from asset acquisition	(11,799)	(11,762)
Proceeds from issuance of common stock	141,000	—
Payment of fees in connection with issuance of common stock	(296)	—
Net cash provided by (used in) financing activities	136,232	(10,192)
Net increase (decrease) in cash and cash equivalents	304,695	(177,424)
Cash and cash equivalents – beginning of period	137,636	298,395
Cash and cash equivalents – end of period	$ 442,331	$ 120,971
Supplemental disclosures of cash flow information:		
Cash paid for income taxes	$ 51,691	$ 41,663
Cash paid for interest	$ 1,301	$ 650
Non-cash investing and financing activities:		
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, patient-centric biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare and difficult to treat diseases. The Company currently markets three drug products, FIRDAPSE® (amifampridine), FYCOMPA® (perampanel), and AGAMREE® (vamorolone). The Company is also currently seeking to further expand its product portfolio, with a focus on acquiring the rights to late-stage products to treat rare (orphan) central nervous system and adjacent rare (orphan) diseases. With an unwavering patient focus embedded in everything it does, the Company is committed to providing innovative, best-in-class medications with the hope of making a meaningful impact on those affected by these conditions.

The Company's New Drug Application (NDA) 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 (U.S.) 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, Inc. (KYE). In the third quarter of 2022, the FDA approved the Company's supplemental New Drug Application approving an expansion of the FIRDAPSE® label to include pediatric patients (ages six and older). In the second quarter of 2024, the FDA approved the Company's supplemental New Drug Application increasing the indicated maximum daily dose of FIRDAPSE® (amifampridine) for adults and pediatric patients weighing more than 45 kg from 80 mg to 100 mg for the treatment of LEMS.

On December 17, 2022, the Company entered into an asset purchase agreement with Eisai Co., Ltd. (Eisai) for the acquisition of the U.S. 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 the U.S. rights to FYCOMPA® on January 24, 2023 and is now marketing FYCOMPA® in the U.S.

In July 2023, the Company completed its acquisition from Santhera Pharmaceuticals Holdings (Santhera) of an exclusive license for North America for AGAMREE® (vamorolone), a treatment for patients suffering with Duchenne muscular dystrophy (DMD). The license is for exclusive commercial rights in the U.S., Canada, and Mexico, as well as the right of first negotiation in Japan should Santhera pursue partnership opportunities in that jurisdiction. Additionally, the Company holds the North American rights for any future approved indications of AGAMREE®. AGAMREE® has previously received FDA Orphan Drug and Fast Track designations. On October 26, 2023, the FDA approved AGAMREE® oral suspension 40 mg/ml for the treatment of DMD in patients aged two years and older, and on March 13, 2024, the Company began marketing AGAMREE® in the U.S.

The Company has devoted substantially all its efforts to selling its products, business planning, recruiting management and technical staff, acquiring operating assets, raising capital, and research and development. 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

Based on forecasts of available cash, the Company believes that it has sufficient resources to support the currently anticipated operations for at least the next 12 months from the 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.

On January 9, 2024, the Company completed a public offering of 10 million shares of its common stock, raising net proceeds of approximately $140.7 million. The proceeds of the offering will be used to potentially acquire new products and for general corporate purposes.

Risks and Uncertainties

The Company is subject to risks and uncertainties that could affect its business in unforeseen ways.

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 U.S. 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, 2023 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, 2023 included in the 2023 Annual Report on Form 10-K filed by the Company with the SEC. The results of operations for the nine months ended September 30, 2024 are not necessarily indicative of the results to be expected for any future period or for the full 2024 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 primarily invests in high credit-quality instruments in order to obtain higher yields on its 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 a significant amount of its cash and cash equivalents deposited in money market accounts with two financial institutions.

e. INVESTMENTS. At September 30, 2024 investments consisted of an investment in equity securities. At December 31, 2023, investments consisted of U.S. Treasuries and an investment in equity securities. Such investments are not insured by the U.S. Federal Deposit Insurance Corporation.

There were no U.S. Treasuries held at September 30, 2024 and U.S. Treasuries held at December 31, 2023 were 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.

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 (expense), net in the consolidated statements of operations and comprehensive income (loss) and are derived using the specific identification method for determining the cost of securities sold. Interest income (expense) is recognized when earned and is included in other income (expense), net in the consolidated statements of operations and comprehensive income (loss). 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 (loss). The Company has not recorded an allowance for credit loss on its available-for-sale securities. See Note 3 (Investments).

In July 2023, the Company made a strategic equity investment into Santhera by acquiring 1,414,688 of Santhera's post reverse-split ordinary shares (representing approximately 11.26% of Santhera's outstanding ordinary shares immediately following the transaction). The investment is denominated in Swiss Francs. The Company has determined that it does not have significant influence over the operations of Santhera and accordingly the investment in Santhera's ordinary shares is recorded under ASC 321, Equity Securities, with changes in fair value, inclusive of changes resulting from movements in foreign exchange rates, in other income (expense), net in the consolidated statements of operations and comprehensive income (loss).

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

f. **ACCOUNTS RECEIVABLE, NET.** Accounts receivable are 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, current and future economic and market conditions and individual customer circumstances. The Company has not historically experienced any significant credit losses. All customer accounts are actively managed. At September 30, 2024 and December 31, 2023, the Company determined that an allowance for expected credit losses was not required. No amounts were written off during the periods presented.

g. **INVENTORY**. Inventories are stated at the lower of cost or net realizable value. Inventories consist of raw materials, work-in-process and finished goods. Costs to be capitalized as inventories primarily include third-party manufacturing costs and other overhead costs. Cost is determined using a standard cost method, which approximates actual cost, and assumes a first-in, first out (FIFO) flow of goods. 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®, FYCOMPA® and AGAMREE® 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®, FYCOMPA® and AGAMREE® utilized for both commercial and clinical programs are identical and, as a result, the inventories have 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, prepaid co-pay assistance program, 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 costs consist 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, as per Company policy. 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 test 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 test is met, the transaction is accounted for as an asset acquisition. If the screen test 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.

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

See Notes 12 (Commitments and Contingencies) and 13 (Agreements) for further discussion of the Company's exclusive license agreement with Jacobus Pharmaceutical Company, Inc. (Jacobus), for the rights to develop and commercialize RUZURGI® in the U.S. and Mexico, which the Company accounted for as an asset acquisition under ASC 805-50. See Note 13 (Agreements) for further discussion on the Company's acquisitions of the U.S. rights to FYCOMPA® from Eisai, and on the exclusive license for North America acquired from Santhera for AGAMREE®, both of which the Company accounted for as asset acquisitions under ASC 805-50.

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 September 30, 2024 and December 31, 2023, 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 September 30, 2024	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	$ 335,850	$ 335,850	$ —	$ —
Investment in equity securities:				
Equity securities	$ 14,842	$ 14,842	$ —	$ —

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

	Fair Value Measurements at Reporting Date Using (in thousands)			
	Balances as of December 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	$ 18,256	$ 18,256	$ —	$ —
U.S. Treasuries	$ 94,523	$ 94,523	$ —	$ —
Investment in equity securities:				
Equity securities	$ 16,489	$ 16,489	$ —	$ —

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, net, 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. 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 customers obtain 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® and AGAMREE®, subsequent to receiving FDA approvals, the Company entered into an arrangement with one distributor (the Customer), which is the exclusive distributor of FIRDAPSE® and AGAMREE® in the U.S. The Customer subsequently resells FIRDAPSE® and AGAMREE® 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® and AGAMREE®.

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

During 2023, the Company sold FYCOMPA® in the U.S. commercial market through a Transition Service Agreement with a U.S. subsidiary of Eisai to major wholesalers and specialty pharmaceutical distributors. These sales are often subject to contracts held with managed care organizations and government agencies. The distribution services under the Transition Services Agreement ended on December 31, 2023, and beginning on January 1, 2024, the Company commenced direct sales of FYCOMPA® in the U.S. commercial market.

Product Revenue, Net: The Company recognizes revenue on product sales when its customers obtain control of the Company's products, which occur 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 60 days.

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

If taxes should be collected from the Customer relating to product sales and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the three and nine months ended September 30, 2024 and 2023.

During the three and nine months ended September 30, 2024 and 2023, substantially all of the Company's product revenues were from sales to customers in the U.S.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
FIRDAPSE®	$ 79,303	$ 66,224	$ 223,517	$ 188,648
FYCOMPA®+	32,075	36,393	99,035	98,750
AGAMREE®*	15,046	—	24,966	—
Total product revenue, net	$ 126,424	$ 102,617	$ 347,518	$ 287,398

+FYCOMPA® net product revenue for the nine months ended September 30, 2023 is for the period between January 24, 2023 (date of acquisition) and September 30, 2023.

*AGAMREE® net product revenue for the nine months ended September 30, 2024 is for the period between March 13, 2024 (date of commercial launch) and September 30, 2024.

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, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its 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 its customers) or a current liability (if the amount is payable to a party other than its 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.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplates application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of September 30, 2024 and, therefore, the transaction price was not reduced further during the three and nine months ended September 30, 2024 and 2023. 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.

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

Trade Discounts, Allowances and Wholesaler Fees: The Company provides its 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. To the extent the services received are distinct from the sale of products to its customers, these payments are classified in selling, general and administrative expenses in the Company's consolidated statements of operations and comprehensive income (loss). However, if the Company has determined such services received are not distinct from the Company's sale of products to its customers, these payments have been recorded as a reduction of revenue within the consolidated statements of operations and comprehensive income (loss) through September 30, 2024 and 2023, as well as a reduction to accounts receivable, net on the consolidated balance sheets.

Prompt Payment Discounts: The Company provides its 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 liabilities in the consolidated balance sheets.

Product Returns: Consistent with industry practice, the Company offers its 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 customers and records this estimate as a reduction of revenue in the period in which 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. Return payments related to the sale of products 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 liabilities in the consolidated balance sheets.

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 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, as well as an estimate of chargeback claims 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.

Government Rebates: The Company is subject to discount obligations under state Medicaid, Medicare and other government programs. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue. For reserves related to the sale of its products, there is an establishment of a current liability, which is included in accrued expenses and other 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.

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

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.

Payor Rebates: The Company contracts with certain private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue, net and the establishment of a current liability, which is included in accrued expenses and other liabilities on the consolidated balances sheets.

Bridge and Patient Assistance Programs: The Company provides FIRDAPSE® and AGAMREE® 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® or AGAMREE® while the Company is determining the patient's third-party insurance, prescription drug benefit or other third-party coverage for FIRDAPSE® or AGAMREE®. The Patient Assistance Program provides FIRDAPSE® or AGAMREE® free of charge for longer periods of time for those who are uninsured or functionally uninsured with respect to FIRDAPSE® or AGAMREE® 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 (loss).

