CATALYST PHARMACEUTICALS, INC.

FORM 10-Q
(Quarterly Report)

Filed 08/06/25 for the Period Ending 06/30/25

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Symbol	CPRX
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Industry	Pharmaceuticals
Sector	Healthcare
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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 June 30, 2025

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 122,391,010 shares of common stock, $0.001 par value per share, were outstanding as of August 4, 2025.

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)

	June 30, 2025 (unaudited)	December 31, 2024
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 652,800	$ 517,553
Accounts receivable, net	65,863	65,476
Inventory, net	18,650	19,541
Prepaid expenses and other current assets	21,426	21,039
Total current assets	758,739	623,609
Operating lease right-of-use asset, net	2,084	2,230
Property and equipment, net	1,149	1,354
License and acquired intangibles, net	137,983	156,672
Deferred tax assets, net	50,704	45,982
Investment in equity securities	21,256	21,564
Total assets	$ 971,915	$ 851,411
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 5,528	$ 16,593
Accrued expenses and other liabilities	107,479	104,085
Total current liabilities	113,007	120,678
Operating lease liability, net of current portion	2,572	2,786
Other non-current liabilities	309	315
Total liabilities	115,888	123,779
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized: none issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized; 122,385,569 shares and 120,879,099 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	122	121
Additional paid-in capital	461,868	442,286
Retained earnings	394,006	285,161
Accumulated other comprehensive income (loss) (Note 4)	31	64
Total stockholders' equity	856,027	727,632
Total liabilities and stockholders' equity	$ 971,915	$ 851,411

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

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Revenues:				
Product revenue, net	$ 146,540	$ 122,653	$ 287,940	$ 221,094
License and other revenue	23	57	44	125
Total revenues	146,563	122,710	287,984	221,219
Operating costs and expenses:				
Cost of sales (a)	20,614	15,405	38,525	27,925
Research and development	4,358	2,985	8,245	5,566
Selling, general and administrative (a)	45,949	40,730	92,860	87,668
Amortization of intangible assets	9,344	9,344	18,689	18,688
Total operating costs and expenses	80,265	68,464	158,319	139,847
Operating income	66,298	54,246	129,665	81,372
Other income, net	2,995	1,542	10,914	3,505
Net income before income taxes	69,293	55,788	140,579	84,877
Income tax provision	17,185	14,994	31,734	20,808
Net income	$ 52,108	$ 40,794	$ 108,845	$ 64,069
Net income per share:				
Basic	$ 0.43	$ 0.35	$ 0.89	$ 0.55
Diluted	$ 0.41	$ 0.33	$ 0.86	$ 0.52
Weighted average shares outstanding:				
Basic	122,163,212	118,180,396	121,819,748	117,493,257
Diluted	127,543,284	124,655,999	127,261,527	124,028,752
Net income	$ 52,108	$ 40,794	$ 108,845	$ 64,069
Other comprehensive income (Note 4):				
Unrealized gain (loss) on available-for-sale securities, net of tax of ($15), $0, $10 and $4, respectively	48	—	(33)	(14)
Comprehensive income	$ 52,156	$ 40,794	$ 108,812	$ 64,055

(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 six months ended June 30, 2025 and 2024
(in thousands)

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total
Balance at December 31, 2024	$ —	120,879	$ 121	$ 442,286	$ 285,161	$ 64	$ 727,632
Stock-based compensation	—	—	—	5,850	—	—	5,850
Exercise of stock options for common stock	—	975	1	4,786	—	—	4,787
Issuance of common stock upon vesting of restricted stock units, net	—	105	—	(642)	—	—	(642)
Other comprehensive gain (loss)	—	—	—	—	—	(81)	(81)
Net income	—	—	—	—	56,737	—	56,737
Balance at March 31, 2025	—	121,959	122	452,280	341,898	(17)	794,283
Stock-based compensation	—	—	—	7,597	—	—	7,597
Exercise of stock options for common stock	—	407	—	2,210	—	—	2,210
Issuance of common stock upon vesting of restricted stock units, net	—	20	—	(219)	—	—	(219)
Other comprehensive gain (loss)	—	—	—	—	—	48	48
Net income	—	—	—	—	52,108	—	52,108
Balance at June 30, 2025	$ —	122,386	$ 122	$ 461,868	$ 394,006	$ 31	$ 856,027

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	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	—	—	—	—	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	—	—	—	—	40,794	—	40,794
Balance at June 30, 2024	$ —	118,521	$ 119	$ 423,195	$ 185,341	$ —	$ 608,655

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 Six Months Ended June 30,	
	2025	2024
Operating Activities:		
Net income	$ 108,845	$ 64,069
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation	231	177
Stock-based compensation	13,447	12,656
Amortization of intangible assets	18,689	18,688
Deferred taxes	(4,755)	(3,359)
Accretion of discount	(138)	287
Reduction in the carrying amount of right-of-use asset	146	137
Change in fair value of equity securities	308	3,406
Inventory reserve and write-offs	673	—
(Increase) decrease in:		
Accounts receivable, net	(387)	(3,658)
Inventory, net	218	(2,370)
Prepaid expenses and other current assets	(387)	(11,015)
Increase (decrease) in:		
Accounts payable	(11,065)	(7,679)
Accrued expenses and other liabilities	5,713	24,902
Operating lease liability	(197)	(181)
Net cash provided by (used in) operating activities	131,341	96,060
Investing Activities:		
Purchases of property and equipment	(26)	(209)
Net cash provided by (used in) investing activities	(26)	(209)
Financing Activities:		
Payment of employee withholding tax related to stock-based compensation	(861)	(204)
Proceeds from exercise of stock options	6,997	3,553
Payment of liabilities arising from asset acquisition	(2,204)	(1,847)
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	3,932	142,206
Net increase (decrease) in cash and cash equivalents	135,247	238,057
Cash and cash equivalents – beginning of period	517,553	137,636
Cash and cash equivalents – end of period	$ 652,800	$ 375,693
Supplemental disclosures of cash flow information:		
Cash paid for income taxes	$ 39,240	$ 34,101
Cash paid for interest	$ 215	$ 140

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 markets three commercial stage drug products, FIRDAPSE® (amifampridine), AGAMREE® (vamorolone), and FYCOMPA® (perampanel). The Company is currently seeking to further expand its product portfolio, with a focus on acquiring the rights to near-term accretive and late-stage products to treat orphan, rare diseases across therapeutic areas. 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® 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 U.S. as a treatment for adults with LEMS. Additionally, 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). Further, 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). Additionally, in the second quarter of 2024, the FDA approved the Company's supplemental New Drug Application increasing the indicated maximum daily dose of FIRDAPSE® for adults and pediatric patients weighing more than 45 kg from 80 mg to 100 mg for the treatment of LEMS. Finally, Japan's national healthcare regulatory agency, the Ministry of Health, Labour and Welfare (MHLW), approved the use of FIRDAPSE® for the treatment of patients in Japan with LEMS in 2024 and beginning in January 2025, FIRDAPSE® is commercially available in Japan for the treatment of patients with LEMS through a license agreement with DyDo Pharma, Inc. (DyDo).

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® 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®, a treatment for patients suffering from Duchenne muscular dystrophy (DMD). Additionally, the Company holds the North American rights for any future approved indications of AGAMREE®. AGAMREE® previously received FDA Orphan Drug and Fast Track designations and 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. On March 13, 2024, the Company commercially launched AGAMREE® in the U.S.

The Company has devoted substantially all its efforts since inception 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 profits generated from sales of its drug products and through offerings of its securities. See Note 15 (Stockholders' Equity).

Capital Resources

Based on the Company's current financial condition, including its profitability, cash flows generated from operations and forecasts of available cash, the Company believes it has sufficient funds to support operations for at least the next 12 months.

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.

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 acquire new products and for general corporate purposes.

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, 2024 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, 2024 included in the 2024 Annual Report on Form 10-K filed by the Company with the SEC. The results of operations for the three and six months ended June 30, 2025 are not necessarily indicative of the results to be expected for any future period or for the full 2025 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 its cash and cash equivalents deposited with two financial institutions.

e. INVESTMENTS. At June 30, 2025 and December 31, 2024, 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.

U.S. Treasuries held at June 30, 2025 and December 31, 2024 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 the Company's consolidated balance sheets.

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

In July 2023, the Company 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). 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, net in the consolidated statements of operations and comprehensive income.

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

f. **ACCOUNTS RECEIVABLE, NET.** Accounts receivable are recorded net of customer allowances 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 June 30, 2025 and December 31, 2024, the Company determined that an allowance for expected credit losses was not required. No amounts were written off during the periods presented.

g. **INVENTORY, NET**. 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 to cost of sales within the consolidated statements of operations.

Products that have been approved by the FDA or other regulatory authorities, such as FIRDAPSE®, AGAMREE® and FYCOMPA® are also used in clinical programs to assess the safety and efficacy of the products for usage in treating diseases that have not been approved by the FDA or other regulatory authorities. The forms of FIRDAPSE®, AGAMREE® and FYCOMPA® 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, net 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. The Company records a reserve equal to the difference between the cost of the inventory and the estimated net realizable value.

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. 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 certain components of accrued expenses and other liabilities. At June 30, 2025 and December 31, 2024, the fair value of these instruments approximated their carrying value as a result of their respective short-term duration.

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 June 30, 2025	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	$ 102,194	$ 102,194	$ —	$ —
U.S. Treasuries	$ 407,687	$ 407,687	$ —	$ —
Investment in equity securities:				
Equity securities	$ 21,256	$ 21,256	$ —	$ —

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

	Fair Value Measurements at Reporting Date Using (in thousands)			
	Balances as of December 31, 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	$ 109,947	$ 109,947	$ —	$ —
U.S. Treasuries	$ 329,457	$ 329,457	$ —	$ —
Investment in equity securities:				
Equity securities	$ 21,564	$ 21,564	$ —	$ —

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. No shares were repurchased during the three and six months ended June 30, 2025 and 2024, respectively, and the share repurchase program expired in March 2025.

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 licensing arrangements. 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 agreements. 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.

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 or six months ended June 30, 2025 and 2024.

During the three and six months ended June 30, 2025 and 2024, 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 June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
FIRDAPSE®	$ 84,845	$ 77,372	$ 168,576	$ 144,214
FYCOMPA®	34,332	36,535	69,959	66,960
AGAMREE®*	27,363	8,746	49,405	9,920
Total product revenue, net	$ 146,540	$ 122,653	$ 287,940	$ 221,094

*AGAMREE® net product revenue for the six months ended June 30, 2024 is for the period between March 13, 2024 (date of commercial launch) and June 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 analysis 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 June 30, 2025 and, therefore, the transaction price was not reduced further during the three and six months ended June 30, 2025 and 2024. 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. 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 through June 30, 2025 and 2024, 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.

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

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 historically estimated 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; however, the coverage gap program was replaced with a redesign of the Medicare program under the Inflation Reduction Act (IRA).

While most components of the new Medicare program began in 2025, the inflation penalty portion was effective as of 2024. Specifically, the program imposes manufacturer rebates on certain Part B and Part D drugs when prices rise faster than the rate of inflation. The Company has estimated this impact and has accounted for these inflation-related rebates, as well as the other components of the program, as a reduction of product revenue to the extent they apply to its drug portfolio. Similar to the coverage gap rebates, the associated reserve is accrued for as a current liability, which is included in accrued expenses and other liabilities on the consolidated balance sheets.

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.

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.

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

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.

Revenue is included in product revenue, net in the Company's consolidated statements of operations and comprehensive income.

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

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. Revenue is included in license and other revenue in the Company's consolidated statements of operations and comprehensive income.

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 $3.7 million and $6.3 million in advertising costs during the three and six months ended June 30, 2025, respectively, and approximately $1.2 million and $5.1 million in advertising costs during the three and six months ended June 30, 2024, respectively, which are included in selling, general and administrative expenses in the Company's consolidated statements of operations and comprehensive income.

s. **STOCK-BASED COMPENSATION.** The Company recognizes expense in the consolidated statements of operations and comprehensive income 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.

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

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.

As of June 30, 2025, 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®, AGAMREE® and FYCOMPA® to constitute virtually all of the Company's product revenue for the foreseeable future.

The Company relies exclusively on third parties to formulate and manufacture 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 June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Customer A	76.5%	70.2%	75.3%	69.7%
Customer B	8.5%	11.2%	9.1%	10.4%
Total	85.0%	81.4%	84.4%	80.1%

u. ROYALTIES. Royalties incurred in connection with the Company's license agreements for its products, 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.

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

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 2021. 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. See Note 14 (Income Taxes).

w. COMPREHENSIVE INCOME. U.S. GAAP requires that all components of comprehensive income be reported in the financial statements in the period in which they are recognized. Comprehensive income is net income, plus certain other items that are recorded directly into stockholders' equity. The Company's comprehensive income is shown on the consolidated statements of operations and comprehensive income for the three and six months ended June 30, 2025 and 2024, respectively, and is comprised of net unrealized gains (losses) on the Company's available-for-sale securities.

