

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

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2024  
**OR**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
Commission file number: 001-37813

**SYROS PHARMACEUTICALS, INC.**  
(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

45-3772460  
(I.R.S. Employer  
Identification No.)

35 CambridgePark Drive, 4<sup>th</sup> Floor  
Cambridge, Massachusetts  
(Address of Principal Executive Offices)

02140  
(Zip Code)

(617) 744-1340  
(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, \$0.001 par value	SYRS	Nasdaq Global Select Market

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

Number of shares of the registrant's common stock, \$0.001 par value, outstanding on October 24, 2024: 26,832,457

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### Cautionary Note Regarding Forward-Looking Statements and Industry Data

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. The forward-looking statements and opinions contained in this Quarterly Report are based upon information available to us as of the date of this Quarterly Report and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.

These forward-looking statements include, among other things, statements about:

- our expectations for the timing, quantity and quality of information to be reported from our SELECT-MDS-1 clinical trial;
- our plans with respect to SELECT-MDS-1 or any future clinical trials, whether conducted by us or by any collaborators, including the timing of these trials and of the anticipated results;
- our ability to replicate in any clinical trial of a product candidate the results we observed in preclinical or earlier clinical studies of such product candidate;
- our ability to replicate in the final results of any clinical trial of one of our product candidates the results we observed in interim results of such clinical trial;
- our plans to research, develop, seek approval for, manufacture and commercialize tamibarotene or any future product candidates;
- our plans to develop and seek approval of diagnostic tests for use in identifying patients who may benefit from treatment with tamibarotene or any future product candidates;
- our ability to enter into, and the terms and timing of, any collaborations, license agreements, asset sales, or other arrangements;
- the potential benefits of any collaboration;
- developments relating to our competitors and our industry;
- the impact of government laws and regulations;
- the timing of and our ability to file new drug applications and obtain and maintain regulatory approvals for tamibarotene or any future product candidates;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional products or product candidates with significant commercial potential;
- our expectations related to the use of our current cash and cash equivalents and the period of time in which such capital will be sufficient to fund our planned operations;
- our estimates regarding expenses, future revenue, capital requirements and need for additional financing;
- our ability to secure sufficient additional capital in the near term or implement other strategies needed to alleviate our current doubt about our ability to continue as a going concern; and
- general economic conditions, including inflation and recession risk.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report.

Our forward-looking statements also do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

This report also includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties as well as our own estimates. All of the market data used in this report involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for tamibarotene or any future product candidate include several key assumptions based on our industry knowledge, industry publications, third-party research, and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that the statistical and other industry and market data included in this Quarterly Report is based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the "Risk Factors" section included in this Quarterly Report. These and other factors could cause results to differ materially from those expressed in the estimates and observations made by the independent parties or by us.

You should read this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

SYROS PHARMACEUTICALS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(in thousands, except share and per share data)  
(unaudited)