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.

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

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 latter 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 statements 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.

See 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.

The Company records upfront and milestone payments made to third parties under licensing and collaboration arrangements that occur before a compound receives regulatory approval as acquired in-process research and development (IPR&D). IPR&D acquired as part of an asset acquisition with no alternative future use is expensed immediately to research and development. Milestone payments made after regulatory approval are capitalized as a developed asset and unless the asset is determined to have an indefinite life, the Company amortizes its definite-lived intangible assets using the straight-line method, which is considered the best estimate of economic benefit, over their estimated useful lives.

r. **ADVERTISING EXPENSE.** Advertising costs are expensed as incurred. The Company incurred approximately $2.5 million and $7.6 million in advertising costs during the three and nine months ended September 30, 2024, respectively, and approximately $1.7 million and $5.4 million during the three and nine months ended September 30, 2023, respectively, which are included in selling, general and administrative expenses in the Company's consolidated statements of operations and comprehensive income (loss).

s. **STOCK-BASED COMPENSATION.** The Company recognizes expense in the consolidated statements of operations and comprehensive income (loss) 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, 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 products, FIRDAPSE® and AGAMREE®, in the U.S. 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 related to these products. The Company sells its product, FYCOMPA®, directly to major wholesalers and specialty pharmaceutical distributors and indirectly to managed care organizations and government agencies. The creditworthiness of its customers 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 creditworthiness of its customers, historical payment patterns, aging of receivable balances and general economic conditions.

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

As of September 30, 2024, the Company had three FDA approved 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 sales of FIRDAPSE®, FYCOMPA®, and AGAMREE® 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 its products and any future drug candidates. The commercialization of its products 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®. The Company relies on the same third-party manufacturers for FYCOMPA® as utilized by Eisai prior to the Company's acquisition of the U.S. rights to the product in January 2023. It also relies on Santhera and its supplier as its sole source of supply for AGAMREE®. 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.

The following table illustrates the approximate percentage of the Company's total net product revenue attributed to the Company's largest customers for the periods presented:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Customer A	74.6%	64.5%	71.5%	65.6%
Customer B*	—	35.5%	—	34.4%
Customer C	9.4%	—	10.0%	—
Total	84.0%	100.0%	81.5%	100.0%

*During 2023, the Company sold FYCOMPA® through a Transition Service Agreement with a U.S. subsidiary of Eisai. Effective January 1, 2024, FYCOMPA® is being sold and distributed through a third-party logistics (3PL) organization. Customers B and C both relate to sales of FYCOMPA®.

u. ROYALTIES. Royalties incurred in connection with the Company's license agreement for FIRDAPSE® and AGAMREE®, 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 July 11, 2022 (the Effective Date) 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 2020. 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 (LOSS). U.S. GAAP requires that all components of comprehensive income (loss) be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is net income (loss), plus certain other items that are recorded directly into stockholders' equity. The Company's comprehensive income (loss) is shown on the consolidated statements of operations and comprehensive income (loss) for the three and nine months ended September 30, 2024 and 2023, and is comprised of net unrealized gains (losses) on the Company's available-for-sale securities.

x. NET INCOME (LOSS) PER COMMON SHARE. Basic net income (loss) per share is computed by dividing net income (loss) 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 (loss) per common share is computed by dividing net income (loss) 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 September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Basic weighted average common shares outstanding	118,931,153	106,568,137	117,976,056	106,133,077
Effect of dilutive securities	6,476,126	—	6,543,782	7,618,293
Diluted weighted average common shares outstanding	125,407,279	106,568,137	124,519,838	113,751,370

Outstanding common stock equivalents totaling approximately 5.1 million and 5.2 million were excluded from the calculation of diluted net income (loss) per common share for the three and nine months ended September 30, 2024, respectively, as their effect would be anti-dilutive. For the three months ended September 30, 2023, approximately 12.1 million shares of outstanding common stock equivalents were excluded from the calculation of diluted net income (loss) per common share because a net loss was reported and therefore their effect was anti-dilutive. Potentially dilutive options to purchase common stock for the three months ending September 30, 2023, had exercise prices ranging from $1.13 to $19.02. Outstanding common stock equivalents totaling approximately 2.0 million were excluded from the calculation of diluted net income (loss) per common share for the nine months ended September 30, 2023, 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 and nine months ended September 30, 2024.

In November 2023, the FASB issued ASU No. 2023-07, *Improvements to Reportable Segment Disclosures* (ASU 2023-07) which is intended to improve reportable segment disclosures primarily through enhanced disclosure of reportable segment expenses and requires that a public entity that has a single reportable segment provide all the disclosures required by ASU 2023-07 and all existing segment disclosures in Topic 280. The new guidance is required to be applied retrospectively to all prior periods presented in the financial statements and is effective for the Company for fiscal periods beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. The Company has one reportable segment and is evaluating the impact of the standard on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* which requires significant disclosures about income taxes, primarily focused on the disclosure of income taxes paid and the rate reconciliation table. The new guidance will be applied prospectively and is effective for the Company for fiscal periods beginning after December 15, 2024. The Company is evaluating the impact of the standard on the Company's consolidated financial statements.

3. Investments.

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

	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost
At September 30, 2024:				
U.S. Treasuries - Cash equivalents	$ —	$ —	$ —	$ —
Total	$ —	$ —	$ —	$ —
At December 31, 2023:				
U.S. Treasuries - Cash equivalents	$ 94,523	$ 18	$ —	$ 94,505
Total	$ 94,523	$ 18	$ —	$ 94,505

There were no realized gains or losses from available-for-sale securities during the three and nine months ended September 30, 2024 and 2023.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Equity securities:				
Net gains (losses) recognized during the period on equity securities	$ 1,759	$ (568)	$ (1,647)	$ (568)
Unrealized net gains (losses) recognized during the period on equity securities still held at the reporting date	$ 1,759	$ (568)	$ (1,647)	$ (568)

There were no sales of equity securities during the three and nine months ended September 30, 2024 and 2023.

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 and nine months ended September 30, 2024 and 2023.

There were no reclassifications out of accumulated other comprehensive income during the three and nine months ended September 30, 2024 and 2023.

	Total Accumulated Other Comprehensive Income
Balance at June 30, 2024	$ —
Other comprehensive loss before reclassifications	—
Amount reclassified from accumulated other comprehensive income	—
Net current period other comprehensive gain (loss)	—
Balance at September 30, 2024	$ —
Balance at December 31, 2023	$ 14
Other comprehensive loss before reclassifications	(14)
Amount reclassified from accumulated other comprehensive income	—
Net current period other comprehensive gain (loss)	(14)
Balance at September 30, 2024	$ —

4. Accumulated Other Comprehensive Income (continued).

	Total Accumulated Other Comprehensive Income
Balance at June 30, 2023	$ 19
Other comprehensive loss before reclassifications	(4)
Amount reclassified from accumulated other comprehensive income	—
Net current period other comprehensive gain (loss)	(4)
Balance at September 30, 2023	$ 15
Balance at December 31, 2022	$ 24
Other comprehensive loss before reclassifications	(9)
Amount reclassified from accumulated other comprehensive income	—
Net current period other comprehensive gain (loss)	(9)
Balance at September 30, 2023	$ 15

5. Inventory.

Inventory consists of the following (in thousands):

	September 30, 2024	December 31, 2023
Raw materials	$ 6,948	$ 1,910
Work-in-process	3,826	4,573
Finished goods	9,243	9,161
Total inventory	$ 20,017	$ 15,644

6. Prepaid Expenses and Other Current Assets.

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

	September 30, 2024	December 31, 2023
Prepaid manufacturing costs	$ 180	$ 2,005
Prepaid tax	6,166	1,238
Prepaid insurance	489	1,332
Prepaid subscriptions fees	1,870	1,299
Prepaid research fees	1,833	1,500
Prepaid commercialization expenses	4,543	3,038
Due from collaborative and licensing arrangements	—	138
Prepaid conference and travel expenses	1,233	771
Prepaid co-pay assistance program	1,561	863
Other	509	351
Total prepaid expenses and other current assets	$ 18,384	$ 12,535

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. The Company has 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.

7. Operating Leases (continued).

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease cost	$ 108	$ 108	$ 323	$ 323

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

	For the Nine Months Ended September 30,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows	$ 391	$ 379
Right-of-use assets obtained in exchange for lease obligations:		
Operating lease	$ 67	$ 67

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

	September 30, 2024	December 31, 2023
Operating lease right-of-use assets, net	$ 2,301	$ 2,508
Other current liabilities	$ 393	$ 369
Operating lease liabilities, net of current portion	2,889	3,188
Total operating lease liabilities	$ 3,282	$ 3,557

As of September 30, 2024 and December 31, 2023, the weighted average remaining lease term was 6.6 years and 7.3 years, respectively. The weighted average discount rate used to determine the operating lease liabilities was 4.51% as of September 30, 2024 and December 31, 2023.

Remaining payments of lease liabilities as of September 30, 2024 were as follows (in thousands):

2024 (remaining three months)	$ 131
2025	537
2026	553
2027	570
2028	587
Thereafter	1,440
Total lease payments	3,818
Less: imputed interest	(536)
Total	$ 3,282

Rent expense was approximately $0.1 million and $0.3 million for both the three and nine months ended September 30, 2024 and 2023, respectively.

8. Property and Equipment, Net.

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

	September 30, 2024	December 31, 2023
Furniture and equipment	$ 962	$ 494
Leasehold improvements	991	991
Software	433	433
Less: Accumulated depreciation	(1,006)	(723)
Total property and equipment, net	$ 1,380	$ 1,195

9. License and Acquired Intangibles, Net.

The following table presents the Company's intangible assets at September 30, 2024 (in thousands):

	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Intangible assets:			
License and acquired intangibles for RUZURGI®	$ 33,569	$ 5,158	$ 28,411
License and acquired intangibles for FYCOMPA®	158,143	53,395	104,748
License and acquired intangibles for AGAMREE®	36,000	3,143	32,857
Total	$ 227,712	$ 61,696	$ 166,016

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

	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Intangible assets:			
License and acquired intangibles for RUZURGI®	$ 33,569	$ 3,418	$ 30,151
License and acquired intangibles for FYCOMPA®	158,143	29,673	128,470
License and acquired intangibles for AGAMREE®	36,000	572	35,428
Total	$ 227,712	$ 33,663	$ 194,049

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 estimated useful life used for this purpose for RUZURGI®, FYCOMPA® and AGAMREE® was approximately 14.5 years, 5 years and 10.5 years, respectively.