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

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

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Basic weighted average common shares outstanding	122,163,212	118,180,396	121,819,748	117,493,257
Effect of dilutive securities	5,380,072	6,475,603	5,441,779	6,535,495
Diluted weighted average common shares outstanding	127,543,284	124,655,999	127,261,527	124,028,752

Outstanding common stock equivalents totaling approximately 2.2 million and 2.5 million, were excluded from the calculation of diluted net income per common share for the three and six months ended June 30, 2025, respectively, as their effect would be anti-dilutive. For both the three and six months ended June 30, 2024, approximately 5.2 million shares of common stock were excluded from the calculation of diluted net income per common share 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. The Company's chief operating decision maker (CODM) is its president and chief executive officer, who reviews financial information presented on a consolidated basis. The CODM uses consolidated operating margin (operating income divided by product revenue, net) and net income to assess financial performance and allocate resources. These financial metrics are used by the CODM to make key operating decisions, such as the determination of the rate at which the Company seeks to grow operating margin and the allocation of budget between cost of revenues, selling, research and development, and general and administrative expenses.

The following table illustrates information about significant segment expenses, inclusive of stock-based compensation:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	$ 4,358	$ 2,985	$ 8,245	$ 5,566
Selling	31,133	28,100	63,233	55,098
General and administrative (a)	14,816	12,630	29,627	32,570
Total	$ 50,307	$ 43,715	$ 101,105	$ 93,234

(a) exclusive of amortization of intangible assets

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

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. 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 annual periods beginning after December 15, 2024. The Company adopted this guidance as of January 1, 2025, and it will include the necessary disclosures in its annual Form 10-K. The disclosures are required on an annual basis so there was no impact to this Form 10-Q.

In November 2024, the FASB issued ASU 2024-03, *Income Statement: Reporting Comprehensive Income— Expense Disaggregation Disclosures (Subtopic 220-40)* which requires more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation, amortization, and depletion) included in certain expense captions presented on the face of the income statement, as well as disclosures about selling expenses. This ASU is effective for fiscal years beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

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 June 30, 2025:				
U.S. Treasuries - Cash equivalents	$ 407,687	$ 41	$ —	$ 407,646
Total	$ 407,687	$ 41	$ —	$ 407,646
At December 31, 2024:				
U.S. Treasuries - Cash equivalents	$ 329,457	$ 84	$ —	$ 329,373
Total	$ 329,457	$ 84	$ —	$ 329,373

There were no realized gains or losses from available-for-sale securities during the three and six months ended June 30, 2025 and 2024.

The estimated fair values of available-for-sale securities at June 30, 2025, by contractual maturity, are summarized as follows (in thousands):

	June 30, 2025
Due in one year or less	$ 407,687

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Equity securities:				
Net gains (losses) recognized during the period on equity securities	$ (2,952)	$ (2,262)	$ (308)	$ (3,406)
Unrealized net gains (losses) recognized during the period on equity securities still held at the reporting date	$ (2,952)	$ (2,262)	$ (308)	$ (3,406)

There were no purchases or sales of equity securities during the three and six months ended June 30, 2025 and 2024.

4. Accumulated Other Comprehensive Income (Loss).

The following table summarizes the changes in accumulated other comprehensive income (loss), net of tax from unrealized gains (losses) on available-for-sale securities (in thousands), the Company's only component of accumulated other comprehensive income (loss) for the three and six months ended June 30, 2025 and 2024.

There were no reclassifications out of accumulated other comprehensive income (loss) during the three and six months ended June 30, 2025 and 2024.

	Total Accumulated Other Comprehensive Income (Loss)
Balance at March 31, 2025	$ (17)
Other comprehensive gain (loss) before reclassifications	48
Net current period other comprehensive gain (loss)	48
Balance at June 30, 2025	$ 31
Balance at December 31, 2024	$ 64
Other comprehensive loss before reclassifications	(33)
Net current period other comprehensive gain (loss)	(33)
Balance at June 30, 2025	$ 31

	Total Accumulated Other Comprehensive Income (Loss)
Balance at March 31, 2024	$ —
Other comprehensive gain (loss) before reclassifications	—
Net current period other comprehensive gain (loss)	—
Balance at June 30, 2024	$ —
Balance at December 31, 2023	$ 14
Other comprehensive loss before reclassifications	(14)
Net current period other comprehensive gain (loss)	(14)
Balance at June 30, 2024	$ —

5. Inventory, Net.

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

	June 30, 2025	December 31, 2024
Raw materials	$ 5,186	$ 6,518
Work-in-process	5,345	3,445
Finished goods	8,119	9,578
Total inventory, net	$ 18,650	$ 19,541

The Company's inventory write-offs were approximately $0.5 million as of June 30, 2025 and were recorded within prepaid expenses and other current assets in the consolidated balance sheet as the Company believes it will be reimbursed by the contract manufacturer. The Company's inventory reserve was approximately $0.2 million during both the three and six months ended June 30, 2025 and was recorded within cost of sales in the consolidated statements of operations and relates to slow-moving FYCOMPA® inventory. There were no inventory write-offs or reserves during the three and six months ended June 30, 2024.

6. Prepaid Expenses and Other Current Assets.

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

	June 30, 2025	December 31, 2024
Prepaid manufacturing costs	$ 463	$ 206
Prepaid tax	10,215	7,959
Prepaid insurance	1,057	1,660
Prepaid subscriptions fees	1,268	1,233
Prepaid research fees	1,034	1,135
Prepaid commercialization expenses	4,198	4,957
Due from collaborative and licensing arrangements	23	11
Prepaid conference and travel expenses	743	1,287
Prepaid co-pay assistance program	755	1,561
Interest receivable	427	536
Other	1,243	494
Total prepaid expenses and other current assets	$ 21,426	$ 21,039

7. Operating Leases.

The Company has an operating lease agreement for its corporate office that commenced in March 2021 for approximately 10,700 square feet of space. 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 components of lease expense were as follows (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Operating lease cost	$ 108	$ 108	$ 215	$ 215

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

	For the Six Months Ended June 30,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows	$ 267	$ 260
Right-of-use assets obtained in exchange for lease obligations:		
Operating lease	$ 45	$ 45

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

	June 30, 2025	December 31, 2024
Operating lease right-of-use assets, net	$ 2,084	$ 2,230
Other current liabilities	$ 419	$ 402
Operating lease liabilities, net of current portion	2,572	2,786
Total operating lease liabilities	$ 2,991	$ 3,188

As of June 30, 2025 and December 31, 2024, the weighted average remaining lease term was 5.8 years and 6.3 years, respectively. The weighted average discount rate used to determine the operating lease liabilities was 4.51% as of June 30, 2025 and December 31, 2024.

Remaining payments of lease liabilities as of June 30, 2025 were as follows (in thousands):

2025 (remaining six months)	$ 270
2026	553
2027	570
2028	587
2029	605
Thereafter	835
Total lease payments	3,420
Less: imputed interest	(429)
Total	$ 2,991

Rent expense was approximately $0.1 million and $0.2 million for both the three and six months ended June 30, 2025 and 2024, respectively.

8. Property and Equipment, Net.

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

	June 30, 2025	December 31, 2024
Furniture and equipment	$ 1,076	$ 1,050
Leasehold improvements	991	991
Software	433	433
Less: Accumulated depreciation	(1,351)	(1,120)
Total property and equipment, net	$ 1,149	$ 1,354

9. License and Acquired Intangibles, Net.

The following table presents the Company's intangible assets at June 30, 2025 (in thousands):

	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Intangible assets:			
License and acquired intangibles for RUZURGI®	$ 33,569	$ 6,899	$ 26,670
License and acquired intangibles for FYCOMPA®	158,143	77,116	81,027
License and acquired intangibles for AGAMREE®	36,000	5,714	30,286
Total	$ 227,712	$ 89,729	$ 137,983

The following table presents the Company's intangible assets at December 31, 2024 (in thousands):

	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Intangible assets:			
License and acquired intangibles for RUZURGI®	$ 33,569	$ 5,739	$ 27,830
License and acquired intangibles for FYCOMPA®	158,143	61,301	96,842
License and acquired intangibles for AGAMREE®	36,000	4,000	32,000
Total	$ 227,712	$ 71,040	$ 156,672

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 $0.6 million and $1.2 million in amortization expense related to the licensed and acquired intangibles for RUZURGI® during both the three and six months ended June 30, 2025 and 2024, respectively, within selling, general and administrative expenses in the consolidated statements of operations and comprehensive income. The Company recorded approximately $7.9 million and $15.8 million in amortization expense related to the licensed and acquired intangibles for FYCOMPA® during both the three and six months ended June 30, 2025 and 2024, respectively, within cost of sales in the consolidated statement of operations and comprehensive income. The Company recorded approximately $0.8 million and $1.7 million in amortization expense related to the licensed and acquired intangibles for AGAMREE® during both the three and six months ended June 30, 2025 and 2024, respectively, within cost of sales in the consolidated statement of operations and comprehensive income. 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.

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

2025 (remaining six months)	$ 18,689
2026	37,378
2027	37,378
2028	7,705
2029	5,750
Thereafter	31,083
Total	$ 137,983

At June 30, 2025 and December 31, 2024, the weighted average amortization period remaining for intangible assets was 4.9 years and 5.4 years, respectively.

There were no impairment charges recognized on definite-lived intangibles for the three and six months ended June 30, 2025 or 2024.

10. Accrued Expenses and Other Liabilities.

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

	June 30, 2025	December 31, 2024
Accrued preclinical and clinical trial expenses	$ 455	$ 267
Accrued professional fees	8,315	11,011
Accrued compensation and benefits	9,437	10,746
Accrued license fees	22,742	30,991
Accrued purchases	464	447
Operating lease liability	419	402
Accrued gross-to-net revenue liabilities	62,736	44,939
Accrued income tax	439	894
Due to licensor	1,378	3,582
Accrued interest payable	347	389
Other	747	417
Current accrued expenses and other liabilities	107,479	104,085
Lease liability – non-current	2,572	2,786
Other – non-current	309	315
Non-current accrued expenses and other liabilities	2,881	3,101
Total accrued expenses and other liabilities	$ 110,360	$ 107,186

11. Collaborative and Licensing Arrangements.

KYE Pharmaceuticals, Inc.

In August 2020, the Company entered into a collaboration and license agreement with KYE, for the commercialization of FIRDAPSE® in Canada. Under the agreement, 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 (i) an up-front payment, (ii) payment upon transfer of Marketing Authorization, and (iii) payment for supply of FIRDAPSE®. Further, the Company will receive milestone payments and a sharing of defined net profits 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.

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®.

Both of these agreements are in form identified as collaborative agreements, although 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 are recognized in the quarter in which the sales occurred.

Revenues from the arrangements with KYE for the three and six months ended June 30, 2025 and 2024 were not material. Revenue is included in product revenue, net and license and other revenue in the accompanying consolidated statements of operations and comprehensive income. Expenses incurred, net have been included in selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive income.

11. Collaborative and Licensing Arrangements (continued).

DyDo Pharma, Inc.

On June 28, 2021, the Company entered into a license agreement with 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 earned an up-front payment and certain regulatory milestones and may earn sales-based milestones for FIRDAPSE®, as well as revenue on sales of 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 existed at the point in time in which the right to the license was 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.

On September 24, 2024, DyDo advised the Company that the MHLW had approved DyDo's Japan NDA to commercialize FIRDAPSE® for the treatment of patients with LEMS and, on January 21, 2025, DyDo launched FIRDAPSE® in Japan.

There was $0 and $1.1 million in revenue from the arrangement with DyDo for the three and six months ended June 30, 2025, respectively, which is included in product revenue, net in the accompanying consolidated statements of operations and comprehensive income. There were no revenues from the arrangement with DyDo for the three and six months ended June 30, 2024.

12. Commitments and Contingencies.

In May 2019, the FDA approved a NDA for RUZURGI®, Jacobus' 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 ultimately prevailed in its litigation in September 2021 when the U.S. Court of Appeals for the 11th Circuit determined that the FDA's approval of RUZURGI® violated the Company's rights to Orphan Drug Exclusivity.

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 paid the following consideration to Jacobus:

- $30 million of cash, of which $10 million was paid at the closing of the settlement, $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; and
- 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.

In January 2023, the Company received Paragraph IV Certification Notice Letters from three generic drug manufacturers (Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Inc. (collectively Teva), Hetero USA, Inc. (Hetero), and Lupin Pharmaceuticals, Inc. (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.

Additionally, in October 2023, the Company received a Paragraph IV Certification Notice Letter from a fourth generic drug manufacturer (Inventia Life Science Pty Ltd. (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.

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 U.S. Patent No. 10,626,088 which is the patent expiring in 2037, so the litigation continues.