The Company recorded approximately $0.5 million and $1.7 million in amortization expense related to the licensed and acquired intangibles for RUZURGI® during the three and nine months ended September 30, 2024, within selling, general and administrative expenses in the consolidated statements of operations and comprehensive income (loss). The Company recorded approximately $7.9 million and $23.7 million in amortization expense related to the licensed and acquired intangibles for FYCOMPA® during the three and nine months ended September 30, 2024, within cost of sales in the consolidated statements of operations and comprehensive income (loss). The Company recorded approximately $0.9 million and $2.6 million in amortization expense related to the licensed and acquired intangibles for AGAMREE® during the three and nine months ended September 30, 2024, within cost of sales in the consolidated statements of operations and comprehensive income (loss). The Company recorded approximately $0.6 million and $1.8 million in amortization expense related to the licensed and acquired intangibles for RUZURGI® during the three and nine months ended September 30, 2023, within selling, general and administrative expenses in the consolidated statements of operations and comprehensive income (loss). The Company recorded approximately $7.9 million and $21.8 million in amortization expense related to the licensed and acquired intangibles for FYCOMPA® during the three and nine months ended September 30, 2023, within cost of sales in the consolidated statements of operations and comprehensive income (loss). The Company recorded no amortization expense related to the licensed and acquired intangibles for AGAMREE® during the three and nine months ended September 30, 2023. Amortization of the FYCOMPA®, RUZURGI® and AGAMREE® intangible assets are reported together as amortization of intangible assets in the consolidated statements of operations and comprehensive income (loss).

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

2024 (remaining three months)	$ 9,345
2025	37,378
2026	37,378
2027	37,378
2028	7,705
Thereafter	36,832
Total	$ 166,016

At September 30, 2024 and December 31, 2023, the weighted average amortization period remaining for intangible assets was 5.7 years and 6.5 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 and nine months ended September 30, 2024 or 2023.

10. Accrued Expenses and Other Liabilities.

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

	September 30, 2024	December 31, 2023
Accrued preclinical and clinical trial expenses	$ 869	$ 1,015
Accrued professional fees	8,250	4,730
Accrued compensation and benefits	8,013	8,883
Accrued license fees	24,667	24,437
Accrued purchases	513	192
Operating lease liability	393	369
Accrued gross-to-net revenue liabilities*	47,455	6,877
Accrued income tax	—	729
Due to licensor	2,871	12,540
Accrued interest payable	352	1,031
Other	449	465
Current accrued expenses and other liabilities	93,832	61,268
Lease liability – non-current	2,889	3,188
Due to licensor – non-current	610	2,497
Other – non-current	2,175	485
Non-current accrued expenses and other liabilities	5,674	6,170
Total accrued expenses and other liabilities	$ 99,506	$ 67,438

* During 2023, the Company sold FYCOMPA® through a Transition Service Agreement with Eisai. Effective January 1, 2024, FYCOMPA® is being sold and distributed through a 3PL organization.

11. Collaborative and Licensing Arrangements.

Endo, Inc.

In December 2018, the Company entered into a collaboration and license agreement (Collaboration) with Endo, Inc. (formerly, Endo International plc) (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, Inc. (Par). Under the Collaboration, Endo assumed all development, manufacturing, clinical, regulatory, sales and marketing costs under the collaboration, while the Company was responsible for exercising commercially reasonable efforts to develop, or cause the development of, a final finished, stable dosage form of generic Sabril® tablets.

In July 2024, a termination and mutual release agreement was finalized between Endo and the Company that discontinued work on the collaboration for development and commercialization of vigabatrin. The end of the collaboration does not have a material impact on the Company's consolidated financial statements.

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 received an up-front payment, has received payment upon transfer of Marketing Authorization and delivery of commercial product, received payment for supply of FIRDAPSE®, and 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 the 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.

11. Collaborative and Licensing Arrangements (continued).

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.

In July 2024, the Company entered into a license, supply and commercialization agreement with KYE, for the commercialization of AGAMREE® in Canada granting KYE the exclusive Canadian commercial rights to market AGAMREE® in Canada for DMD and other indications.

Under the agreement, KYE will be responsible for obtaining regulatory approval of the product from Health Canada and the Company will supply product to KYE. Further, the Company received an upfront payment from KYE and will be eligible to receive further reimbursement, sales milestones and sales royalties for AGAMREE®.

These agreements are in form identified as collaborative agreements and the Company has concluded for accounting purposes that they also represent contracts with a customer. This is because the Company grants to KYE a license and provides supply of FIRDAPSE® and AGAMREE® in exchange for consideration, which are outputs of the Company's ongoing activities. Accordingly, the Company has concluded that these collaborative arrangements will be accounted for pursuant to Topic 606.

Revenue from sales by KYE is recognized in the quarter in which the sales occurred.

Revenues from the arrangements with KYE for the three and nine months ended September 30, 2024 and 2023 were not material. Revenue is included in license and other revenue in the accompanying consolidated statements of operations and comprehensive income (loss). Expenses incurred, net have been included in selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive income (loss).

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.

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 latter 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 were revenues of $2.1 million from the arrangement with DyDo for both the three and nine months ended September 30, 2024, which consisted of a milestone payment earned upon DyDo receiving regulatory approval to commercialize FIRDAPSE® for the treatment of patients with LEMS in Japan and is included in license and other revenue in the accompanying consolidated statements of operations and comprehensive income (loss). There were revenues of $0 and $0.5 million from the arrangement with DyDo for the three and nine months ended September 30, 2023, respectively, which is included in product revenue, net in the accompanying consolidated statements of operations and comprehensive income (loss). Further, on September 24, 2024, DyDo advised the Company that the Ministry of Health, Labour and Welfare (MHLW) had approved DyDo's Japan NDA to commercialize FIRDAPSE® for the treatment of patients with LEMS in Japan and that DyDo expects to launch the product in Japan by the end of the fourth quarter of 2024.

12. Commitments and Contingencies.

In May 2019, the FDA approved a 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 the Magistrate Judge recommended to the District Judge handling the case that the District Judge 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 11th 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 U.S. 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 U.S. 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 its patent case against Jacobus, which was 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.

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, $10 million was paid on the first anniversary of the closing, and the remaining $10 million was paid on the second anniversary of the closing;
- An annual royalty on the Company's net sales (as defined in the License and Asset Purchase Agreement between Catalyst and Jacobus) of amifampridine products in the U.S. 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 the Company's FIRDAPSE® patents in the U.S., 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 the Company 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.

12. Commitments and Contingencies (continued).

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 due to Medunik's use of the Company's protected data in its application. After two decisions by the trial judge to quash the RUZURGI® approval and remand the matter back to Health Canada, the Canadian Federal Appellate Court overturned the trial judge's decision. The Minister subsequently reapproved RUZURGI®'s NOC for Canada in 2023. The Company does not expect the approval of RUZURGI® in Canada to have a material impact on the Company's consolidated financial statements.

In January 2023, the Company received Paragraph IV Certification Notice Letters from three generic drug manufacturers (Teva, Hetero and Lupin) 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 U.S. 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, 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. In June 2024, Lupin converted five of its Paragraph IV Certifications in its ANDA to Paragraph III certifications acknowledging the validity and their ANDA's infringement of five of those patents, the latest ending in 2034. The Company subsequently dismissed all of its claims against Lupin related to those five patents but maintains its claims against Lupin for the remaining Paragraph IV certification for United States Patent No. 10,626,088 which is the patent expiring in 2037, so the litigation continues. Further, the litigation with Teva and Hetero continues with respect to all six patents.

Further, in October 2023, the Company received a Paragraph IV Certification Notice Letter from a fourth generic drug manufacturer (Inventia), and the Company filed a similar lawsuit against that manufacturer in November 2023. On July 30, 2024, the Company settled its patent litigation with Inventia for FIRDAPSE®. In that settlement, Inventia acknowledged both the validity of the Company's FIRDAPSE® patents and also the infringement by the ANDA filer's product of the Company's patents. As part of the settlement, Inventia also agreed not to commercialize its product until the earlier of all FIRDAPSE® patents expiration scheduled for February 2037, or the earlier entry into the market of another ANDA product meeting certain conditions.

The outcome of patent litigation with Paragraph IV challengers is always uncertain and there can be no assurance that the Company will prevail in this litigation. However, the Company is vigorously defending its intellectual property for FIRDAPSE® in this litigation and believes that its patent estate will protect FIRDAPSE® from generic competition for the life of its patents.

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. This lawsuit was settled in June 2024. As part of this settlement, this Paragraph IV filer agreed not to commercialize their proposed ANDA products for both the oral suspension formulation of FYCOMPA® and for FYCOMPA® tablets until at least December 15, 2025.

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's commercial territory will be expanded under the license agreement to include most of Asia, as well as Latin America, upon the acceptance by the Pharmaceuticals and Medical Devices Agency (PMDA) of a Japan MAA for FIRDAPSE® for LEMS. Under the amendment, the Company will pay royalties to its 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.

On December 18, 2023, DyDo filed a Japan NDA with the PMDA, which was accepted for filing upon its submission. As a result, the Company's territory automatically expanded on that date to include most of Asia and Latin America.

In January 2020, the Company was advised that BioMarin has transferred substantially all of its rights under the license agreement to SERB S.A., and SERB S.A. is now the Company's licensor under the license agreement.

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 U.S. 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 also paid an additional $10 million on the first annual anniversary of the Effective Date (July 11, 2023). The Company paid the final $10 million installment on the second annual anniversary of the Effective Date (July 11, 2024). The Company is also obligated to pay tiered royalty payments on net sales (as defined in the license agreement) of all of the Company's amifampridine products in the U.S. 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 U.S.

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 U.S.) of $5 million unless a competing product or generic version of FIRDAPSE® is being marketed or sold in the U.S. 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.

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 U.S. for RUZURGI®, its U.S. 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 was recorded as an expense in research and development expenses in the consolidated statements of operations and comprehensive income (loss) for 2022.

13. Agreements (continued).

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. The aggregate consideration for the acquisition was $164.2 million in cash, including the reimbursement of certain liabilities and the payment of transaction costs.

Eisai was eligible to receive a contingent payment of $25 million if a certain regulatory milestone was met. As meeting the regulatory milestone was 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 will recognize the royalty payments in cost of sales as revenue from product sales is recognized.

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.

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

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 the acquisition date and reimbursement was fully applied as of June 30, 2023.

(ii) As of September 30, 2024, the full $5.9 million has been paid in cash.

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® product 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. LICENSE AGREEMENT FOR AGAMREE® (VAMOROLONE). In July 2023, the Company completed its acquisition from Santhera of an exclusive license for North America for AGAMREE® (vamorolone), a treatment for patients suffering with DMD which was approved by the FDA on October 26, 2023. On March 13, 2024, the Company announced the U.S. commercial launch of AGAMREE® for the treatment of DMD in patients aged two years or older. The license is for exclusive commercial rights in the U.S., Canada, and Mexico, as well as the right of first negotiation in Europe and Japan should Santhera pursue partnership opportunities in those jurisdictions. Additionally, the Company will hold North American rights for any future approved indications of AGAMREE®. The Company made an all-cash initial payment of $75 million at the closing of the acquisition to acquire the license.

Under the license agreement, the Company pays: (i) royalties to the licensor until the later of expiration of product exclusivity or ten years from the first commercial sale of AGAMREE® equal to 5% of net sales (as defined in the license agreement) in North America for any calendar year for sales equal to or less than $100 million (prior to December 31, 2025 only), 7% of net sales for sales in excess of $100 million and up to $200 million, 9% of net sales for sales in excess of $200 million and up to $300 million, 11% of net sales for sales in excess of $300 million; and (ii) royalties to the third-party licensor of the rights sublicensed to the Company until the later of expiration of product exclusivity or ten years from the first commercial sale of AGAMREE® equal to 7% of net sales (as defined in the license agreement) in North America for any single calendar year for sales equal to or less than $250 million, 8.5% of net sales for sales in excess of $250 million and up to $500 million, 10% of net sales for sales in excess of $500 million and up to $750 million, 12% of net sales for sales in excess of $750 million and up to $1 billion, 13% of net sales for sales in excess of $1 billion and up to $2 billion and 15% of net sales for sales in excess of $2 billion. Furthermore, the Company may pay Santhera sales-based milestones of up to $105 million as well as up to 11% percent royalties for all additional indications and milestones of up to $50 million for the first three additional indications.

Simultaneously, the Company made a strategic equity investment into Santhera by acquiring 1,414,688 of Santhera's post reverse-split ordinary shares (representing approximately 11.26% of Santhera's outstanding ordinary shares immediately following the transaction), which are traded on the SIX Swiss Exchange, at an investment price of CHF 9.477 per share (corresponding to a mutually agreed volume-weighted average price prior to signing), with the funds invested into Santhera to be used by Santhera for Phase IV studies in DMD and further development of additional indications for AGAMREE®. The Company may also be obligated under certain circumstances to make milestone payments and to pay royalties to Santhera.

13. Agreements (continued).

The following table summarizes the aggregate amount paid for the assets acquired by the Company in connection with the acquisition of AGAMREE® and the strategic equity investment (in thousands):

Initial cash payment	$	75,000
Investment in Santhera		13,465
Transaction costs		6,513
Total purchase consideration	$	94,978

The transaction has been accounted for as an asset acquisition in accordance with ASC 805-50. The Company accounted for the transaction as an asset acquisition because substantially all of the fair value of the assets acquired is concentrated in a single asset, the rights to develop, commercialize and manufacture AGAMREE®. The AGAMREE® rights consist of certain licenses and regulatory approvals 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. Additionally, the Company did not acquire a substantive process. 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. 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 non-financial assets based on relative fair values.

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

License and acquired intangibles for AGAMREE® (vamorolone) (IPR&D)	$	81,513
Investment in Santhera[(i)]		13,465
Total purchase consideration	$	94,978

(i) The fair value of the investment in Santhera was determined based on the closing market price (CHF 8.25) of Santhera shares and the exchange rate (1.1537) of CHF to USD on the date the shares were transferred, July 19, 2023.

In accordance with FASB ASC 730-10-25, as AGAMREE® (vamorolone) had not achieved regulatory approval when acquired, the portion of the purchase price allocated to the IPR&D asset acquired (which includes all transaction costs related to the transactions with Santhera) was immediately expensed to research and development. Milestone payments made are either expensed as research and development or capitalized as a developed asset based on when regulatory approval is obtained. As the transaction is accounted for as an asset acquisition under U.S. GAAP, the Company will recognize all sales-based milestone and royalty payments in cost of sales as revenue from product sales is recognized.

Following the approval of the NDA for AGAMREE® on October 26, 2023, the Company became obligated to make a milestone payment of $36 million to Santhera. The $36 million payment was made during the fourth quarter of 2023. The Company capitalized the $36 million payment which is amortized using the straight-line method over the product's estimated useful life of 10.5 years.

The strategic equity investment in Santhera is accounted for as an investment in equity securities, and is recognized as a non-current asset, as the Company does not intend on selling the shares within 12 months. Since Santhera shares have a readily determinable fair value, the investment will be measured quarterly at fair value with changes reported in earnings in other income (expense), net in the accompanying consolidated statements of operations and comprehensive income (loss).

e. 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 24.0% and 23.5% for the nine months ended September 30, 2024 and 2023, respectively. Differences in the effective tax and the statutory federal income tax rate of 21% are increased by state income taxes, fluctuations in the value of investments and anticipated annual permanent differences offset by equity compensation deductions.

The Company had no uncertain tax positions as of September 30, 2024 and December 31, 2023.

15. Stockholders' Equity.

Preferred Stock

The Company has 5,000,000 shares of authorized preferred stock, $0.001 par value per share. At September 30, 2024 and December 31, 2023, no shares of preferred stock were outstanding.

Common Stock

The Company has 200,000,000 shares of authorized common stock, par value $0.001 per share. At September 30, 2024 and December 31, 2023, 119,266,561 and 107,121,549 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. No shares were repurchased during the three and nine months ended September 30, 2024 and 2023.

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. The Company's 2020 Shelf Registration Statement expired on July 31, 2023.

2023 Shelf Registration Statement

On September 8, 2023, the Company filed a shelf registration statement with the SEC to sell up to $500 million of common stock, preferred stock, warrants to purchase common stock, debt securities and units consisting of one or more of such securities (the "2023 Shelf Registration Statement"). The 2023 Shelf Registration Statement (file no. 333-274427) became effective upon filing. On January 9, 2024, the Company completed a public offering of 10 million shares of its common stock, raising net proceeds of approximately $140.7 million under the Company's 2023 Shelf Registration Statement.

16. Stock Compensation.

For the three and nine months ended September 30, 2024 and 2023, the Company recorded stock-based compensation expense as follows (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 402	$ 372	$ 1,314	$ 1,062
Selling, general and administrative	4,022	3,438	15,766	8,938
Total stock-based compensation	$ 4,424	$ 3,810	$ 17,080	$ 10,000

Stock Options

As of September 30, 2024, there were outstanding stock options to purchase 13,026,223 shares of common stock, of which stock options to purchase 8,036,208 shares of common stock were exercisable.

During the three and nine months ended September 30, 2024, the Company granted seven-year term options to purchase an aggregate of 40,000 and 880,995 shares, respectively, of the Company's common stock to employees. The Company recorded stock-based compensation related to stock options totaling $3.6 million and $12.6 million, respectively, during the three and nine months ended September 30, 2024.

16. Stock Compensation (continued).

During the three and nine months ended September 30, 2023, the Company granted seven-year term options to purchase an aggregate of 41,000 and 1,086,000 shares, respectively, of the Company's common stock to employees. The Company recorded stock-based compensation related to stock options totaling $2.9 million and $7.7 million, respectively, during the three and nine months ended September 30, 2023.

During the three and nine months ended September 30, 2024, options to purchase 745,195 shares and 1,901,467 shares, respectively, of the Company's common stock were exercised, with proceeds of $4.0 million and $7.5 million, respectively, to the Company.

During the three and nine months ended September 30, 2023, options to purchase 91,748 shares and 1,196,614 shares, respectively, of the Company's common stock were exercised, with proceeds of $0.2 million and $2.1 million, respectively, to the Company.

As of September 30, 2024, there was approximately $29.5 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 2.8 years.

Restricted Stock Units

The Company granted no restricted stock units and 35,693 restricted stock units during three and nine months ended September 30, 2024, respectively. The Company granted no restricted stock units during the three and nine months ended September 30, 2023. During the three and nine months ended September 30, 2024, the Company recorded non-cash stock-based compensation expense related to restricted stock units totaling $0.8 million and $4.5 million, respectively. During the three and nine months ended September 30, 2023, the Company recorded non-cash stock-based compensation expense related to restricted stock units totaling $0.9 million and $2.3 million, respectively.

As of September 30, 2024, there was approximately $6.2 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 2.8 years.

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

Introduction

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

- Overview. This section provides a general description of our business and information about our business that we believe is important in understanding our financial condition and results of operations.
- Basis of Presentation. This section provides information about key accounting estimates and policies that we followed in preparing our consolidated financial statements for the third quarter of fiscal 2024.
- Critical Accounting Policies and Estimates. This section discusses those accounting policies that are both considered important to our financial condition and results of operations and require significant judgment and estimates on the part of management in their application. All of our significant accounting policies, including the critical accounting policies, are also summarized in the notes to our interim consolidated financial statements that are included in this report.
- Results of Operations. This section provides an analysis of our results of operations for the three and nine months ended September 30, 2024 as compared to the three and nine months ended September 30, 2023.
- Liquidity and Capital Resources. This section provides an analysis of our cash flows, capital resources, off-balance sheet arrangements, and outstanding commitments.
- 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 and difficult to treat diseases. We currently market three drug products, FIRDAPSE® (amifampridine), FYCOMPA® (perampanel), and AGAMREE® (vamorolone). We are also currently seeking to further expand our drug portfolio, with a focus on acquiring the rights to late-stage products to treat rare (orphan) central nervous system and adjacent rare (orphan) diseases. With an unwavering patient focus embedded in everything we do, we are committed to providing innovative, best-in-class medications with the hope of making a meaningful impact on those affected by these conditions.

FIRDAPSE®

On November 28, 2018, we received approval from the FDA for our new drug application, or NDA, for FIRDAPSE® Tablets 10 mg for the treatment of adult patients (ages 17 and above) with Lambert-Eaton myasthenic syndrome (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. Finally, on May 30, 2024, we reported that the FDA had approved our sNDA increasing the indicated maximum daily dosage of FIRDAPSE® tablets for the treatment of patients with LEMS from 80 mg to 100 mg. We believe that this most recent sNDA approval offers healthcare providers and patients greater flexibility in treatment regimens for the management of LEMS.