Further, on January 8, 2025, the Company reached a settlement with Teva in which Teva agreed not to market a generic version of FIRDAPSE® in the U.S. any earlier than February 25, 2035, if approved by the FDA, unless certain limited circumstances customarily included in these types of agreements occur. In accordance with the settlement agreement, the parties terminated all ongoing patent litigation between the Company and Teva regarding FIRDAPSE® patents pending in the U.S. District Court for the District of New Jersey.

12. Commitments and Contingencies (continued).

The pending FIRDAPSE® patent litigation against the remaining defendants, Hetero (for all of FIRDAPSE®'s Orange Book-listed patents) and Lupin (only for FIRDAPSE® patent expiring in 2037), remains ongoing, and there can be no assurance as to whether the currently ongoing litigation with Hetero and Lupin will allow a generic version of FIRDAPSE® to be marketed in the U.S. prior to February 25, 2035. At this time, the Markman hearing relating to these cases has been scheduled for October 7, 2025. Further, a trial date has not been set for either of the remaining defendants, although the Company expects that a trial date may be set in the near future for sometime late in the fourth quarter of 2025 or early in the first quarter of 2026 (but in both cases prior to the expiration of the 30-month stay on May 26, 2026), should one or both of these cases fail to settle prior to trial. Of course, any final trial dates will be subject to the trial Judge's management of his docket.

Since cases of this type are complex and the results of patent litigation with Paragraph IV challengers is always uncertain, there can be no assurance as to whether the Company will prevail in these litigations. As a result, there can be no assurance as to whether a generic version of FIRDAPSE® will be marketed in the U.S. prior to Teva's licensed entry into the market on February 25, 2035.

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®. 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, the Company has entered into a purchase commitment with a contract manufacturing organization for approximately $5.4 million, which it expects to fulfill within the next twelve months.

Finally, 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 each country for any calendar year for sales up to $100 million, with the rate increasing to 10% of net sales for any total net sales in excess of $100 million in North America; and (ii) royalties to the third party licensor of the rights sublicensed to the Company for seven years from the approval of the U.S. NDA for FIRDAPSE® at 7% of U.S. net sales (as defined in the license agreement between BioMarin and the third party licensor) in any calendar year and after that 7th anniversary of the U.S. approval, royalties at 3.5% of U.S. net sales in any calendar year until the earlier of the 12th anniversary of the U.S. approval or the entry of a U.S. generic competitor. All royalty obligations to the third party licensor for Ex-U.S. sales have concluded.

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 expanded its commercial territory for FIRDAPSE®, which originally was comprised of North America, to include Japan. Additionally, the Company's commercial territory was further expanded under the license agreement in December 2023 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.

In January 2020, the Company was advised that BioMarin has transferred substantially all of its rights under the license agreement to SERB S.A. (SERB), and SERB 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, 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, $10 million on the first annual anniversary of the Effective Date (July 11, 2023), and $10 million 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®.

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® 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 protection 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 patent protection 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, 2023, the full $5.9 million was 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®. In July 2023, the Company completed its acquisition from Santhera of an exclusive license for North America for AGAMREE®, 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. 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 be obligated to 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 each of 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®.

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® (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® 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. The Company may be obligated to pay Santhera sales-based milestones of up to $105 million, which includes a sales-based milestone payment of up to $12.5 million upon achievement of revenues of $100 million. Such sales-based milestone payments are capitalized as intangible assets and amortized to cost of sales over the remaining estimated useful life of the approved product when the milestone is achieved and becomes payable by the Company. As the transaction is accounted for as an asset acquisition under U.S. GAAP, the Company will recognize all 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 being 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 to sell 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, net in the accompanying consolidated statements of operations and comprehensive income.

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 22.6% and 24.5% for the six months ended June 30, 2025 and 2024, respectively. Differences in the effective tax and the statutory federal income tax rate of 21% are driven by state income taxes, fluctuations in the value of investments and anticipated annual permanent differences offset by equity compensation deductions.

The Company had no material uncertain tax positions as of June 30, 2025 and December 31, 2024.

On July 4, 2025, the U.S. Congress passed budget reconciliation bill H.R. 1 referred to as the One Big Beautiful Bill Act (OBBBA). The OBBBA contains several changes to corporate taxation including modifications to capitalization of research and development expenses and accelerated fixed asset depreciation. The Company is in the process of evaluating the full effects of the legislation on its estimated annual effective tax rate and cash tax position, but does not expect that the legislation will have a material impact on its effective tax rate.

15. Stockholders' Equity.

Preferred Stock

The Company has 5,000,000 shares of authorized preferred stock, $0.001 par value per share. At June 30, 2025 and December 31, 2024, 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 June 30, 2025 and December 31, 2024, 122,385,569 and 120,879,099 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 authorized the repurchase of up to $40 million of the Company's common stock, pursuant to a repurchase plan under Rule 10b-18 of the Securities Act. The share repurchase program commenced on March 22, 2021 and expired on March 22, 2025. No shares were repurchased during the three and six months ended June 30, 2025 and 2024, respectively.

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 six months ended June 30, 2025 and 2024, the Company recorded stock-based compensation expense as follows (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	$ 904	$ 403	$ 1,329	$ 912
Selling, general and administrative	6,693	4,005	12,118	11,744
Total stock-based compensation	$ 7,597	$ 4,408	$ 13,447	$ 12,656

Stock Options

As of June 30, 2025, there were outstanding stock options to purchase 12,177,015 shares of common stock, of which stock options to purchase 7,119,649 shares of common stock were exercisable.

During the three and six months ended June 30, 2025, the Company granted seven-year term options to purchase an aggregate of 180,447 and 691,403 shares, respectively, of the Company's common stock to employees. The Company recorded stock-based compensation related to stock options totaling $6.1 million and $10.9 million, respectively, during the three and six months ended June 30, 2025.

16. Stock Compensation (continued).

During the three and six months ended June 30, 2024, the Company granted seven-year term options to purchase an aggregate of 47,500 and 840,995 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 $9.0 million, respectively, during the three and six months ended June 30, 2024.

During the three and six months ended June 30, 2025, options to purchase 406,372 shares and 1,381,527 shares, respectively, of the Company's common stock were exercised, with proceeds of $2.2 million and $7.0 million, respectively, to the Company.

During the three and six months ended June 30, 2024, options to purchase 491,840 shares and 1,156,272 shares, respectively, of the Company's common stock were exercised, with proceeds of $2.0 million and $3.6 million, respectively, to the Company.

As of June 30, 2025, there was approximately $36.7 million of unrecognized compensation expense related to non-vested stock option awards granted under the 2018 Stock Incentive Plan. The cost is expected to be recognized over a weighted average period of approximately 2.5 years.

Restricted Stock Units

The Company granted 15,261 restricted stock units and 18,700 restricted stock units during the three and six months ended June 30, 2025, respectively. The Company granted no restricted stock units and 35,693 restricted stock units during the three and six months ended June 30, 2024. During the three and six months ended June 30, 2025, the Company recorded non-cash stock-based compensation expense related to restricted stock units totaling $1.5 million and $2.5 million, respectively. During the three and six months ended June 30, 2024, the Company recorded non-cash stock-based compensation expense related to restricted stock units totaling $0.8 million and $3.7 million, respectively.

As of June 30, 2025, there was approximately $7.1 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 2.7 years.

17. Subsequent Events.

On August 1, 2025, the Board of Directors appointed Daniel J. Curran, MD, age 58, to the Board to fill a vacancy. Dr. Curran will serve on the Board until the Company's 2026 annual meeting of stockholders or until his resignation, removal, or death, if earlier.

On August 6, 2025, the Company announced that the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Cell Lung Cancer (SCLC) now include new additions involving Lambert Eaton myasthenic syndrome (LEMS), amifampridine, and the tests for PQ- and N-type voltage-gated calcium channel (VGCC) antibodies.

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 second quarter of fiscal 2025.
- 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 six months ended June 30, 2025 as compared to the three and six months ended June 30, 2024.
- 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 commercial stage drug products, FIRDAPSE® (amifampridine), AGAMREE® (vamorolone), and FYCOMPA® (perampanel). We are also currently seeking to further expand our product portfolio, with a focus on acquiring the rights to near-term accretive and late-stage products to treat orphan/rare diseases across therapeutic areas. 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 positive impact on those affected by these conditions.

Currently, we have a total of 59 field personnel supporting FIRDAPSE® and AGAMREE® and 18 field personnel supporting FYCOMPA®. We also have 20 patient assistance and insurance navigation support (Patient Access Liaisons) personnel who support both FIRDAPSE® and AGAMREE®. Further, we have 18 medical science liaisons who help educate the medical community about scientific literature concerning our products and the diseases they treat.

When we launched AGAMREE®, in March 2024, we utilized the FIRDAPSE® commercial and medical field-based forces to market AGAMREE®. In early 2025, we made a strategic decision to split each of these field-based forces into two units, one for each function expressly focused on supporting FIRDAPSE® and one for each function expressly focused on supporting AGAMREE®. This change was made in an effort to allow us to better focus the support for each product. This division of our field-based forces into two units became effective on April 1, 2025.

FIRDAPSE®

On November 28, 2018, we received approval from the FDA for our new drug application, (NDA) for FIRDAPSE® Tablets 10 mg for the treatment of adult patients (ages 17 and above) with LEMS, and in January 2019, we launched FIRDAPSE® in the U.S. Further, on September 29, 2022, the FDA approved our supplemental NDA (sNDA) to expand the indicated age range for FIRDAPSE® Tablets 10 mg for the treatment of LEMS to include pediatric patients six years of age and older. Additionally, on May 30, 2024, the FDA 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.

Effective April 1, 2025, we sell FIRDAPSE® in the U.S. through a field-based force experienced in neurologic, central nervous system or rare disease products consisting at this time of approximately 23 field personnel, including sales (Regional Account Managers and Area Business Directors), National Account Directors and thought leader liaisons.

We also use non-personal promotion to reach the 20,000 neurologists who are potential LEMS treaters and the 16,000 oncologists who might be treating a LEMS patient who also has small cell lung cancer. Finally, we make available for online ordering a no-cost 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.

Further, 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 in the U.S. 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 task, which can be difficult, 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 orphan and ultra-orphan, rare diseases, 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 as little as $0 whenever possible (currently an average of less than $2/mo). Our co-pay assistance programs, including the one for FIRDAPSE®, are 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. However, we continue to donate funds to one or more 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 program in place to help patients who are uninsured and underinsured. Subject to compliance with applicable regulatory requirements, our goal is that no LEMS patient is ever denied access to their medication for financial reasons.

FIRDAPSE® is currently marketed for the treatment of LEMS in Canada through our exclusive sublicensee, KYE. We supply product to KYE at agreed upon prices and we are also eligible to earn sales milestones and sales royalties based on net revenues from sales of the product in Canada. Further, FIRDAPSE® is commercially available (since January 21, 2025) for the treatment of LEMS in Japan through our sublicensee for Japan, DyDo Pharma, Inc. (DyDo). We will generate revenue from DyDo through the receipt of additional milestone payments, as such milestones are achieved, and a transfer price on the product supplied by us to DyDo (in lieu of royalties).

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 26, 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 were permitted to submit applications for the product challenging our patents starting in 2023.

In that regard, in January 2023, we received Paragraph IV Certification Notice Letters from three generic drug manufacturers (Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Inc. (collectively Teva), Hetero USA, Inc. (Hetero), and Lupin Pharmaceuticals, Inc. (Lupin)) 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 26, 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.

Additionally, in October 2023, we received a Paragraph IV Certification Notice Letter from a fourth generic drug manufacturer (Inventia Life Science Pty Ltd. (Inventia)), 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 Inventia for FIRDAPSE®. In this settlement, Inventia 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, Inventia also 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.

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. We subsequently dismissed all of our claims against Lupin related to those five patents but maintain our claims against Lupin for the remaining Paragraph IV certification for U.S. Patent No. 10,626,088, which is the patent expiring in 2037, accordingly the litigation continues.

Further, on January 8, 2025, we reached a settlement with Teva in which Teva agreed not to market a generic version of FIRDAPSE® in the U.S. any earlier than February 25, 2035, if approved by the FDA, unless certain limited circumstances customarily included in these types of agreements occur. In accordance with the settlement agreement, the parties terminated all ongoing patent litigation between us and Teva regarding FIRDAPSE® patents pending in the U.S. District Court for the District of New Jersey.

The pending FIRDAPSE® patent litigation against the remaining defendants, Hetero (relating to the FIRDAPSE®'s Orange Book-listed patents expiring in 2032, 2034 and 2037) and Lupin (relating only to the FIRDAPSE® patent expiring in 2037), remains ongoing. At this time, a trial date has not been set for a trial with either of the remaining defendants, although the Markman hearing for these cases has been set for October 7, 2025 and further, we expect that a trial date for either or both cases may be set in the near future for sometime late in the fourth quarter of 2025 or early in the first quarter of 2026 (but in both cases prior to the expiration of the 30-month stay on May 26, 2026), should one or both of these cases fail to settle prior to trial. Of course, any final trial dates will be subject to the trial Judge's management of his docket.