We sell FIRDAPSE® in the United States through a field force experienced in neurologic, central nervous system or rare disease products consisting at this time of approximately 40 field personnel, including sales (Regional Account Managers), thought leader liaisons and patient assistance and insurance navigation support (Patient Access Liaisons). We also have a field-based force of nine medical science liaisons who are helping educate the medical community about scientific literature concerning LEMS and FIRDAPSE®. Additionally, we 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 who also has small cell lung cancer. Further, we continue to make available at no-cost a LEMS voltage gated calcium channel antibody diagnostic 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 products and services to potential patients and their healthcare providers. We also work with several rare disease advocacy organizations (including the Myasthenia Gravis Foundation of America, the National Organization for Rare Disorders, and the LEMS Family Association) 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. The program 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 market drug products for ultra-orphan conditions, have developed an array of financial assistance programs to reduce out-of-pocket costs that makes FIRDAPSE® accessible and affordable. A co-pay assistance program has been designed to reduce commercial patients' out of pocket costs to $0 whenever possible. 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 committing to continue to donate, money to qualified, independent charitable foundations dedicated to providing assistance to any U.S. LEMS patients in financial need, who meet those independent organizations guidelines. In addition, we have a safety net program in place for patients who are uninsured and underinsured. Subject to compliance with regulatory requirements, our goal is that no LEMS patient is ever denied access to their medication for financial reasons.

On December 18, 2023, DyDo Pharma, Inc. (DyDo), our sub-licensee for FIRDAPSE® in Japan, filed a Japan NDA with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan seeking approval to commercialize FIRDAPSE® for the treatment of LEMS in Japan. Upon acceptance of the Japan NDA by the PMDA on December 18, 2023, our license for FIRDAPSE® automatically expanded to include other key markets in Asia and Latin America, and we are currently seeking opportunities to expand FIRDAPSE®'s global footprint through strategic partnerships (with the current focus on the Asia Pacific and Latin American regions). Further, on September 24, 2024, DyDo advised us that the Ministry of Health, Labour and Welfare (MHLW) had approved DyDo's Japan NDA to commercialize FIRDAPSE® for the treatment of patients with LEMS in Japan and that they expect to launch the product in Japan by the end of the fourth quarter of 2024.

We control six U.S. patents for FIRDAPSE® that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), the earliest of which expires in 2032 and the latest of which expires in 2037. We also have orphan drug exclusivity (ODE) for the product that will not expire until November 2025, and no Abbreviated New Drug Application (ANDA) for the product can be finally approved by the FDA until the ODE exclusivity period has expired. Nevertheless, generic drug manufacturers are permitted to file applications for the product challenging our patents, and in January 2023, we received Paragraph IV Certification Notice Letters from three generic drug manufacturers advising that they had each submitted an ANDA to the FDA seeking authorization from the FDA to manufacture, use or sell a generic version of FIRDAPSE® in the U.S. The notice letters each alleged that the six patents protecting FIRDAPSE® that are listed in the Orange Book in connection with 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, we had 45 days from receipt of the notice letters to determine if there were grounds to bring a lawsuit and, if so, to commence patent infringement lawsuits against these generic drug manufacturers in a federal district court, which would trigger a statutory stay precluding the FDA from final approval of the subject ANDA until May 2026 or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first in all cases (but not earlier than the expiration of orphan drug exclusivity on November 28, 2025). 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. All of these lawsuits are progressing. For updated information, see Note 12 (Commitments and Contingencies) in Notes to Unaudited Consolidated Financial Statements in Item I of this Form 10-Q.

Further, in October 2023, we received a Paragraph IV Certification Notice Letter from a fourth generic drug manufacturer, and we filed a similar lawsuit against that manufacturer in November 2023 in the U.S. District Court for the District of New Jersey. On July 30, 2024, we settled this patent litigation with the fourth of the ANDA filers to file an ANDA for FIRDAPSE®. In that settlement, the ANDA filer acknowledged both the validity of our FIRDAPSE® patents and also the infringement by the ANDA filer's product of our patents. As part of the settlement, the ANDA filer agreed not to commercialize its product until the earlier of all FIRDAPSE® patents expiration or the entry into the market of another ANDA product meeting certain conditions.

The outcome of patent litigation with Paragraph IV challengers is always uncertain and there can be no assurance to whether we will prevail in this litigation. However, we are vigorously defending our intellectual property for FIRDAPSE® in this litigation and while there can be no assurance, we believe that our patent estate will protect FIRDAPSE® from generic competition for the life of our patents. For updated information, see Note 12 (Commitments and Contingencies) in Notes to Unaudited Consolidated Financial Statements in Item I of this Form 10-Q.

FYCOMPA®

On December 17, 2022, we entered into an agreement with Eisai Co., Ltd. (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 certain types of focal onset seizures (seizures that involve only one part of the brain) in adults and children four years of age and older. It is also used in combination with other medications to treat certain types of 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 an upfront payment of $160 million in cash. We also 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 the asset purchase, we entered into two additional agreements, a Transition Services Agreement (TSA) and a Supply Agreement. Under the Supply Agreement, Eisai 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), and under the TSA, a U.S. subsidiary of Eisai provided us with certain transitional services (which transition services ended on December 31, 2023).

We sell FYCOMPA® in the United States through a field force experienced in epilepsy products consisting at this time of approximately 29 field personnel, including sales (Regional Account Managers) and payor reimbursement (National Account Managers). We also have a field-based force of seven medical science liaisons who are helping educate the medical community who treat epilepsy about scientific literature regarding epilepsy and FYCOMPA®. Further, effective January 1, 2024, FYCOMPA® is being sold and distributed through a 3PL organization.

We are supporting patients using FYCOMPA® through an Instant Savings Card Program. Through the program, eligible commercially insured patients could pay as little as $5 for their FYCOMPA® co-pay (with a maximum savings of $2,500 per year). The FYCOMPA® Instant Savings Card Program is not available to patients enrolled in state or federal healthcare programs, including Medicare, Medicaid, Department of Veterans Affairs (VA), Department of Defense (DoD), or TRICARE.

Patent protection for FYCOMPA® is primarily derived from two patents listed in the FDA's Orange Book. The first, U.S. patent no. 6,949,571 (the '571 patent), will expire on May 23, 2025, including patent term extension. The second FYCOMPA® patent in the Orange Book is U.S. Patent No. 8,772,497 (the '497 patent), which expires on July 1, 2026. The '497 patent, which covers the API used in both FYCOMPA® tablets and oral solution, has been the subject of previous Paragraph IV certifications from three ANDA filers for the tablet formulation, which were not contested by Eisai prior to our acquisition of the drug. Following our acquisition of the drug, we attempted to obtain an extension of the patent term for the '571 patent, which was ultimately unsuccessful. As a result, the '571 patent will expire on May 23, 2025 and the initial ANDA filers who did not challenge this patent may seek approval of their ANDA applications on or after that date.

In February 2023 we received a Paragraph IV certification for the '571 patent from an ANDA filer for two applications, one for the FYCOMPA® tablets and another for the FYCOMPA® oral suspension. After due diligence we filed lawsuits on April 5, 2023 in the U.S. District Court for the District of New Jersey against the drug manufacturer who notified us of their ANDA submissions alleging infringement of both patents. In June 2024, we settled the pending Paragraph IV litigation with the Paragraph IV filer for both ANDAs. As part of that settlement, this Paragraph IV filer agreed not to commercialize their proposed ANDA products for both the oral suspension formulation of FYCOMPA® and for FYCOMPA® tablets until at least December 15, 2025.

AGAMREE®

On June 19, 2023, we entered into a License and Collaboration Agreement (AGAMREE® License Agreement) and an Investment Agreement (Investment Agreement) with Santhera Pharmaceuticals Holding, Inc. (Santhera). Under the AGAMREE® License Agreement, we contracted to obtain an exclusive North America license, manufacturing and supply agreement for Santhera's investigational product candidate, AGAMREE® (vamorolone), a novel corticosteroid for the treatment of DMD. Under the Investment Agreement, we agreed to make a strategic investment into Santhera.

Both transactions closed on July 18, 2023. Under the AGAMREE® License Agreement, upon closing we made a $75 million payment to Santhera in return for the exclusive North American license for AGAMREE®. In addition to the rights to commercialize the product in North America, the AGAMREE® License Agreement provides us with the right of first negotiation for AGAMREE® in Japan should Santhera pursue partnership opportunities in that territory. Additionally, we will hold the North

American rights to any future approved indications for AGAMREE®. Finally, under our AGAMREE® License Agreement with Santhera, we have agreed to purchase commercial supply of AGAMREE® from Santhera at agreed upon prices.

Concurrent with the closing of the AGAMREE® License Agreement, we made a strategic investment into Santhera in which we acquired 1,414,688 of Santhera's ordinary shares (representing approximately 11.26% of Santhera's outstanding ordinary shares immediately following the transaction) at an investment price of CHF 9.477 per share, with the approximately $15.7 million USD in equity investment proceeds to be used by Santhera for Phase IV studies of AGAMREE® in DMD and future development of additional indications for AGAMREE®. On November 4, 2024, the closing price of Santhera's common shares on the SIX Swiss Exchange was CHF 8.66 per share (approximately $10.03 USD based on current exchange rates).

On October 26, 2023, the U.S. FDA approved Santhera's NDA for AGAMREE® for use in treating DMD in patients aged two years and older. Shortly thereafter, as part of the previously described transaction, Santhera transferred the approved New Drug Application to us. Additionally, following approval of the NDA for the drug, we became obligated to make a milestone payment of $36 million to Santhera, which we paid during the 2023 fourth quarter. We may also be obligated to pay future regulatory and commercial milestone payments to Santhera tied to calendar year sales of AGAMREE®, as well as commercial royalties.

On March 13, 2024, we announced the U.S. commercial launch of AGAMREE® for the treatment of DMD in patients aged two years or older. During the first quarter of 2024 in connection with our preparation for the commercial launch of AGAMREE® we incurred substantial commercialization expenses, including sales, marketing, analytical infrastructure, patient services, patient advocacy, and other commercialization related expenses. Due to the synergy of this product with our existing neuromuscular franchise, in connection with the launch of AGAMREE® we have only needed to add approximately 10 additional members to our commercial team to market the product. We are further supporting the distribution of AGAMREE® through our Catalyst Pathways® patient services program to ensure that patients have access to a dedicated, personalized support team that assists families through the AGAMREE® patient journey, from answering questions to coordinating financial assistance programs for eligible patients. Finally, we are intending to donate funds to one or more qualified, independent charitable financial foundations who assist U.S. DMD patients in accessing their medication, to the extent permitted by each such organization's guidelines.

Finally, we have established a joint steering committee with Santhera that is overseeing the lifecycle management and development of AGAMREE® for additional indications beyond DMD.

DMD, the most common form of muscular dystrophy, is a rare and life-threatening neuromuscular disorder characterized by progressive muscle dysfunction, ultimately leading to loss of ambulation, respiratory failure, and fatality. Current standard treatment for DMD involves corticosteroids, which often come with significant side effects. It is estimated that between 11,000 and 13,000 patients in the U.S. are affected by DMD, with approximately 70% of patients currently receiving a corticosteroid treatment. Steroids are expected to remain the backbone of therapy for DMD patients and dosed concomitantly with other therapies.

AGAMREE®'s unique mode of action is based on differential effects on glucocorticoid and mineralocorticoid receptors and modifying further downstream activity. As such, it is considered a novel corticosteroid that we hope has the potential to demonstrate comparable efficacy to corticosteroids, with the potential for a better-tolerated side effect profile. This mechanism of action may allow vamorolone to emerge as an effective alternative to the current standard of care corticosteroids in children, adolescents, and adult patients with DMD. In that regard, we have launched a long-term registry study of AGAMREE®, which we have designated as the SUMMIT study, which aims to gather long-term patient safety and quality of life data, offering a deeper understanding of the product's potential long-term benefits for patients.

On October 13, 2023, Santhera announced that the European Union's Committee for Medicinal Products for Human Use (CHMP) adopted a positive position in favor of AGAMREE® for the treatment of DMD patients aged four and older. In its recommendation for approval, CHMP acknowledged that there was a positive benefit-risk profile of AGAMREE® in such patient population, including certain safety benefits of AGAMREE® compared to standard of care corticosteroids in the treatment of DMD. Further, on December 18, 2023, the European Commission (EC) granted to Santhera marketing authorization for AGAMREE® for the treatment of DMD in patents ages four years and older and on January 12, 2024 Santhera announced that AGAMREE® had received approval by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom. Finally, on January 15, 2024, Santhera announced that AGAMREE® was commercially launched in Germany.

In the United States, AGAMREE® has New Chemical Entity exclusivity that expires in October 2028. AGAMREE® also enjoys Orphan Drug Exclusivity expiring in October 2030. AGAMREE® is further protected by six Orange Book listed patents expiring as early as May 28, 2029 and as late as July 16, 2040. The Company has also requested Patent Term Extension and will update the relevant expiration date in the Orange Book upon a final determination by the USPTO. The earliest a generic manufacturer could file an ANDA is October 26, 2027. If we were to pursue a patent infringement action if any such ANDA challenges any of AGAMREE®'s Orange Book patents, then the automatic statutory 30-month stay would prevent FDA approval of such ANDA until April 26, 2031.

Finally, on July 23, 2024 we entered into a license, supply and commercialization agreement with KYE Pharmaceuticals, Inc. (KYE) granting KYE the exclusive Canadian commercial rights to market AGAMREE® in Canada for DMD and other indications.

Under the agreement, KYE (which is also the Company's sublicensee for FIRDAPSE® in Canada) will be responsible for obtaining regulatory approval of the product from Health Canada (of which there can be no assurance), and we will supply product to KYE. Further, during the third quarter of 2024, we received an upfront payment from KYE, and we will be eligible to receive further reimbursement and sales milestones and sales royalties for AGAMREE®. Also, KYE has advised us that they expect to file an application with Health Canada seeking approval to commercialize AGAMREE® in Canada in early 2025. There can be no assurance that any such application when and if filed will be approved, and even if such application is approved that KYE will be successful in commercializing AGAMREE® in Canada.

Business Development

We continue to advance our strategic initiatives and portfolio expansion efforts, focusing on broadening and diversifying our rare (orphan) Neurology product portfolio with innovative therapies that address critical unmet medical needs and expanding the geographical footprint of our existing products. In that regard, we are currently exploring clinically differentiated and adequately de-risked opportunities, with a keen focus on products to treat rare (orphan) central nervous system (CNS) and adjacent rare (orphan) diseases. These prospects include evaluating companies with existing commercial drug products or drugs in development, for potential partnerships, licensing, geographical expansion opportunities with our existing products, and/or asset acquisitions. We continue to employ a disciplined, comprehensive, and exhaustive approach to identifying and evaluating opportunities that we believe will add significant value to our company over the near, mid, and long term. However, other than the recent sublicense described above between the Company and KYE for AGAMREE® in Canada, no definitive agreements have been entered into to-date, and there can be no assurance that any of the Company's business development initiatives will be successful.

Capital Resources

At September 30, 2024, we had cash and cash equivalents of approximately $442.3 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®, FYCOMPA® and AGAMREE®, 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.

Basis of Presentation

Revenues.

During the three and nine months ended September 30, 2024, we generated revenues from U.S. product sales of FIRDAPSE®, FYCOMPA®, and AGAMREE®. We expect these revenues to fluctuate in future periods based on our sales of our products. We received approval from Health Canada on July 31, 2020, for FIRDAPSE® for the symptomatic treatment of LEMS and as of December 31, 2020, our sub-licensee KYE Pharmaceuticals launched FIRDAPSE® in Canada. During the three and nine months ended September 30, 2024, 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 three and nine months ended September 30, 2024, no revenues were generated under our collaborative agreement with Endo, Inc. (formerly, Endo International plc) (Endo). In July 2024, a termination and mutual release agreement was finalized between Endo and us that discontinued work on the collaboration for development and commercialization of vigabatrin. The end of the collaboration does not have a material impact on our consolidated financial statements.

For the three and nine months ended September 30, 2024, we generated approximately $2.1 million in revenues from our collaborative agreement with DyDo, which consisted of a milestone payment earned upon DyDo receiving regulatory approval to commercialize FIRDAPSE® for the treatment of patients with LEMS in Japan. We expect our revenue from the DyDo license agreement to fluctuate in future periods based on DyDo’s ability to meet various regulatory and potential sales 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 and manufacturing variances.

Research and Development Expenses.

Our research and development expenses consist of costs incurred for company-sponsored research and development activities, support for selected investigator-sponsored research, and support for our commercial activities. 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 and support for our commercial efforts. Prior to January 2023, all of our research and development resources were devoted to the development of FIRDAPSE® and two previously discontinued R&D projects, CPP-109 (our version of vigabatrin), and 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 and commercial support of FIRDAPSE® and AGAMREE®.

Our expense 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.

Since 2019, we have incurred substantial commercialization expenses for FIRDAPSE®, including sales, marketing, patient services, patient advocacy and other commercialization related expenses. We are also now incurring substantial commercialization expenses for FYCOMPA® and AGAMREE®.

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

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. We also capitalized the $36 million of milestone payment paid to Santhera during the fourth quarter of 2023 which is being amortized over the product's estimated useful life of 10.5 years.

Stock-Based Compensation.

We recognize expense for the fair value of all stock-based awards to employees, directors, and consultants in accordance with 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 net income (loss) 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 2023 Annual Report on Form 10-K that we filed with the SEC on February 28, 2024. 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 2023 Annual Report on Form 10-K.

Results of Operations

Revenues.

For the three and nine months ended September 30, 2024, we recognized total revenues of $128.7 million and $349.9 million, respectively, compared to $102.7 million and $287.6 million, respectively, in the same periods of 2023. FIRDAPSE® net sales were approximately $79.3 million and $223.5 million, respectively, for the three and nine months ended September 30, 2024 compared to $66.2 million and $188.6 million, respectively, for the three and nine months ended September 30, 2023. FYCOMPA® net sales were approximately $32.1 million and $99.0 million, respectively, for the three and nine months ended September 30, 2024 compared to $36.4 million for the three months ended September 30, 2023 and $98.8 million for the period between January 24, 2023 (date of acquisition) and September 30, 2023. AGAMREE® net sales were approximately $15.0 million for the three months ended September 30, 2024 and $25.0 million for the period between March 13, 2024 (date of commercial launch) and September 30, 2024.

Net revenues from product sales of FIRDAPSE® increased by 19.7% and 18.5%, respectively, from the three and nine month periods ended September 30, 2023 compared to the three and nine month periods ended September 30, 2024. Product revenue for FYCOMPA® during the three and nine months ended September 30, 2024 were affected by differences in variable consideration (gross-to-net) compared to the three months ended September 30, 2023 and the period between January 24, 2023 (date of acquisition) and September 30, 2023, when revenues were booked under Eisai's cost arrangements with distributors and government authorities. Starting on January 1, 2024, all such costs are tied to arrangements between us and those distributors and government agencies, which costs are higher than Eisai's costs, thereby increasing the gross-to-net deductions for FYCOMPA® and correspondingly decreasing FYCOMPA® net product revenue. In the first quarter of the calendar year, like many companies in our industry, we are also impacted by the reset of patient insurance deductibles.

For the three and nine months ended September 30, 2024, we also recognized $2.3 million and $2.4 million, respectively, in license and other revenue. For the three and nine months ended September 30, 2023, we also recognized $0.1 million and $0.2 million, respectively, in license and other revenue.

Cost of Sales.

Cost of sales was approximately $19.3 million and $47.2 million, respectively, for the three and nine months ended September 30, 2024, compared to $14.2 million and $36.2 million, respectively, for the three and nine months ended September 30, 2023. Cost of sales in both periods consisted principally of royalty payments, which are based on net revenue as defined in the applicable license agreements. 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® in both periods consisted of product costs and excludes the amortization of the FYCOMPA® intangible assets. Cost of sales for AGAMREE® for the three and nine months ended September 30, 2024 consisted of royalties payable on the terms set forth below in Liquidity and Capital Resources—*Contractual Obligations and Arrangements*, product costs and excludes the amortization of the AGAMREE® intangible asset. 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 $9.3 million and $28.0 million, respectively, for the three and nine months ended September 30, 2024 compared to $8.5 million and $23.5 million, respectively, for the three and nine months ended September 30, 2023. 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. We also capitalized a $36 million milestone payment paid to Santhera during the fourth quarter of 2023, which is being amortized over the product's estimated useful life of 10.5 years.

Research and Development Expenses.

Research and development expenses for the three months ended September 30, 2024 and 2023 were approximately $3.3 million and $83.7 million, respectively, and represented approximately 4% and 60% of total operating costs and expenses, respectively. Research and development expenses for the three months ended September 30, 2024 and 2023 were as follows (in thousands):

	For the Three Months Ended September 30,		Change	
	2024	2023	$	%
Salary and benefit expense	$ 996	$ 851	145	17.0
Employee stock-based compensation expense	402	372	30	8.1
Research and clinical trial expense	1,484	891	593	66.6
Acquired in-process research and development	—	81,513	(81,513)	(100.0)
Additional research and development expense	402	35	367	1,048.6
Total research and development expenses	$ 3,284	$ 83,662	(80,378)	(96.1)

Research and development expenses for the nine months ended September 30, 2024 and 2023 were approximately $8.9 million and $91.2 million, respectively, and represented approximately 4% and 38% of total operating costs and expenses, respectively. Research and development expenses for the nine months ended September 30, 2024 and 2023 were as follows (in thousands):

	For the Nine Months Ended September 30,		Change	
	2024	2023	$	%
Salary and benefit expense	$ 3,095	$ 2,552	543	21.3
Employee stock-based compensation expense	1,314	1,062	252	23.7
Research and clinical trial expense	3,479	4,868	(1,389)	(28.5)
Acquired in-process research and development	—	81,513	(81,513)	(100.0)
Additional research and development expense	962	1,183	(221)	(18.7)
Total research and development expenses	$ 8,850	$ 91,178	(82,328)	(90.3)

For the three and nine months ended September 30, 2024, research and development expenses decreased approximately $80.4 million and $82.3 million, respectively, compared to the same periods in 2023. The decrease in both periods is primarily attributable to the $81.5 million IPR&D purchase consideration for the acquisition of the license in North America for vamorolone during the third quarter of 2023. For the three and nine months ended September 30, 2024, research and development expenses primarily consisted of costs for development activities supporting our commercial products. For the three and nine months ended September 30, 2023, research and development expenses consisted of costs relating to closing out sites for both our MuSK-MG clinical trial and our previously operated expanded access program, as well as costs for development activities supporting our commercial products.