Since cases of this type are complex and the results of patent litigation with Paragraph IV challengers is always uncertain, there can be no assurance as to whether we will prevail in these litigations. As a result, there can be no assurance as to whether our currently ongoing litigation with Hetero and/or Lupin will allow a generic version of FIRDAPSE® to be marketed in the U.S. prior to Teva's licensed entry into the market on February 25, 2035.

On August 6, 2025, we announced that the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Cell Lung Cancer (SCLC) now include new additions involving Lambert Eaton myasthenic syndrome (LEMS), amifampridine, and the tests for PQ- and N-type voltage-gated calcium channel (VGCC) antibodies.

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 AG (collectively, 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®, 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®. Additionally, we 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 August 4, 2025, the closing price of Santhera's common shares on the SIX Swiss Exchange was CHF 14.10 per share (approximately $17.48 USD based on then-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 NDA 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 fourth quarter of 2023. We may also be obligated to pay future regulatory and commercial milestone payments to Santhera tied to calendar year sales of AGAMREE® (the first such sales-based royalty to become due when our AGAMREE® net product revenues in any calendar year exceed $100 million), as well as commercial royalties.

On March 13, 2024, utilizing our FIRDAPSE® field-based force, we launched AGAMREE® for the treatment of DMD in the U.S. 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. Initially, we added approximately 10 additional members to our FIRDAPSE® commercial team, and our commercial team marketed both products.

However, in early 2025, we made a strategic decision to split our commercial field-based force into two units, one expressly focused on the marketing of FIRDAPSE® and one expressly focused on the marketing of AGAMREE®. This change became effective on April 1, 2025 and we expect that this change will allow us to better focus our sales efforts on the market for each product. Under the new

arrangement, we now sell AGAMREE® in the U.S. through a field-based force of approximately 16, including sales (12 Regional Account Managers and 2 Area Business Directors) and Area Marketing Directors.

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. Additionally, we continue to donate funds to one or more qualified, independent charitable financial foundations dedicated to providing assistance to any U.S. DMD patients in financial need for paying the costs of care (including medication), to the extent permitted by each such organization's guidelines.

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 people in the U.S. are affected by DMD, with approximately 70% of patients currently receiving a corticosteroid treatment. We believe that steroids are and will continue to remain the foundational 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 and are currently enrolling patients in our SUMMIT study to evaluate data about long-term patient safety and quality of life data from the use of our product, with the hope of offering a deeper understanding of the product's potential long-term benefits for patients, such as in the areas of stature, bone health, and cardiovascular health.

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 patients 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. Further, on January 15, 2024, Santhera announced that AGAMREE® was commercially launched in Germany. Additionally, on January 16, 2025, the National Institute for Health and Care Excellence (NICE) issued positive Final Guidance that recommends AGAMREE® for use in the National Health Service (NHS) in England, Wales and Northern Ireland for the treatment of DMD in patients four years of age and older and on February 13, 2025, Santhera announced an agreement with the German National Association of Statutory Health Insurance Funds (GKV-SV) on the reimbursement for AGAMREE® for the treatment of DMD. This agreement makes AGAMREE® the first product to receive an agreed federal price in Germany for the treatment of DMD in patients four (4) years of age and older, independent of the underlying genetic mutation.

We are currently taking the first steps to seek to expand the number of diseases that can be treated with AGAMREE®. In furtherance of that objective, we are currently conducting a Phase 1 study in healthy adults comparing a single dose of vamorolone, prednisone, and deflazacort, and studying the immunosuppressive effect of multiple ascending doses of AGAMREE®, which study will attempt to define the immunosuppressive dose of vamorolone for future indications and for the use of our product in conjunction with gene and cell therapies that are approved to treat DMD and require a concurrent immunosuppressive regimen of a corticosteroid when administered. We expect to have the results of both parts of this study by the end of 2025 or early 2026, and we hope that the results of this study will provide important information for use in marketing our product to HCPs in an effort to help with the treatment of their DMD patients.

Further, we have established a joint steering committee with Santhera that is overseeing the lifecycle management and development of AGAMREE®. There can be no assurance that we can develop our product for the treatment of diseases other than DMD. Finally, we are currently working to validate a U.S. manufacturing site for the product.

In the U.S., AGAMREE® has New Chemical Entity exclusivity that expires in October 2028. AGAMREE® also has Orphan Drug Exclusivity expiring in October 2030. AGAMREE® is further protected by seven 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 (PTE) and will update the relevant expiration date in the Orange Book upon a final determination by the U.S. Patent and Trademark Office (USPTO). On June 25, 2025, the FDA published a notice (Determination of Regulatory Review Period for Purposes of Patent Extension; AGAMREE®) in the Federal Register regarding the requested extension of patent numbers 8,334,279, 10,857,161, and 11,833,159, all of which currently expire on May 28, 2029, as listed in the FDA's Orange Book. With the publication of this notice, there is a 180 day period for third parties to submit comments and/or due diligence petitions to the FDA. If no comments or petitions are submitted within this period, the FDA will notify the USPTO so that the USPTO can then determine the length of the PTE for each patent for which an extension was requested. Upon completion of the PTE determination, USPTO will mail a Notice of Final Determination of PTE. We will then have one month from the mailing of the Notice of Final Determination to elect one of the three patents for an extension patent term.

The earliest a generic manufacturer could submit an ANDA is October 26, 2027. If we were to pursue a patent infringement action of any such ANDA challenges of 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.

On July 23, 2024 we entered into a license, supply and commercialization agreement with KYE, which is already our sublicensee for FIRDAPSE® in Canada, granting KYE the exclusive Canadian commercial rights to market AGAMREE® in Canada for DMD and other indications. Under the agreement, KYE is 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. On April 8, 2025, we announced that Health Canada had accepted for review KYE's New Drug Submission (NDS) for AGAMREE®. The NDS submission was granted priority review, which expedites the regulatory process. There can be no assurance that the NDS will be approved, and even if approved, that KYE will be successful in commercializing AGAMREE® in Canada.

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® CIII. FYCOMPA® is a selective non-competitive antagonist of AMPA receptors, the major subtype of ionotropic glutamate receptors. It was the first, and still is 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 U.S. through a field-based force experienced in epilepsy products consisting at this time of approximately 18 field personnel, including sales (Regional Account Managers and Area Business Directors), and payor reimbursement (National Account Managers). Further, since January 1, 2024, FYCOMPA® is being sold and distributed through a 3PL organization under our contracts.

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, VA, DoD, or TRICARE.

Patent protection for FYCOMPA® tablets and oral solution 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), expired 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 will expire on July 1, 2026. The '497 patent, which covers the API used in both FYCOMPA® tablets and oral solution, had 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. As a result, the '571 patent expired on May 23, 2025 and, to our knowledge based on publicly available information, one ANDA filer for the tablet formulation has to date obtained approval of and is marketing a generic version of FYCOMPA® tablets. We will lose exclusivity for the oral suspension version of FYCOMPA® on December 15, 2025 and expect generic competition on that formulation at that time. We are continuing to market FYCOMPA® tablets following the loss of exclusivity and we intend to do the same with the oral suspension version when it loses exclusivity.

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. In that regard, we are currently exploring near-term accretive, clinically differentiated and adequately de-risked opportunities, with a keen focus on orphan, rare disease products across therapeutic areas. These prospects include evaluating companies with existing commercial drug products or drugs in development, for potential licensing or acquisitions. We maintain a well-established U.S. presence, which remains the cornerstone of our commercial strategy, while continuously evaluating strategic opportunities to expand our global footprint.

We 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, no definitive agreements have been entered into to date to acquire the rights to any additional products, and there can be no assurance that any of the Company's business development initiatives will be successful.

Appointment of a New Director

On August 1, 2025, Daniel J. Curran, MD, age 58, was appointed to our Board to fill a vacancy. Dr. Curran will serve on the Board until the Company's 2026 annual meeting of stockholders or until his resignation, removal, or death, if earlier. Dr. Curran has more than 25 years of pharmaceutical experience in strategy, business development, project leadership and development roles. Since March 2024, Dr. Curran has served as a managing partner at Mountainfield Venture Partners, LLC, a company-creation firm. Further, since January 2025, he has served as the Chief Executive Officer of Timberline Therapeutics, a clinical-stage biopharmaceutical company focused on the development and commercialization of transformational therapies for autoimmune diseases. Previously, between 2008 and 2023, Dr. Curran held roles of increasing responsibility at Takeda Pharmaceutical Company Ltd., and most recently served as a senior vice president and the head of the rare genetics and hematology therapeutic area unit from January 2019 until December 2023. Prior to joining Takeda, he served as vice president, corporate development at Millennium Pharmaceuticals, Inc, from 1999 to 2008. Prior to joining Millennium, Dr. Curran held a business development role in the product planning and acquisition group at DuPont Merck Pharmaceuticals, a pharmaceutical company. Dr. Curran previously served on the board of directors of Tome Biosciences, a private biotechnology company, and he currently serves on the Board of Directors of Xilio Therapeutics, Inc. (NASDAQ: XLO), a clinical stage biotechnology company discovering and developing tumor-activated, or masked, immuno-oncology (I-O) therapies with the goal of significantly improving outcomes for people living with cancer without the systemic side effects of current I-O treatments. Dr. Curran received an M.D. from the University of Pennsylvania School of Medicine, an M.B.A. from The Wharton School of the University of Pennsylvania, and a B.S. in chemistry from King’s College.

Capital Resources

At June 30, 2025, we had cash and investments of approximately $652.8 million. Based on our current financial condition, including our profitability, cash flows generated from operations and forecasts of available cash, absent the use of cash to acquire potential business development opportunities, 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® and AGAMREE®, that our forecasts about the commercialization of FYCOMPA® after the expiration of its patents will be correct, or that we will continue to be profitable and cash flow positive. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources” below for further information on our liquidity and cash flow.

Basis of Presentation

Revenues.

During the three and six months ended June 30, 2025, we generated revenues from product sales of FIRDAPSE®, AGAMREE®, and FYCOMPA®. We expect these revenues to fluctuate in future periods based on our sales during such periods 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 launched FIRDAPSE® in Canada. During the three and six months ended June 30, 2025, revenues generated under our collaboration agreement with KYE were immaterial. In July 2024, we announced that we had entered into a collaboration agreement with KYE for the commercialization of AGAMREE® in Canada, assuming it is approved by Health Canada.

On September 24, 2024, we were informed by DyDo that it had received approval of its New Drug Application for the sale of FIRDAPSE® in Japan. Further, DyDo informed us that they had launched FIRDAPSE® in Japan in January 2025.

We expect revenues from both the KYE and DyDo agreements to be immaterial in 2025, as distribution ramps up in each jurisdiction and KYE seeks approval to market AGAMREE® in Canada.

Cost of Sales.

Cost of sales consists of third party manufacturing costs, freight, royalties, milestone payments, 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, as well as support for selected investigator-sponsored research. The major components of research and development costs include acquired IPR&D, preclinical study costs, clinical manufacturing costs, clinical study and trial expenses, insurance coverage for clinical trials, consulting, and other third party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs related to our product development efforts.

Prior to January 2023, all of our research and development resources had been devoted to the development of FIRDAPSE®, and until we acquire or license new products we currently expect that our future development costs will be attributable principally to the continued development of FIRDAPSE®, and AGAMREE®.

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

Selling, General and Administrative Expenses.

During 2019, we began to commit funds to developing our commercialization program for FIRDAPSE® and we have continued to incur substantial commercialization expenses, including sales, marketing, patient services, patient advocacy and other commercialization related expenses as we have continued our sales program for FIRDAPSE®. We are also now incurring substantial commercialization expenses for AGAMREE® and FYCOMPA®, as we continue commercialization of both products. We expect that such expenses for FYCOMPA® should begin to decline as a result of a potential decline in sales upon the expiration of patent protection and the commencement of generic competition during 2025.

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, IT, 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, the RUZURGI® product rights, which are amortized using the straight-line method over its estimated useful life of 14.5 years, and the milestone payment made to Santhera relating to the approval of AGAMREE® in the U.S. in October 2023, which is amortized using the straight-line method over its 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 accounting principles generally accepted in the U.S. (U.S. GAAP). For stock options, we use the Black-Scholes option valuation model in calculating the fair value of the awards.

Income Taxes.

Our effective income tax rate is the ratio of income tax expense over our net income before income taxes.

Recently Issued Accounting Standards.

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

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenues and expenses during the reporting periods. For a full discussion of our accounting policies, please refer to Note 2 on the Financial Statements included in our 2024 Annual Report on Form 10-K that we filed with the SEC on February 26, 2025. 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 2024 Annual Report on Form 10-K.

Results of Operations

Revenues.