We are continuing to focus our business development efforts on acquiring additional drug products that are (or may be, if approved) used to treat rare and difficult to treat diseases. If we make future acquisitions of products in earlier stages of development, or if we determine to evaluate products already approved for the treatment of additional indications or additional diseases, we expect that our research and development expenses during such future periods will become more significant.

Selling, General and Administrative Expenses.

Selling, general and administrative expenses for the three months ended September 30, 2024 and 2023 were approximately $45.9 million and $33.6 million, respectively, and represented approximately 59% and 24% of total operating costs and expenses, respectively. Selling, general and administrative expenses for the three months ended September 30, 2024 and 2023 were as follows (in thousands):

	For the Three Months Ended September 30,		Change	
	2024	2023	$	%
Selling	$ 29,105	$ 21,681	7,424	34.2
General and administrative	12,753	8,441	4,312	51.1
Employee stock-based compensation	4,022	3,438	584	17.0
Total selling, general and administrative expenses	$ 45,880	$ 33,560	12,320	36.7

Selling, general and administrative expenses for the nine months ended September 30, 2024 and 2023 were approximately $133.5 million and $91.7 million, respectively, and represented approximately 61% and 38% of total operating costs and expenses, respectively. Selling, general and administrative expenses for the nine months ended September 30, 2024 and 2023 were as follows (in thousands):

	For the Nine Months Ended September 30,		Change	
	2024	2023	$	%
Selling	$ 80,673	$ 57,757	22,916	39.7
General and administrative	37,109	24,979	12,130	48.6
Employee stock-based compensation	15,766	8,938	6,828	76.4
Total selling, general and administrative expenses	$ 133,548	$ 91,674	41,874	45.7

For the three and nine months ended September 30, 2024, selling, general and administrative expenses increased approximately $12.3 million and $41.9 million, respectively, compared to the same periods in 2023. This was primarily attributable to an approximately $16.3 million increase in employee compensation and stock-based compensation related to annual merit increases and an increase in headcount resulting from the acquisitions of FYCOMPA® and AGAMREE®, an approximately $17.6 million increase in commercialization expenses related to the launch of AGAMREE® and to the timing of our commitments to make contributions to 501(c)(3) organizations supporting LEMS patients of approximately $0.5 million. Further, an approximately $3.9 million increase in stock-based compensation expense is related to the retirement of two former executive officers, which was recorded during the first quarter of 2024 upon lapse of the applicable revocation periods under the respective separation agreements with these former executives.

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 AGAMREE®, and take steps to further expand our business.

Stock-*Based Compensation.*

Total stock-based compensation for the three and nine months ended September 30, 2024 was $4.4 million and $17.1 million, respectively, and for the three and nine months ended September 30, 2023 was $3.8 million and $10.0 million, respectively. In the first three quarters of 2024 and 2023, grants were principally for stock options relating to year-end bonus awards and grants to new employees.

Other Income (Expense), Net.

We reported other income (expense), net in all periods, primarily relating to interest on our investment of our cash and cash equivalents of $6.3 million and $9.8 million for the three and nine months ended September 30, 2024 compared to ($0.8) million and $2.7 million for the three and nine months ended September 30, 2023.

Since Santhera's shares are traded on the SIX Swiss Exchange, they have a readily determinable fair value, and as a result the investment is measured quarterly, at fair value, with changes reported in other income (expense), net.

The components of other income (expense), net were as follows (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Interest income (expense), net	$ 4,537	$ (265)	$ 11,448	$ 3,252
Net gains (losses) recognized during the period on equity securities	1,759	(568)	(1,647)	(568)
Total other income (expense), net	$ 6,296	$ (833)	$ 9,801	$ 2,684

Income Taxes.

Our effective income tax rate was 24.0% and 23.5% for the nine months ended September 30, 2024 and 2023, respectively. Differences in our effective tax and the statutory federal income tax rate of 21% are increased by state income taxes, fluctuations in the value of investments and anticipated annual permanent differences offset by equity compensation deductions. Our 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.

We had no uncertain tax positions as of September 30, 2024 and December 31, 2023.

Net Income (Loss).

Our net income (loss) was $43.9 million and $108.0 million, respectively, for the three and nine months ended September 30, 2024 ($0.37 and $0.92, respectively, per basic share and $0.35 and $0.87, respectively, per diluted share) as compared to net income (loss) of ($30.8) million and $36.6 million, respectively, for the three and nine months ended September 30, 2023 (($0.29) and $0.34, respectively, per basic share and ($0.29) and $0.32, respectively, per diluted share).

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through multiple offerings of our securities and revenues from product sales. At September 30, 2024 we had cash and cash equivalents aggregating $442.3 million and working capital of $433.6 million. At December 31, 2023, we had cash and cash equivalents aggregating $137.6 million and working capital of $143.3 million. At September 30, 2024, substantially all of our cash and cash equivalents were deposited with two financial institutions, and such balances were in excess of federally insured limits. Further, as of such date, a significant amount of such funds were invested in money market accounts.

On September 8, 2023, we filed a shelf registration statement with the SEC to sell up to $500 million of common stock, preferred stock, warrants to purchase common stock, debt securities and units consisting of one or more of such securities (the 2023 Shelf Registration Statement). The 2023 Shelf Registration Statement (file no. 333-274427) became effective upon filing. On January 9, 2024, we completed a public offering of 10 million shares of our common stock under the 2023 Shelf Registration Statement, raising net proceeds of approximately $140.7 million.

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®, FYCOMPA® and AGAMREE® 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 if and when it is required.

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

- the cost of diligence in seeking potential acquisitions and of the completion of such acquisitions, if any future acquisitions occur;
- 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 amount of net revenues that we report from sales of FIRDAPSE®, FYCOMPA® and AGAMREE®;
- 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 product development efforts or product acquisitions, even if we have sufficient funds for our planned operations. Any sale by us of additional equity or convertible debt securities could result in dilution to our stockholders. There can be no assurance that any such required additional funding will be available to us at all or available on terms acceptable to us. Further, to the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant sublicenses on terms that are not favorable to us. If we are not able to secure

additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, which could have an adverse effect on our business.

Cash Flows.

Net cash provided by operating activities was $168.9 million and $88.0 million, respectively, for the nine months ended September 30, 2024 and 2023. During the nine months ended September 30, 2024, net cash provided by operating activities was primarily attributable to our net income of $108.0 million, an increase of $44.9 million in accrued expenses and other liabilities, $17.1 million in stock-based compensation, $28.3 million in amortization of intangible assets and depreciation and $1.1 million in non-cash expenses. This was partially offset by increases of $4.8 million in accounts receivable, net, $4.4 million in inventory and $5.8 million prepaid expenses and other current assets, decreases of $3.2 million in accounts payable and $0.3 million in operating lease liability and $11.9 million in deferred taxes. During the nine months ended September 30, 2023, net cash provided by operating activities was primarily attributable to our net income of $36.6 million, a decrease of $1.9 million in inventory, an increase of $0.6 million in accounts payable, $10.0 million in stock-based compensation, $23.7 million in amortization of intangible assets and depreciation, $79.3 million in acquired IPR&D and $2.0 million of non-cash expenses. This was partially offset by increases of $37.6 million in accounts receivable, net, $7.2 million in prepaid expenses and other current assets and decreases of $2.4 million in accrued expenses and other liabilities and $0.3 million in operating lease liability and $18.7 million in deferred taxes.

Net cash used in investing activities was $0.5 million for the nine months ended September 30, 2024, consisting primarily of purchases of property and equipment. Net cash used in investing activities was $255.2 million for the nine months ended September 30, 2023, consisting primarily of payment in connection with the FYCOMPA® asset acquisition and acquired IPR&D and purchase of equity securities in connection with the vamorolone acquisition.

Net cash provided by financing activities during the nine months ended September 30, 2024 was $136.2 million, consisting primarily of proceeds from the issuance of common stock. Net cash used in financing activities during the nine months ended September 30, 2023 was $10.2 million, consisting primarily of payment of liabilities arising from asset acquisition and payment of employee withholding tax related to stock-based compensation 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 FIRDAPSE® 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 FIRDAPSE® License Agreement between BioMarin and the third-party licensor) in any calendar year for the duration of regulatory exclusivity within a territory and 3.5% for territories in any calendar year in territories without regulatory exclusivity.

  For the three and nine months ended September 30, 2024, we recognized an aggregate of approximately $13.6 million and $34.0 million, respectively, of royalties payable under these license agreements, which is included in cost of sales in the accompanying consolidated statements of operations and comprehensive income (loss). For the three and nine months ended September 30, 2023, we recognized an aggregate of approximately $10.9 million and $27.7 million, respectively, of royalties payable under these license agreements, which is included in cost of sales in the accompanying consolidated statements of operations and comprehensive income (loss).

  Further, 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 for non-U.S. sales under our original FIRDAPSE® 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, $10 million was paid on the first anniversary of closing and the remaining $10 million was paid on the 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 U.S. 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 U.S., 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.

For the three and nine months ended September 30, 2024, we recognized an aggregate of approximately $1.2 million and $3.3 million, respectively, of royalties payable to Jacobus. For the three and nine months ended September 30, 2023, we recognized an aggregate of approximately $1.0 million and $2.7 million, respectively, 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 our asset purchase agreement with Eisai Co., Ltd. (Eisai):
  - We paid at closing a $160 million upfront cash payment, plus $1.6 million for reimbursement of certain prepayments. Eisai was also eligible to receive a contingent payment of $25 million if a patent term extension for FYCOMPA® was approved until June 8, 2026 by the USPTO, which request for reconsideration of the patent term extension was denied by the USPTO;
  - 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 TSA for commercial and manufacturing services (to which transition services ended on December 31, 2023) and (ii) a long-term Supply Agreement for the manufacturing of FYCOMPA®. Under the TSA, a U.S. subsidiary of Eisai provided certain 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 have entered into the following contractual arrangements with respect to AGAMREE® (vamorolone):

- *Payments due under our license agreement for AGAMREE®.* In connection with our recent acquisition from Santhera:
  - At closing we paid a $75 million initial cash payment.
  - In the fourth quarter of 2023, following regulatory approval of Santhera's NDA by the FDA, we paid a regulatory milestone payment of $36 million. We are also obligated to pay additional regulatory milestone payments upon regulatory approval by the FDA in the U.S. of an NDA for the product for the first, second, and third additional indications in the amounts of $50 million, $45 million, and $45 million, respectively.
  - Under the license agreement, we pay: (i) royalties to the licensor until the later of expiration of product exclusivity or ten years from the first commercial sale of AGAMREE® equal to 5% of net sales (as defined in the license agreement) in North America for any calendar year for sales equal to or less than $100 million (prior to December 31, 2025 only), 7% of net sales for sales in excess of $100 million and up to $200 million, 9% of net sales for sales in excess of $200 million and up to $300 million, 11% of net sales for sales in excess of $300 million; and (ii) royalties to the third-party licensor of the rights sublicensed us until the later of expiration of product exclusivity or ten years from the first commercial sale of AGAMREE® equal to 7% of net sales (as defined in the license agreement) in North America for any single calendar year for sales equal to or less than $250 million, 8.5% of net sales for sales in excess of $250 million and up to $500 million, 10% of net sales for sales in excess of $500 million and up to $750 million, 12% of net sales for sales in excess of $750 million and up to $1 billion, 13% of net sales for sales in excess of $1 billion and up to $2 billion and 15% of net sales for sales in excess of $2 billion. Furthermore, we may pay Santhera sales-based milestones of up to $105 million as well as up to 11% percent royalties for all additional indications and milestones of up to $50 million for the first three additional indications.

- We are obligated to pay sales-based milestone payments if the applicable amount of net sales of all products in the territory in a single calendar year reach one of more of the net sales threshold levels set forth in the AGAMREE® License Agreement.
- Until January 1, 2026, we are obligated to purchase all of the requirements for product solely from Santhera, and Santhera is required to manufacture, supply, and sell product to us at an agreed upon supply price.
- Simultaneously with entering into the license agreement, we made a strategic equity investment into Santhera by acquiring 1,414,688 of Santhera's ordinary shares (representing approximately 11.26% of Santhera's outstanding ordinary shares immediately following the transaction) at an investment price of CHF 9.477 per share (corresponding to a mutually agreed volume-weighted average price prior to signing), with the approximately $15.7 million USD in equity investment proceeds, inclusive of the approximately $13.5 million USD fair value of the investment in Santhera and approximately $2.2 million USD of transaction costs included in acquired in-process research and development, to be used by Santhera for Phase IV studies in DMD and further development of additional indications for AGAMREE®.

For the three and nine months ended September 30, 2024, we recognized an aggregate of approximately $1.7 million and $2.7 million, respectively, of royalties payable under this license agreement, which is included in cost of sales in the accompanying consolidated statements of operations and comprehensive income (loss).

We also have entered into the following contractual arrangements:

- *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 2024.
- *Lease for office space*. We operate our business in leased office space in Coral Gables, Florida. We lease approximately 10,700 square feet of office space and 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® (amifampridine), FYCOMPA® (perampanel) CIII, and AGAMREE® (vamorolone) are highly uncertain. Factors that will affect our success include the uncertainty of:

- Whether we will be able to continue to successfully market and sell FIRDAPSE®, FYCOMPA®, and AGAMREE® while maintaining full compliance with applicable federal and state laws, rules and regulations;
- Whether we will be able to continue to attract and retain the qualified personnel necessary to run our business;
- 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 the daily dose of FIRDAPSE® taken by patients changes over time and affects our results of operations;
- Whether we will be able to locate LEMS patients who are undiagnosed or are misdiagnosed with other diseases;
- Whether patients will discontinue from the use of our products at rates that are higher than historically experienced or are higher than we project;
- Whether new FIRDAPSE®, FYCOMPA®, and AGAMREE® patients can be successfully titrated to stable therapy;
- Whether we can continue to market our products on a profitable and cash flow positive basis;
- Whether we will be able to demonstrate, to the satisfaction of the FDA and third-party payors, whether AGAMREE® offers advantages compared to corticosteroids or competitor's products;

- Whether DMD patients transitioning to current or future gene therapy treatments will delay initiating use of AGAMREE® while waiting for access to such gene therapy or stop their AGAMREE® therapy during the course of their gene therapy treatment;
- Whether the acquisition of the North American license for AGAMREE® will prove to be accretive to our EBITDA and EPS in 2024 and beyond;
- Whether any revenue or earnings guidance that we provide to the public market will turn out to be accurate;
- Whether payors will continue to provide coverage and reimburse for our products at the price that we charge for our products;
- The ability of our third-party suppliers and contract manufacturers to continue to supply sufficient product to meet our customers' needs in a timely manner;
- 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 our products;
- Our ability to maintain compliance with the applicable rules that relate to our contributions to 501(c)(3) organizations that support patients in financial need;
- 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®, FYCOMPA®, or AGAMREE®;
- 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 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® and AGAMREE® after our orphan drug exclusivity for each product expires;
- Whether we will be successful in our litigation to enforce our patents against the Paragraph IV challengers who have filed Abbreviated New Drug Applications (ANDAs) seeking to introduce generic versions of FIRDAPSE®;
- Whether we will be able to continue to successfully commercialize FYCOMPA® after its patents expire in 2025;
- The impact on our profits and cash flow of adverse changes in reimbursement and coverage policies or regulations 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;
- Whether we and Santhera can successfully develop additional indications for AGAMREE® and obtain the ability to commercialize the product for these additional indications;
- The state of the economy generally and its impact on our business;
- The scope, rate of progress and expense of future clinical trials and studies, pre-clinical studies, proof-of-concept studies, and our other drug development activities, and whether any trials and studies we undertake 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;

- Whether AGAMREE® will be approved by Health Canada for commercialization in Canada and whether, if the product is approved, KYE can successfully commercialize it in Canada;
- Whether KYE will successfully file an application seeking to commercialize AGAMREE® in Canada by early 2025 or at all;
- The impact on sales of FIRDAPSE® in the U.S. if an amifampridine product is purchased in Canada for use in the U.S.;
- Now that FIRDAPSE® has been approved for commercialization in Japan, whether DyDo will be successful in launching and commercializing the product in Japan;
- Whether our plans to expand the reach of FIRDAPSE® and AGAMREE® into other global regions will be successful; and
- System failures or security or data breaches due to cyber-attacks, or cyber intrusions, including ransomware, phishing attacks and other malicious intrusions whether it occurs directly to us or indirectly through third-parties.

Our current plans and objectives are based on assumptions relating to the continued commercialization of FIRDAPSE®, FYCOMPA®, and AGAMREE® 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 September 30, 2024, our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act, was recorded, processed, summarized or reported within the time periods specified in the rules and regulations of the SEC, and include controls and procedures designed to ensure that information required to be disclosed by us in such reports was accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

b. During the three months ended September 30, 2024, 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 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 U.S. The notice letters each alleged that the six patents listed in the FDA Orange Book in connection with 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, we had 45 days from receipt of the notice letters to determine if there were grounds to bring a lawsuit and, if so, to commence patent infringement lawsuits against these generic drug manufacturers in a federal district court, which would trigger a statutory stay precluding the FDA from final approval of the subject ANDAs 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. All of these lawsuits are progressing. For updated information on the cases relating to FIRDAPSE® patents, see Note 12 (Commitments and Contingencies) in Notes to Unaudited Consolidated Financial Statements in Item I of this Form 10-Q.

Further, in October 2023, we received a Paragraph IV Certification Notice Letter from a fourth generic drug manufacturer, and we filed a similar lawsuit against the manufacturer in November 2023. On July 30, 2024, we settled this patent litigation with the fourth of the ANDA filers for FIRDAPSE®. In the settlement, the ANDA filer acknowledged both the validity of our FIRDAPSE® patents and also the infringement by the ANDA filer's product of our patents. As part of the settlement, the ANDA filer agreed not to commercialize its product until the earlier of all FIRDAPSE® patents expiration or the entry into the market of another ANDA product meeting certain conditions. For updated information on the cases relating to FIRDAPSE® patents, see Note 12 (Commitments and Contingencies) in Notes to Unaudited Consolidated Financial Statements in Item I of this Form 10-Q.

The outcome of patent litigation with Paragraph IV challengers is always uncertain and there can be no assurance to whether we will prevail in this litigation. However, we are vigorously defending our intellectual property for FIRDAPSE® in this litigation and we believe that our patent estate will protect FIRDAPSE® from generic competition for the life of our patents.

On February 20, 2023, we 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 us 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. Accordingly, the FDA may not approve any ANDA prior to expiration of the ‘571 patent on May 23, 2025. After due diligence we filed lawsuits on April 5, 2023 in the U.S. District Court for the District of New Jersey against the drug manufacturer who notified us of their ANDA submissions for both FYCOMPA® formulations, thus triggering the 30 month stay for each application. In June 2024, we settled this lawsuit. As part of the settlement, this Paragraph IV filer agreed to not seek to commercialize its ANDA products for both the oral suspension formulation of FYCOMPA® and FYCOMPA® tablets until at least December 15, 2025.

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 2023 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 and currently expires in March 2025.

During the three and nine months ended September 30, 2024, we did not repurchase any of our common stock. As of September 30, 2024, approximately $21 million remains available for share repurchases under the Share Repurchase Program. At present the Company has elected to retain cash for business development activities rather than making repurchases of its shares.

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	Inline XBRL Instance Document–the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
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/ Michael W. Kalb
Michael W. Kalb
Executive Vice President and Chief Financial Officer

Date: November 6, 2024

Exhibit 31.1

Certification of Principal Executive Officer

I, Richard J. Daly, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2024

/s/ Richard J. Daly
Richard J. Daly
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer

I, Michael W. Kalb, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2024

/s/ Michael W. Kalb

Michael W. Kalb
Executive Vice President and 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, Richard J. Daly as Principal Executive Officer of Catalyst Pharmaceuticals, Inc. (the Company), certify, pursuant to 18 U.S.C. Section 1350 (as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002), that to my knowledge:

1. the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2024 (the Report), filed with the U.S. Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: November 6, 2024

/s/ Richard J. Daly
Richard J. Daly
President and 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, Michael W. Kalb as Principal Financial Officer of Catalyst Pharmaceuticals, Inc. (the Company), certify, pursuant to 18 U.S.C. Section 1350 (as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002), that to my knowledge:

1. the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2024 (the Report), filed with the U.S. Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: November 6, 2024

/s/ Michael W. Kalb
Michael W. Kalb
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)