For the three and six months ended June 30, 2025, we recognized total revenues of approximately $146.6 million and $288.0 million, respectively, which included approximately $146.5 million and $287.9 million, respectively, in net revenue from product sales primarily in the U.S. For the three and six months ended June 30, 2024, we recognized total revenues of approximately $122.7 million and $221.2 million, respectively, which included approximately $122.7 million and $221.1 million, respectively, in net revenue from product sales primarily in the U.S.

FIRDAPSE® net product revenue was approximately $84.8 million and $168.6 million, respectively, for the three and six months ended June 30, 2025, compared to approximately $77.4 million and $144.2 million, respectively, for the three and six months ended June 30, 2024.

AGAMREE® net product revenue was approximately $27.4 million and $49.4 million, respectively, for the three and six months ended June 30, 2025, compared to approximately $8.7 million for the three months ended June 30, 2024 and $9.9 million for the period between March 13, 2024 (date of commercial launch) and June 30, 2024.

FYCOMPA® net product revenue was approximately $34.3 million and $70.0 million, respectively, for the three and six months ended June 30, 2025, compared to approximately $36.5 million and $67.0 million, respectively, for the three and six months ended June 30, 2024.

The increases of approximately $23.9 million and $66.8 million, respectively, in net product revenues when comparing the three and six months ended June 30, 2025 and 2024 was primarily due to the commercialization of AGAMREE® in March 2024 and related product sales. Additionally, FIRDAPSE® net product revenue increased by approximately $7.5 million or 9.7% and $24.4 million or 16.9%, respectively, from the three and six month periods ended June 30, 2024 compared to the three and six month periods ended June 30, 2025, which was primarily driven by an increase in sales volumes, a portion of which is attributed to a delay in patient claims to certain non-Medicare payors in certain states resulting from the Change Healthcare cybersecurity incident that occurred in the first quarter of 2024 and was resolved in the second quarter of 2024. Further, FYCOMPA® net product revenue decreased by approximately $2.2 million or 6.0% and increased by $3.0 million or 4.5%, respectively, from the three and six month periods ended June 30, 2024 compared to the three and six month periods ended June 30, 2025, which included a reduction in variable consideration (gross-to-net) resulting from a decrease in wholesaler distribution fees.

In the first quarter of each calendar year, like many companies in our industry, we were also impacted by the reset of patient insurance deductibles.

We expect that net product revenue for FYCOMPA® will likely decrease in the future, since patent protection for FYCOMPA® tablets expired on May 23, 2025 and will expire on December 15, 2025 for the oral suspension.

For the three and six months ended June 30, 2025, we recognized $23 thousand and $44 thousand, respectively, in license and other revenue. For both the three and six months ended June 30, 2024, we recognized $0.1 million in license and other revenue.

Cost of Sales.

Cost of sales was approximately $20.6 million and $38.5 million, respectively, for the three and six months ended June 30, 2025, compared to $15.4 million and $27.9 million, respectively, for the three and six months ended June 30, 2024. Cost of sales in all 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® for the three and six months ended June 30, 2025 consisted of product costs and excludes the amortization of the FYCOMPA® intangible assets. Cost of sales for AGAMREE® for the three and six months ended June 30, 2025 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. Royalties on sales of AGAMREE® in future years may increase as a percentage of net sales exceed certain amounts of net revenues over $100 million. See Note 13 of the Notes to Consolidated Financial Statements included elsewhere in this report.

Amortization of Intangible Assets.

Amortization of intangible assets was approximately $9.3 million and $18.7 million, respectively, for each of the three and six month periods ended June 30, 2025 and 2024. 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, the RUZURGI® rights, which are amortized using the straight-line method over its estimated useful life of 14.5 years and the AGAMREE® rights, which are amortized using the straight-line method over its estimated useful life of 10.5 years.

Each fiscal quarter, we review the value of our intangible assets to determine if they are impaired. If we determine one or more of our intangible assets are impaired during a future period we would record a charge in the amount of that impairment.

Research and Development Expenses.

Research and development expenses for the three months ended June 30, 2025 and 2024 were approximately $4.4 million and $3.0 million, respectively, and represented approximately 5% and 4% of total operating costs and expenses, respectively. Research and development expenses for the three months ended June 30, 2025 and 2024 were as follows (in thousands):

	For the Three Months Ended June 30,		Change	
	2025	2024	$	%
Salary and benefit expense	$ 1,668	$ 1,356	312	23.0
Employee stock-based compensation expense	904	403	501	124.3
Research and clinical trial expense	1,697	857	840	98.0
Additional research and development expense	89	369	(280)	(75.9)
Total research and development expenses	$ 4,358	$ 2,985	1,373	46.0

Research and development expenses for the six months ended June 30, 2025 and 2024 were approximately $8.2 million and $5.6 million, respectively, and represented approximately 5% and 4% of total operating costs and expenses, respectively. Research and development expenses for the six months ended June 30, 2025 and 2024 were as follows (in thousands):

	For the Six Months Ended June 30,		Change	
	2025	2024	$	%
Salary and benefit expense	$ 2,780	$ 2,099	681	32.4
Employee stock-based compensation expense	1,329	912	417	45.7
Research and clinical trial expense	3,787	1,995	1,792	89.8
Additional research and development expense	349	560	(211)	(37.7)
Total research and development expenses	$ 8,245	$ 5,566	2,679	48.1

Research and development expenses remained relatively consistent during the three and six months ended June 30, 2025 when compared to the same periods in 2024. During the three and six months ended June 30, 2025, research and development expenses consisted of costs for company-sponsored research and development activities, support for selected investigator-sponsored research, and support for our commercial activities. Stock-based compensation expense includes a charge related to the retirement of a former executive officer, recorded during the second quarter of 2025, upon lapse of the applicable revocation period under the separation agreement with this former executive. This charge is allocated between research and development expenses and selling, general and administrative expenses.

We expect that research and development activities may become more significant in the future if we seek to execute on the development of additional indications for FIRDAPSE® and AGAMREE® and on our portfolio expansion efforts.

Selling, General and Administrative Expenses.

Selling, general and administrative expenses for the three months ended June 30, 2025 and 2024 were approximately $45.9 million and $40.7 million, respectively, and represented approximately 57% and 59% of total operating costs and expenses, respectively. Selling, general and administrative expenses for the three months ended June 30, 2025 and 2024 were as follows (in thousands):

	For the Three Months Ended June 30,		Change	
	2025	2024	$	%
Selling	$ 28,284	$ 26,247	2,037	7.8
General and administrative	10,972	10,478	494	4.7
Employee stock-based compensation	6,693	4,005	2,688	67.1
Total selling, general and administrative expenses	$ 45,949	$ 40,730	5,219	12.8

Selling, general and administrative expenses for the six months ended June 30, 2025 and 2024 were approximately $92.9 million and $87.7 million, respectively, and represented approximately 59% and 63% of total operating costs and expenses, respectively. Selling, general and administrative expenses for the six months ended June 30, 2025 and 2024 were as follows (in thousands):

	For the Six Months Ended June 30,		Change	
	2025	2024	$	%
Selling	$ 58,185	$ 51,568	6,617	12.8
General and administrative	22,557	24,356	(1,799)	(7.4)
Employee stock-based compensation	12,118	11,744	374	3.2
Total selling, general and administrative expenses	$ 92,860	$ 87,668	5,192	5.9

For the three and six months ended June 30, 2025, selling, general and administrative expenses remained relatively consistent when compared to the same periods in 2024. The increase in selling expenses was primarily attributable to an increase in employee compensation related to annual merit increases and an increase in headcount resulting from the acquisitions of FYCOMPA® and AGAMREE®. Further, the decrease in general and administrative expenses was primarily due to the timing of our commitments to make contributions to 501(c)(3) organizations supporting LEMS patients. Finally, stock-based compensation expense includes charges related to the retirement of three former executive officers, two of which were recorded during the first quarter of 2024 and one of which was recorded during the second quarter of 2025, upon lapse of the applicable revocation periods under the respective separation agreements with these former executives. The charge in the 2025 period is allocated between research and development expenses and selling, general and administrative expenses.

We expect that selling, general, and administrative expenses will continue to be substantial in future periods as we continue to sell FIRDAPSE® and AGAMREE® and as we take other steps in an effort to continue to expand our business.

Stock-Based Compensation.

Total stock-based compensation for the three and six months ended June 30, 2025 was $7.6 million and $13.4 million, respectively, and for the three and six months ended June 30, 2024 was $4.4 million and $12.7 million, respectively. In the 2025 and 2024 periods, grants were principally for stock options and restricted stock units related to year-end bonus awards and grants to new employees. Both periods include charges related to the retirement of three former executive officers, two of which were recorded during the first quarter of 2024 and one was recorded during the second quarter of 2025, upon lapse of the applicable revocation periods under the respective separation agreements with these former executives.

Other Income, Net.

We reported other income, net in all periods, primarily relating to interest on our investment of our cash and cash equivalents of $3.0 million and $10.9 million for the three and six months ended June 30, 2025 compared to $1.5 million and $3.5 million for the three and six months ended June 30, 2024. The increases in other income, net for the three and six months ended June 30, 2025 when compared to the same periods in 2024 was primarily due to higher invested balances offset by a decrease in the share price of our investment in Santhera.

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, net.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Interest income, net	$ 5,947	$ 3,804	$ 11,222	$ 6,911
Net gains (losses) recognized during the period on equity securities	(2,952)	(2,262)	(308)	(3,406)
Total other income, net	$ 2,995	$ 1,542	$ 10,914	$ 3,505

Income Taxes.

Our effective income tax rate was approximately 22.6% and 24.5% for the six months ended June 30, 2025 and 2024, respectively. Differences in our effective tax and the statutory federal income tax of 21% are driven by state income taxes 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 (and may be higher than it was for the six months ended June 30, 2025).

We had no material uncertain tax positions as of June 30, 2025 and December 31, 2024.

Net Income.

Our net income was $52.1 million and $108.8 million, respectively, for the three and six months ended June 30, 2025 ($0.43 and $0.89, respectively, per basic share and $0.41 and $0.86, respectively, per diluted share) as compared to net income of $40.8 million and $64.1 million, respectively, for the three and six months ended June 30, 2024 ($0.35 and $0.55, respectively, per basic share and $0.33 and $0.52, respectively, per diluted share).

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through revenues from product sales and multiple offerings of our securities. At June 30, 2025 we had cash and cash equivalents aggregating $652.8 million and working capital of $645.7 million. At December 31, 2024 we had cash and cash equivalents aggregating $517.6 million and working capital of $502.9 million. At June 30, 2025, 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, substantially all such funds were invested in money market accounts and U.S. Treasuries.

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 our current financial condition, including our profitability, cash flows generated from operations and forecasts of available cash, absent the use of cash to acquire potential business development opportunities, we believe that we have sufficient funds to support our 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®, AGAMREE®, and FYCOMPA® sales, or the products we may acquire and continue to develop and whether our results continue to be profitable and cash flow positive. We may also need to raise additional capital to fund product acquisitions that are valued at more than our available cash. 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®, AGAMREE®, and FYCOMPA®;
- the effect of competition and market developments;
- the cost of filing and potentially prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in other products.

We may raise additional funds through public or private equity offerings, debt financings, corporate collaborations or other means. We also may seek governmental grants for a portion of the required funding for our clinical trials and preclinical trials. We may further seek to raise capital to fund additional 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.

Cash Flows.

Net cash provided by operating activities was $131.3 million and $96.1 million, respectively, for the six months ended June 30, 2025 and 2024. During the six months ended June 30, 2025, net cash provided by operating activities was primarily attributable to our net income of $108.8 million, a decrease of $0.2 million in inventory, net, an increase of $5.7 million in accrued expenses and other liabilities, $13.4 million in stock-based compensation, $18.9 million in amortization of intangible assets and depreciation and $1.0 million in non-cash expenses. This was partially offset by an increases of $0.4 million in accounts receivable, net and $0.4 million in prepaid expenses and other current assets, decreases of $11.1 million in accounts payable and $0.2 million in operating lease liability and $4.8 million in deferred taxes. During the six months ended June 30, 2024, net cash provided by operating activities was primarily attributable to our net income of $64.1 million, an increase of $24.9 million in accrued expenses and other liabilities, $12.7 million in stock-based compensation, $18.9 million in amortization of intangible assets and depreciation and $3.8 million in non-cash expenses. This was partially offset by increases of $3.7 million in accounts receivable, net, $2.4 million in inventory, net and $11.0 million prepaid expenses and other current assets, decreases of $7.7 million in accounts payable and $0.2 million in operating lease liability and $3.4 million in deferred taxes.

Net cash used in investing activities was $26 thousand for the six months ended June 30, 2025, consisting of purchases of property and equipment. Net cash used in investing activities was $0.2 million for the six months ended June 30, 2024, consisting of purchases of property and equipment.

Net cash provided by financing activities during the six months ended June 30, 2025 was $3.9 million, consisting primarily of proceeds from the exercise of stock options, partially offset by the payment of liabilities arising from asset acquisition and payment of employee withholding tax related to stock-based compensation. Net cash provided by financing activities during the six months ended June 30, 2024 was $142.2 million, consisting primarily of proceeds from the issuance of common stock.

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 each country for any calendar year for sales up to $100 million, with the rate increasing to 10% of net sales for any total net sales in excess of $100 million in North America; and
  - Royalties to the third party licensor of the rights sublicensed to us for seven years from the approval of the U.S. NDA for FIRDAPSE® at 7% of U.S. net sales (as defined in the license agreement between BioMarin (since transferred to SERB S.A.) and the third party licensor) in any calendar year and after that 7th anniversary of the U.S. approval, royalties at 3.5% of U.S. net sales in any calendar year until the earlier of the 12th anniversary of the U.S. approval or the entry of a U.S. generic competitor. All royalty obligations to the third party licensor for Ex-U.S. sales have concluded.

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.

For the three and six months ended June 30, 2025, we recognized an aggregate of approximately $13.8 million and $25.4 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. For the three and six months ended June 30, 2024, we recognized an aggregate of approximately $11.5 million and $20.4 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.

- *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 $10 million was paid on the second anniversary of closing; and
  - 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.

For the three and six months ended June 30, 2025, we recognized an aggregate of approximately $1.3 million and $2.5 million, respectively, of royalties payable to Jacobus. For the three and six months ended June 30, 2024, we recognized an aggregate of approximately $1.2 million and $2.1 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 agreed to pay the following consideration to Eisai:
  - We paid at closing a $160 million upfront cash payment, plus $1.6 million for reimbursement of certain prepayments.
  - Royalties commencing on loss of all patent protection 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, 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®:

- *Payments due under our license agreement for AGAMREE®.* In connection with our 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 for AGAMREE® 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.
  - We may be obligated to pay Santhera sales-based milestones of up to $105 million, which includes a sales-based milestone payment of up to $12.5 million upon achievement of revenues in the calendar year in which revenues exceed $100 million, and pay royalties if the applicable amount of net sales of all products in the territory in a single calendar year fall within the range of one or more of the net sales threshold levels set forth in the AGAMREE® License Agreement.
  - At signing, we were obligated to purchase all of our finished goods requirements for products solely from Santhera at a set supply price until January 1, 2026, but the parties have agreed upon an Amendment to the license agreement that allows us to start the process for creating our own supply chain to manufacture Agamree earlier and we have already initiated that process.
  - 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 six months ended June 30, 2025, we recognized an aggregate of approximately $3.2 million and $5.7 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. For the three and six months ended June 30, 2024, we recognized an aggregate of approximately $0.9 million and $1.0 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.

We also have entered into the following contractual arrangements:

- *Purchase commitments*. We have entered into a purchase commitment with a contract manufacturing organization for approximately $0.5 million per year. The agreement expires in December 2025. We also have entered into a purchase commitment with a contract manufacturing organization for approximately $5.4 million, which we expect to fulfill within the next twelve months.
- *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), AGAMREE® (vamorolone), and FYCOMPA® (perampanel) CIII 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®, AGAMREE®, and FYCOMPA® 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 LEMS will prove to be accurate, and whether we can continue to increase FIRDAPSE® net product revenues as quickly as we have done in past periods;
- Whether the daily dose of FIRDAPSE® taken by patients changes over time and how that affects our net product revenues for FIRDAPSE® in future periods;
- Whether we will continue to be able to locate LEMS patients who are undiagnosed or are misdiagnosed with another disease, including LEMS patients who also have small cell lung cancer;
- Whether patients will discontinue from the use of our products at rates that are higher than historically experienced or are higher than we forecast;
- Whether new FIRDAPSE®, AGAMREE®, and FYCOMPA® 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 continue to demonstrate, to the satisfaction of the FDA and third party payors, whether AGAMREE® offers advantages compared to other corticosteroids or competitor's products;
- Whether DMD patients transitioning to current or future approved 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 we will be able to continue to successfully commercialize FYCOMPA® now that its patents have begun to expire and now that generic competition for FYCOMPA® has entered the market;
- Whether the loss of exclusivity and reduced sales of FYCOMPA® result in a future impairment of our intangible asset for FYCOMPA®;
- 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 potential impact of tariffs on our cost of sales for products that are manufactured, in whole or in part, outside of the U.S., should tariffs be implemented for pharmaceuticals imported into the U.S. from any of the countries from which we source either finished goods or active pharmaceutical ingredients;
- 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 challenges to our intellectual property, and, conversely, whether any third party intellectual property presents unanticipated obstacles for FIRDAPSE® 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 were to 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 we will be successful in our litigation to enforce our patents against the Paragraph IV challengers who have filed ANDAs seeking to introduce generic versions of FIRDAPSE®;
- Whether our patents will be sufficient to prevent generic competition for FIRDAPSE® and AGAMREE® after our orphan drug exclusivity for each of these products expire;
- 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, changes (if any) to be made by the current President (including the possibility of seeking to impose Most Favored Nation (MFN) pricing on drug companies) and/or the current Congressional administrations, changes to the review and approval process at the FDA, imposing tariffs on imported product, 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® and AGAMREE® (if approved in Canada) can be successfully commercialized in Canada on a profitable basis through KYE, 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's NDS to commercialize AGAMREE® in Canada will be approved;
- Now that FIRDAPSE® has been approved for commercialization in Japan and launched, whether DyDo will be successful in commercializing the product in Japan;
- The impact on sales of FIRDAPSE® in the U.S. if an amifampridine product is purchased in Canada for use in the U.S.;
- Whether any efforts we undertake to expand the reach of FIRDAPSE® and AGAMREE® into other global regions will be successful;

- 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; and
- Our ability to enhance our systems, processes and procedures to appropriately support the growing complexity and scale of our business.

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

Our exposure to interest rate risk is currently confined to our cash and cash equivalents that are from time to time invested in highly liquid money market funds and U.S. Treasuries. The primary objective of our investment activities is to preserve our capital to fund acquisitions and 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 June 30, 2025, 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 June 30, 2025, 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

For a description of currently ongoing Paragraph IV litigation related to FIRDAPSE®, see "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview – FIRDAPSE®." The outcome of patent litigation with Paragraph IV challengers is always uncertain and there can be no assurance as to whether we will prevail in this litigation or as to whether the results of any such litigation might allow a generic version of FIRDAPSE® to be sold in the U.S. prior to Teva's licensed entry into the market on February 25, 2035.

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 2024 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.

Tariffs could adversely affect our business.

President Donald Trump and Commerce Secretary Howard Lutnick have each recently signaled plans to potentially tax pharmaceutical imports through tariffs. In furtherance of that goal, on April 16, 2025, the U.S. Department of Commerce posted a notice in the Federal Registry announcing that it would begin a probe "to determine the effects on national security of imports of pharmaceuticals and pharmaceutical ingredients" under section 232 of the Trade Expansion Act of 1962, as amended, the results of which could lead to tariffs on pharmaceutical imports.

We source our active pharmaceutical ingredients and finished pills from both U.S. and foreign suppliers. Additionally, we currently purchase AGAMREE® supplies from Santhera while working to set up our own manufacturers and also purchase FYCOMPA® supplies from Eisai through at least the end of 2029, both of which source from manufacturers outside of the U.S. If tariffs make purchases of materials from certain jurisdictions untenable, we may need to obtain materials from other sources, if possible, which could also increase our costs and delay our planned clinical trials and manufacture of our products and product candidates. Finally, retaliatory tariffs introduced by other countries could affect the sales of our products outside of the United States. Any of these factors may adversely affect our financial condition or results of operations.

Most Favored Nation (MFN Pricing) of drug products could adversely affect our business.

The Trump Administration has discussed the possibility that pricing of drugs in other countries could be used to price drug products for sale in the U.S. Recently, President Trump sent letters to 17 major pharmaceutical companies with a list of demands, including MFN pricing to all drugs provided to Medicaid enrollees. He stated in the letter that he wants companies to guarantee that Medicaid, Medicare, and commercial market insurers pay such prices for all new drugs, and he gave the companies 60 days to comply.

There can be no assurance as to what impact such rules, if adopted, might have on our financial condition and results of operations.

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 authorized 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 expired in March 2025. No shares were repurchased during the three and six months ended June 30, 2025 and 2024, respectively.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

10.1	Amendment No. 1 to License and Collaboration Agreement, executed and delivered as of May 22, 2025, by and between Santhera Pharmaceuticals (Schweiz) AG and the Company (Certain identified information has been excluded from this exhibit because it both (i) is not material, and (ii) would be competitively harmful if publicly disclosed)
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: August 6, 2025

Exhibit 10.1

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

TEXT OMITTED FROM THIS EXHIBIT IS MARKED WITH [***]

AMENDMENT NO. 1

TO

LICENSE AND COLLABORATION AGREEMENT

This Amendment No. 1 to the License and Collaboration Agreement dated 19 June 2023, is executed and delivered as of 22 May 2025 (the "Amendment No. 1 Effective Date"), by and between **Santhera Pharmaceuticals (Schweiz) AG**, a corporation organized under the laws of Switzerland and having its principal office at Hohenrainstrasse 24, 4133 Pratteln, Switzerland ("Santhera"), and **Catalyst Pharmaceuticals Inc.**, a corporation organized under the laws of Delaware, U.S. and having its principal office at 355 Alhambra Circle, Suite 801, Coral Gables, FL 33134, U.S. ("Catalyst"). Each of Catalyst and Santhera may be referred to herein as a "Party" or collectively as the "Parties".

RECITALS

a) The Parties entered into a License and Collaboration Agreement dated 19 June 2023 (the "Agreement"), pursuant to which Santhera grants to Catalyst (i) an Exclusive License to Develop and Commercialize the Compound and the Product in the Field in the Territory in accordance with Section 2.1 of the Agreement; and, (ii) a (non-exclusive) Manufacturing License to Manufacture the Compound and the Product in and outside the Territory for purposes of Development and Commercializing the Compound and the Products in the Field in the Territory in accordance with Section 2.1 of the Agreement.

b) The Manufacturing License is exercisable under the circumstances provided in Section 6.3 (Transfer of Manufacturing Responsibility) of the Agreement. Section 6.3 (Transfer of Manufacturing Responsibility) of the Agreement, *inter alia*, provides that, at any time on or after January 1, 2026, Catalyst shall have the right, itself or through any Third Party manufacturer, to obtain the Manufacturing License set forth in Section 2.1 of the Agreement.

c) Catalyst desires to obtain from Santhera the Manufacturing License prior to January 1, 2026, and Santhera is willing to grant such license earlier than foreseen in Section 6.3 (Transfer of Manufacturing Responsibility) of the Agreement on the terms and conditions set forth herein.

Now, therefore, the Parties agree as follows:

1. Definitions

1.1. Capitalized terms used in this Amendment No. 1 and not otherwise defined herein shall have the meaning set forth in the Agreement.

2. Amendments to Definitions

2.1. With effect from the Amendment No. 1 Effective Date, the Parties hereby add the following definitions to Section 1 of the Agreement:

1.8bis [***]

1.8ter "Amendment No. 1" means this Amendment No. 1 to the Agreement.

1.8quater "Amendment No. 1 Effective Date" means the date written at the head of this Amendment No. 1.

1.11bis "Binding Transfer Forecast" has the meaning set forth in Section 6.5(b) of this Amendment No. 1.

1.27bis "Compound Supply Price" means (i) Santhera's actual Manufacturing costs attributable to Manufacturing Compound, including amounts paid by Santhera for raw materials, goods and/or services used in support of the Manufacture of Compound, (ii) plus a mark-up of [***] of such Manufacturing costs, calculated in Dollars.

1.30bis [***]

1.32bis "Defective Compound" means a Compound which fails to conform with the Quality Agreement and/or which has not been Manufactured in accordance with Applicable Laws, including Good Manufacturing Practices, it being clarified that unless otherwise agreed by the Parties, a Compound may not be deemed defective if the alleged defect is solely attributable to Catalyst's acts or omissions (e.g. in terms of proper storage of the Compound after receipt, or due to Regulatory Filings in the Territory (e.g. variations) not previously approved by or notified to Santhera), or if the alleged defect solely results from closely following and complying with Catalyst's written information and instructions, if any, regarding Applicable Laws in the Territory.

1.39bis "Establish" means establishing the capability, through one or more subcontractors, to perform certain Manufacturing steps. For the avoidance of doubt, the term "Establish" shall not include the responsibility for any Regulatory Filings or Regulatory Approvals concerning the Product in relation to a newly Established process of Manufacturing. Rather, each Party shall be responsible in its respective territory for such Regulatory Filings or Regulatory Approvals.

1.42bis [***]

1.47bis [***]

1.81bis "Manufacturing Sites" refers to [***]

1.93bis "Phase 1 Transition Date" has the meaning set forth in Section 6.3(a) of this Amendment No. 1.

1.93ter "Phase 2 Transition Date" has the meaning set forth in Section 6.3(b) of this Amendment No. 1.

1.93quater "Phase 3 Transition Date" has the meaning set forth in Section 6.3(c) of this Amendment No. 1.

1.2. 1.93quinquies [***]

1.100bis [***]

1.116bis [***]

1.116ter [***]

1.133bis "Transfer Forecast" has the meaning set forth in Section 6.5(a) of this Amendment No. 1.

1.133ter "Transfer Purchase Order" has the meaning set forth in Section 6.6(a) of this Amendment No. 1.

1.133quater "True-up Period" has the meaning set forth in Section 6.13bis of this Amendment No. 1.

3. Amendments to License Grants

3.1. With effect from the Amendment No. 1 Effective Date, the Parties hereby amend Section 2.1(b) (Grant to Catalyst) of the Agreement as follows:

2.1 Grant to Catalyst. Subject to the terms and conditions of this Agreement, Santhera hereby grants to Catalyst,

(a) […]; and

(b) as of the Amendment No. 1 Effective Date, a non-exclusive, sublicensable (subject to Section 2.5 (Sublicensing)), transferable (in accordance with Section 14.4 (Assignment)) license under the Licensed Intellectual Property to Manufacture and have Manufactured the Compound and the Product, in and outside the Territory for purposes of Development, filing for and obtaining Regulatory Approval and Commercializing the Compound and the Products in the Field in the Territory (the "Manufacturing License").

3.2. With effect from the Amendment No. 1 Effective Date, the Parties hereby add the below Section 2.2bis (Transfer of Manufacturing Know-How) to the Agreement:

2.2bis Transfer of Licensed Know-How for Practice of Manufacturing License. Promptly following the Amendment No. 1 Effective Date, the Parties shall agree on a technology transfer plan concerning the Licensed Know-How necessary or reasonably useful to practice the Manufacturing License to Catalyst. For the avoidance of doubt, the technology transfer concerning the route of synthesis for the Compound shall only include [***]. The Parties acknowledge that [***] is currently still under Development and that the technology transfer will take place as soon as it is fully Developed. Santhera shall provide reasonable technical support and assistance to Catalyst with respect to the use and practice of such Licensed Know-How during the period of disclosure and transfer of such Licensed Know-How. During the Term, Santhera shall disclose or transfer copies of any additional Licensed Know-How necessary or reasonably useful to practice the Manufacturing License to Catalyst as promptly as practicable, to the extent that such Licensed Know-How arises after the Amendment No. 1 Effective Date or otherwise has not previously been provided or made available to Catalyst.

4. Amendments to Joint Steering Committee

4.1. With effect from the Amendment No. 1 Effective Date, the Parties hereby amend Section 5.3 (Responsibilities) of the Agreement as follows:

5.3 Responsibilities. The duties of the JSC will include (i) exchanging information regarding Development, Manufacturing and Commercialization in and outside of the Territory, (ii) reviewing any Additional Development Proposals, determining whether to pursue Global Additional Development, and reviewing and approving development plans (including budgets) and Cost Allocations pertaining to Global Additional Development and, if applicable, Cost Allocations pertaining to Territory Additional Development, (iii) agreeing upon schedules for the transfer of Know-How as provided in Sections 2.2 and 2.2bis, and (iv) discussing and monitoring for the Territory the following matters:

(a) Development, approval by a Regulatory Authority and maintenance of Regulatory Approval as well as life cycle related development activities,

(b) Manufacturing of the Compound or Product;

(c) Commercialization of the Product and its related activities, including product strategy, alignment on key global activities, marketing and medical activities,

(d) any matters in relation to the Licensed Intellectual Property,

(e) other matters including monetary disputes.

5. Amendments to Manufacture and Supply

5.1. With effect from the Amendment No. 1 Effective Date, the Parties hereby amend Section 6.1 (Manufacture and Supply) of the Agreement as follows:

6.1 Manufacture and Supply. Until the Phase I Transition Date, and subject to the terms and conditions set forth herein, Catalyst shall purchase all of its requirements for Product exclusively from Santhera, and Santhera shall manufacture (or have manufactured), supply and sell to Catalyst all of Catalyst's, its Affiliates' and Sublicensees' Product requirements. From the Phase I Transition Date to the Manufacturing Transfer Date, and subject to the terms and conditions set forth herein, Catalyst shall purchase all of its requirements for Compound Exclusively from Santhera, and Santhera shall manufacture (or have manufactured [***], supply and sell to Catalyst all of Catalyst's, its Affiliates' and Sublicensees' Compound requirements.

Subject to the foregoing and to the terms of this Section 6, Catalyst shall have the right to Manufacture the Compound [***] and the Product in or outside the Territory for purposes of Development, filing for and obtaining Regulatory Approval and Commercializing the Compound and the Products in the Field in the Territory. The different phases of the transition of the manufacturing responsibility from Santhera to Catalyst are set forth in more detail in Section 6.3 (Transfer of Manufacturing Responsibility).

5.2. With effect from the Amendment No. 1 Effective Date, the Parties hereby amend Section 6.2 (Manufacture and Supply of Investigational Medicinal Product) of the Agreement as follows:

6.2 Manufacture and Supply of Investigational Medicinal Product. Catalyst shall also have the non-exclusive right to Manufacture Investigational Medicinal Product for use in the Territory. To the extent the Parties decide to jointly pursue clinical trials, the Parties shall agree on which Party (usually the study sponsor) shall Manufacture and supply Investigational Medicinal Product for use in such clinical trials, and on any further terms

of such Manufacture and Supply. To the extent a Party pursues clinical trials without the participation of the other Party, the Party pursuing such clinical trials shall be responsible for Manufacturing Investigational Medicinal Product for use in such clinical trials.

5.3. With effect from the Amendment No. 1 Effective Date, the Parties hereby amend Section 6.3 (Transfer of Manufacturing Responsibility) of the Agreement as follows:

6.3 Transfer of Manufacturing Responsibility. The Parties agree on the following phases for the transition from Santhera to Catalyst of the Manufacture of the Compound and the Product for use in the Territory:

1.1.1.No later than [***] (the "Phase 1 Transition Date"), Catalyst shall have Established, at its costs, the capability [***] to Manufacture the Product and (i) perform the Secondary Packaging of the Product (incl. serialization) for use in the Territory, and (ii) shall enter into a direct supply agreement with [***] for the supply of Primary Packaged Product for use in the Territory. Following the Phase 1 Transition Date, Santhera's supply obligation to Catalyst shall be limited to the supply of Compound [***], except that Santhera shall remain obligated for a transitional period to supply Product with Primary Packaging destined for use in the U.S. [***] and/or perform Secondary Packaging for Catalyst pursuant to Section 6.3bis(a) and Section 6.3bis(b) of this Amendment No. 1.

1.1.2.Santhera shall use reasonable efforts to have Established, no later than [***] (the "Phase 2 Transition Date"), at its cost [***], the process to Manufacture the Primary Packed Product for use inside and outside of the Territory at [***]. In case Santhera, despite using reasonable efforts, has not been able to Establish the process to Manufacture the Primary Packed Product for use inside and outside of the Territory at [***] by the Phase 2 Transition Date, the Parties may separately agree on a new Phase 2 Transition Date as far as relating to the Manufacture of the Product for use inside and outside of the Territory at [***].

1.1.3.Catalyst shall use reasonable efforts to have Established by Phase 2 Transition Date, at its costs [***], the process to Manufacture the Product for use inside and outside of the Territory at [***].. In case Catalyst, despite using reasonable efforts, has not been able to Establish the process to Manufacture the Product for use inside and outside of the Territory at [***] by the Phase 2 Transition Date, the Parties may separately agree on a new Phase 2 Transition Date as far as relating to the Manufacture of the Product for use inside and outside of the Territory at [***]..

1.1.4.No later than [***] (the "Phase 3 Transition Date") Santhera shall have Established, with reasonable support from Catalyst and at costs to be shared with Catalyst [***],, the process at [***] to Manufacture [***] and supply the Compound for use in the Manufacture of the Product inside and outside of the Territory. In case Santhera, despite using reasonable efforts, has not been able to Establish the process [***] to Manufacture [***] the Compound by the Phase 3 Transition Date, the Parties may separately agree to move the Phase 3 Transition Date to a later date.

1.1.5.No later than [***] (the "Manufacturing Transfer Date") Catalyst shall be responsible to Manufacture the Compound [***] and the Product (including, for the avoidance of doubt, Primary Packaging, Secondary Packaging, serialization, etc.) for use in the Territory. If the Parties agreed to move the Phase 3 Transition Date to a later date, the Manufacturing Transfer Date shall automatically be moved to a later date by adding the same number of days to the Manufacturing Transfer Date as between the original and the extended Phase 3 Transition Date. Following the (initial or extended) Manufacturing Transfer Date, Santhera shall no longer have any supply obligation to Catalyst, neither regarding the Compound nor regarding the Product.

5.4. With effect from the Amendment No. 1 Effective Date, the Parties hereby add the below Sections 6.3bis (Transition Plan Period); 6.3ter (Responsibilities and Related Costs of Manufacturing); 6.3quater (Responsibilities of Transfer of Licensed Know-How for Practice of Manufacturing License); and 6.3quinquies (Back-Up Cooperation) to the Agreement:

6.3bis Transition Plan Period.

(a) Santhera shall supply Product with Primary Packaging and/or with Secondary Packaging to Catalyst destined for use in the U.S. [***] pursuant to [***]..

(b) In case Catalyst, for reasons not attributable to Catalyst, has not been able to enter into a direct supply agreement with [***] for the supply of Primary Packaged Product for use in the Territory by the Phase 1 Transition Date, Santhera shall continue to Manufacture the quantities as per [***] for Catalyst for a limited transitional period [***] under Santhera's contract with [***], subject to a minimum lead time of 4 (four) months between the acceptance

of a Purchase Order and the expected date of delivery.

*(c) In case Catalyst, for reasons not attributable to Catalyst, has not been able to Establish the capability to perform the Secondary Packaging of the quantities as per [***} of the Product for use in the Territory by the Phase 1 Transition Date, the Parties may separately agree that Santhera continue to perform the Secondary Packaging for a limited transitional period until [***] under Santhera's contract with [***], subject to a minimum lead time of 4 (four) months between the acceptance of a Purchase Order and the expected date of delivery.*

(d) Prior to the Phase 1 Transition Date, Catalyst shall purchase a total quantity of [***] of Compound from Santhera, as further detailed in [***]. In relation to the period between the Phase 1 Transition Date and [***], Santhera shall have no obligation to supply a total quantity of Compound in excess of [***] in total.

6.3ter Responsibilities and Related Costs of Manufacturing.

(a) Catalyst shall be solely responsible for the Manufacturing of the Product (including Primary and Secondary Packaging) by its subcontractors at its own cost and expense.

(b) Santhera shall be solely responsible for the Manufacturing of the Product (including Primary and Secondary Packaging) by its subcontractors at its own cost and expense.

6.3quater Responsibilities of Transfer of Licensed Know-How for Practice of Manufacturing License. The Parties shall, within the JSC, agree on the specific technical support and assistance to be provided by Santhera regarding the transfer of the Licensed Know-How to Catalyst for the practice of the Manufacturing License to Catalyst. Catalyst shall reimburse Santhera for all its reasonable and documented internal and external costs and expenses incurred in the Manufacturing transfer to Catalyst (including for transfer project staff, Third Party consultants, etc.) in accordance with a budget agreed in advance by the Parties.

6.3quinquies Back-Up Cooperation. The Parties agree to use reasonable efforts to support one another in the Manufacturing and supply of the Product and Compound in the event of an unexpected failure of Manufacturing and supply at a Manufacturing Site. In such event, the Party not affected by the failure shall try to facilitate the use of one of its CMOs not affected by the failure as a back-up source for Manufacturing and supply of the Product in Primary Packaging to the Party affected by the supply failure, including Santhera directly providing to Catalyst the Compound manufactured using [***] if that is all that is available. To determine the supply price in such scenario, Section 1.127 (Supply Price) shall be applied by analogy. The Party requiring the back-up Manufacturing and Supply shall be responsible (i) to pick up the Product from the relevant Manufacturing Site, (ii) for transportation to the relevant jurisdiction(s), (iii) for Secondary Packaging, and (iv) for market release in accordance with the Quality Agreement (to be amended, if needed, to address the back-up cooperation envisioned under this Section 6.3quinquies) and Applicable Laws. To enable a back-up cooperation as envisioned under this Section 6.3quinquies, the Parties shall keep each other promptly informed of Regulatory Filings concerning the Manufacture of the Product.

5.5. With effect from the Amendment No. 1 Effective Date, the Parties hereby amend Section 6.4 (Quality Requirements) of the Agreement as follows:

6.4 Quality Requirements. The Parties shall determine the Product Specifications, and any later amendments thereto, in the Quality Agreement to be executed pursuant to Section 6.11 (Complaints; Safety Notifications; Recall). As regards the transition of Manufacturing responsibilities from Santhera to Catalyst, the Parties shall determine the Product Specifications for the Compound and the Product in relation to each phase of the transition as set forth in Section 6.3 (Transfer of Manufacturing Responsibility).

6.4bis Control of Regulatory Changes Relating to Manufacture and Supply. Until the Manufacturing Transfer Date, Catalyst shall provide prior notice, along with appropriate pertinent technical information, of any Regulatory Filing in the Territory related to the Manufacture and supply of the Compound or the Product to Santhera for review at least sixty (60) days prior to the expected filing date. Santhera shall review such draft to determine whether such Regulatory Filing may have an impact on Santhera's obligation to Manufacture and supply Compound or Product. Santhera shall notify Catalyst of its reasoned objections, within thirty (30) days from receipt of such draft and all such objections will be resolved through the JSC and the dispute resolution process described in this Agreement. If Catalyst submits a Regulatory Filing prior to resolving Santhera's objections as described above, Santhera shall have no obligation to alter its Manufacture and supply of the Compound or Product to comply with such Regulatory Filing. If Santhera approves a Regulatory Filing, Santhera shall use reasonable efforts to ensure compliance with such Regulatory Filing in the context of its obligation to Manufacture and supply Compound or

Product.

5.6. With effect from the Amendment No. 1 Effective Date, the Parties hereby amend Section 6.5 (Forecasts) of the Agreement as follows:

6.5 Forecasts.

1.1.1.No later than [***] prior to the Phase 1 Transition Date, and until the Manufacturing Transfer Date, on or before the fifth (5th) day of each calendar month, Catalyst shall deliver to Santhera in writing a non-binding rolling twenty-four (24) months forecast for reasonably anticipated orders of the Compound (each, a "Transfer Forecast"), provided that no new order quantities of Compound shall be forecasted beyond the Manufacturing Transfer Date.

1.1.2.As regards the Transfer Forecasts, the quantities of Compound forecasted to be ordered for the first twelve (12) months of each rolling twenty-four (24) months Transfer Forecast shall represent binding obligations of Catalyst to purchase from Santhera and binding obligations of Santhera to supply Catalyst with such quantities of Compound ordered until the Manufacturing Transfer Date (each, a "Binding Transfer Forecast").

1.1.3.During all phases of the transition of the Manufacturing as contemplated under this Amendment No. 1, the Parties shall keep each other reasonably informed, at least once per month, of their forecasts and purchase order quantities for Compound and/or Product from [***] so as to avoid any capacity conflicts at the relevant CMO.

5.7. With effect from the Amendment No. 1 Effective Date, the Parties hereby amend Section 6.6(a) of the Agreement as follows and add the below Section 6.6(f) to Section 6.6 (Purchase Orders; Confirmation) of the Agreement:

6.6 Purchase Orders; Confirmation.

(a) In relation to delivery dates after the Phase 1 Transition Date, Catalyst shall provide to Santhera written purchase orders for the Compound (each, a "Transfer Purchase Order"), each of which shall specify the quantity of Compound ordered and the delivery date, as well as a specification as to which quantities of Compound are to be supplied. The minimum Transfer Purchase Order quantity is forty (40) kilogram or multiples thereof.

(b) With respect to any given month, Catalyst shall not without Santhera's written approval (not to be unreasonably withheld, conditioned or delayed), submit Purchase Orders for Compound, respectively, that aggregate more than ten percent (10%) over the forecasted amounts for such month contained in the most recent Binding Transfer Forecast, respectively, delivered hereunder. The specified delivery date of a Transfer Purchase Order shall be at least eleven (11) monthsafter the date of such Transfer Purchase Order.

[…]

(f) Sections 6.6(c) to (e) shall apply mutatis mutandis to orders for the Compound.

5.8. With effect from the Amendment No. 1 Effective Date, the Parties hereby amend Section 6.7(a) of the Agreement as follows and add the below Section 6.7(g) to Section 6.7 (Delivery; Storage and Handling; Product Risk) of the Agreement:

6.7 Delivery; Storage and Handling; Product Risk.

1.1.1.As of the Effective Date and until the Phase 1 Transition Date (and beyond the Phase 1 Transition Date for [***] with a delivery date after the Phase 1 Transition Date), Santhera shall deliver the Product by making available to Catalyst or Catalyst's designee, the Product on the basis of [***]. Each delivery of Product shall be accompanied by a certificate of analysis and such other documents as shall be required by the Quality Agreement. As of the Phase 1 Transition Date, and until the Manufacturing Transfer Date, Santhera shall only have an obligation to deliver the Compound on the basis of [***]. Each delivery of Compound shall be accompanied by a Santhera batch certificate and such other documents as shall be required by the Quality Agreement.

[…]

(g) Sections 6.7(b) to (f) shall apply mutatis mutandis to the delivery of the Compound.

5.9. With effect from the Amendment No. 1 Effective Date, the Parties hereby add the below Section 6.8(e) to Section 6.8 (Acceptance and Rejection by Catalyst; Defective Product) of the Agreement:

6.8 Acceptance and Rejection by Catalyst; Defective Product.

(e) Sections 6.8(a) to (d) shall apply mutatis mutandis to the delivery of a Defective Compound.

5.10. With effect from the Amendment No. 1 Effective Date, the Parties hereby add the below Section 6.9bis (Regulatory Obligations Regarding Manufacture Following the Phase 1 Transition Date) to the Agreement:

6.9bis Regulatory Obligations Regarding Manufacture Following the Phase 1 Transition Date.

1.1.1.As from the Phase 1 Transition Date, Santhera shall Manufacture the Compound [***] in accordance with Product Specifications and the Quality Agreement (both only as far as applicable to the Compound), and all Applicable Laws, including Good Manufacturing Practices. The terms applicable to inspections as set forth in Section 6.9 of the Agreement (Regulatory Obligations Regarding Manufacture and Supply) shall apply mutatis mutandis, but only insofar as relating to the Manufacture of the Compound.

1.1.2.Until the Phase 1 Transition Date, Catalyst shall provide Santhera with advance notice of (i) any scheduled meeting with a Regulatory Authority in the Territory relating to the Manufacture and supply of the Compound or the Product, or (ii) any inspection by a Regulatory Authority of facilities or records of Santhera, or any of its contractors, relating to the Manufacture and supply of the Compound or the Product. After the Phase 1 Transition Date, Catalyst shall provide Santhera with advance notice of (i) any scheduled meeting with a Regulatory Authority in the Territory relating to the Manufacture and supply of the Compound or the Product (if such Product was supplied by Santhera), or (ii) any inspection by a Regulatory Authority in the Territory of facilities or records of Santhera, or any of its contractors, relating to the Manufacture and supply of the Compound or the Product (if such Product was supplied by Santhera). Santhera shall have the right, at its costs, to have its representatives be present at any such meeting, audit, or inspection, provided, however, that the presence of Santhera at such meeting, inspection or audit is not prohibited by Applicable Laws or by the terms of the applicable contract between Santhera and its contractors. Catalyst shall inform Santhera within twenty-four (24) hours or within the next Business Day of any action by a Regulatory Authority that specifically affects the obligations set forth in this Amendment No. 1. Catalyst shall transmit to Santhera as promptly as practicable, but in no event later than forty-eight (48) hours after receipt, any notice, inspection report or findings, or other communication from a Regulatory Authority in the Territory directly or indirectly related to the Manufacture and supply of the Compound or the Product (if such Product was supplied by Santhera). Except as required by Applicable Laws, Catalyst shall not submit any response, answer, proposed course of action or remediation plan or other document to any Regulatory Authority in the Territory relating to the Manufacture and supply of the Compound or the Product (if such Product was supplied by Santhera) without the prior written consent of Santhera, which shall not be unreasonably withheld, conditioned or delayed. Catalyst shall grant Santhera the opportunity to review, comment upon and participate in the preparation of any such proposed submission.

1.1.3.Until the Phase 1 Transition Date, Catalyst shall not file any documents to a Regulatory Authority in the Territory relating to the Manufacture and supply of the Compound or the Product other than as approved in advance by Santhera, such approval not to be unreasonably withheld, conditioned or delayed. To the extent Catalyst intends to amend any existing Regulatory Documentation in the Territory relating to the Manufacturing and supply of the Compound and the Product, Catalyst shall provide Santhera with reasonable advance notice of any suggested amendments and shall give Santhera the opportunity to review and comment upon any such proposed amendment. After the Phase 1 Transition Date, the obligations in this Section 6.9(c) shall apply only in relation to the Manufacture and supply of the Compound.

5.11. With effect from the Amendment No. 1 Effective Date, the Parties hereby add the below Section 6.10(c) to Section 6.10 (Labeling and Packaging) of the Agreement:

6.10 Labeling and Packaging.

(c) As of the Phase 1 Transition Date, Catalyst shall be solely responsible for the Primary Packaging and Secondary Packaging of the Product intended for Commercialization in the Territory. Catalyst shall ensure that the agreed Product Specifications for the Primary Packaged Product and the Secondary Packaged Product comply with all labelling, bar coding, serialization, regulatory, customs, or other requirements under the Applicable Laws in the

Territory.

5.12. With effect from the Amendment No. 1 Effective Date, the Parties hereby amend Section 6.11(f) (Complaints; Safety Notifications; Recalls) of the Agreement as follows:

6.11 Complaints; Safety Notifications; Recall.

(f) […] As of the Phase 1 Transition Date, this Section 6.10(f) shall apply mutatis mutandis in the event a recall is caused by the delivery of Santhera of a Defective Compound.

5.13. With effect from the Amendment No. 1 Effective Date, the Parties hereby amend Section 6.12 (Documentation of Delivered Product) of the Agreement as follows:

6.12 Documentation of Delivered Product or Compound. Each shipment of Product or Compound constitutes a separate sale and Santhera shall provide to Catalyst a written consignment note for each shipment of Product or Compound.

5.14. With effect from the Amendment No. 1 Effective Date, the Parties hereby add the below Section 6.13bis to the Agreement:

6.13bis Compound Supply Price and True-Up. Santhera shall supply to Catalyst the Compound at the Compound Supply Price, which may differ from one Manufacturing campaign to the other. Santhera shall reasonably estimate the Compound Supply Price for each Manufacturing campaign and issue its invoice to Catalyst for each shipment on this basis. Payment by Catalyst shall be due [***] after receipt by Catalyst of the corresponding invoice for a shipment. Santhera shall keep complete, accurate and authentic records sufficient in particular to ascertain and verify the actual Manufacturing costs attributable to Manufacturing Compound. Santhera shall maintain and store such records in a manner to prevent loss, theft or deterioration for a period of one (1) year following the Calendar Quarter to which they relate, or for such longer period of time as required by Applicable Laws. Within [***] following the end of each of the periods from 1 December to 30 June (seven months), and from 1 July to 30 November (five months) of every year (each period a "True-up Period"), Santhera shall provide Catalyst a true-up report stating the following: (i) Santhera's calculation of the actual Compound Supply Price for each shipment of Compound during the preceding True-up Period, which calculation shall include a reasonably detailed breakdown of the components of the Compound Supply Price, (ii) the amount by which the estimated Compound Supply Price paid by Catalyst for each shipment of Compound during the preceding True-up Period was higher or lower than the actual Compound Supply Price for such shipment, and (iii) a reconciliation of all such positive or negative deviations from the actual Compound Supply Price per shipment so as to determine the total true-up amount that either Santhera or Catalyst is required to pay to the other Party. The true-up amount required to be paid following such true-up process shall be paid by the Party owing such amount to the other Party [***] following Santhera's delivery to Catalyst of the true-up report.

6. No Further Amendments.

6.1. Except as set forth in this Amendment No. 1, the Agreement remains unaffected and shall continue in full force and effect in accordance with its terms.

7. Governing Law; Dispute Resolution.

7.1. Governing Law. This Amendment No. 1 shall be governed by and construed in accordance with the laws of the State of New York, U.S. without regard to its conflict of laws rules and to the Convention on the International Sale of Goods.

7.2. Arbitration. Any Dispute shall be finally settled in accordance with the dispute resolution provisions set forth in Sections 13.2 to 13.5 of the Agreement.

Exhibits:

[***]

Santhera Pharmaceuticals (Schweiz) AG

By: /s/ Mark Schrader By: /s/ Andreas Missy

Marc Schrader Andreas Missy

CTO SVP Corporate Planning & BD

Date: May 22, 2025 Date: May 22, 2025

Catalyst Pharmaceuticals Inc.

By: /s/ Rich Daly By:

Name: Rich Daly Name:

Title: President and CEO Title:

Date: 5/22/2025 Date:

Exhibit 6.3bis(a): [***]

Exhibit 6.3bis(b): [***]

Exhibit 6.3bis(c): [***]

Exhibit 6.3bis(d): [***]

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: August 6, 2025

/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: August 6, 2025

/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 June 30, 2025 (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: August 6, 2025

/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 June 30, 2025 (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: August 6, 2025

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