	September 30, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 58,275	\$ 139,526
Prepaid expenses and other current assets	5,656	5,454
Total current assets	63,931	144,980
Property and equipment, net	6,308	7,298
Other long-term assets	1,366	1,592
Restricted cash	2,119	2,119
Right-of-use asset – operating lease	11,271	12,185
Total assets	<u>\$ 84,995</u>	<u>\$ 168,174</u>
<b>Liabilities and stockholders' (deficit) equity</b>		
Current liabilities:		
Accounts payable	\$ 9,646	\$ 11,544
Accrued expenses and other current liabilities	16,162	16,146
Operating lease obligation, current portion	2,584	2,324
Debt, current portion	—	6,667
Total current liabilities	28,392	36,681
Operating lease obligation, net of current portion	16,561	18,528
Warrant liabilities	10,084	61,747
Debt, net of debt discount, net of current portion	41,081	34,556
Commitments and contingencies (See Note 9)		
Stockholders' (deficit) equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; 0 shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value; 140,000,000 and 70,000,000 shares authorized at September 30, 2024 and December 31, 2023, respectively; 26,832,457 and 26,448,678 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	27	26
Additional paid-in capital	745,088	739,443
Accumulated deficit	(756,238)	(722,807)
Total stockholders' (deficit) equity	(11,123)	16,662
Total liabilities and stockholders' equity	<u>\$ 84,995</u>	<u>\$ 168,174</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**SYROS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	\$ —	\$ 3,762	\$ —	\$ 9,550
Operating expenses:				
Research and development	20,527	28,280	67,134	86,650
General and administrative	5,655	7,764	17,383	22,394
Restructuring (See Note 12)	—	2,354	—	2,354
Total operating expenses	26,182	38,398	84,517	111,398
Loss from operations	(26,182)	(34,636)	(84,517)	(101,848)
Interest income	793	1,633	3,424	5,533
Interest expense	(1,312)	(1,303)	(4,001)	(3,798)
Change in fair value of warrant liabilities	20,305	(5,837)	51,663	(77)
Net loss applicable to common stockholders	<u>\$ (6,396)</u>	<u>\$ (40,143)</u>	<u>\$ (33,431)</u>	<u>\$ (100,190)</u>
Net loss per share applicable to common stockholders - basic and diluted	<u>\$ (0.16)</u>	<u>\$ (1.43)</u>	<u>\$ (0.85)</u>	<u>\$ (3.59)</u>
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	<u>39,335,772</u>	<u>27,990,558</u>	<u>39,194,933</u>	<u>27,915,951</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**SYROS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
(in thousands)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	\$ (6,396)	\$ (40,143)	\$ (33,431)	\$ (100,190)
Other comprehensive loss:				
Unrealized holding loss on marketable securities, net of tax	—	(49)	—	(102)
Comprehensive loss	<u>\$ (6,396)</u>	<u>\$ (40,192)</u>	<u>\$ (33,431)</u>	<u>\$ (100,292)</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
**For the three months ended September 30, 2024 and 2023**  
(in thousands, except share data)  
(unaudited)

	Common Stock			Additional Paid-In Capital	Accumulated Other Comprehensive Gain		Accumulated Deficit	Stockholders' Equity (Deficit)
	Number of Shares	Par Value						
<b>Balance at June 30, 2023</b>	20,708,356	\$ 20	\$	691,450	\$ 49	\$	(618,280)	\$ 73,239
Vesting of restricted stock units	12,091	1		(1)	—		—	—
Stock-based compensation expense	—	—		3,255	—		—	3,255
Other comprehensive loss	—	—		—	(49)		—	(49)
Net loss	—	—		—	—		(40,143)	(40,143)
<b>Balance at September 30, 2023</b>	<u>20,720,447</u>	<u>\$ 21</u>	<u>\$</u>	<u>694,704</u>	<u>\$ —</u>	<u>\$</u>	<u>(658,423)</u>	<u>\$ 36,302</u>
<b>Balance at June 30, 2024</b>	26,809,764	\$ 26	\$	743,464	\$ —	\$	(749,842)	\$ (6,352)
Vesting of restricted stock units	22,693	1		(1)	—		—	—
Stock-based compensation expense	—	—		1,625	—		—	1,625
Net loss	—	—		—	—		(6,396)	(6,396)
<b>Balance at September 30, 2024</b>	<u>26,832,457</u>	<u>\$ 27</u>	<u>\$</u>	<u>745,088</u>	<u>\$ —</u>	<u>\$</u>	<u>(756,238)</u>	<u>\$ (11,123)</u>



**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
**For the nine months ended September 30, 2024 and 2023**  
(in thousands, except share data)  
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain		Accumulated Deficit	Stockholders' Equity (Deficit)
	Number of Shares	Par Value					
<b>Balance at December 31, 2022</b>	20,263,116	\$ 20	\$ 685,847	\$ 102	\$ (558,233)	\$ 127,736	
Vesting of restricted stock units	132,418	1	(1)	—	—	—	
Issuance of shares under Employee Stock Purchase Plan	54,082	—	144	—	—	144	
Exercise of pre-funded warrants	246,831	—	—	—	—	—	
Issuance of restricted stock awards	24,000	—	—	—	—	—	
Stock-based compensation expense	—	—	8,714	—	—	8,714	
Other comprehensive loss	—	—	—	(102)	—	(102)	
Net loss	—	—	—	—	(100,190)	(100,190)	
<b>Balance at September 30, 2023</b>	<u>20,720,447</u>	<u>\$ 21</u>	<u>\$ 694,704</u>	<u>\$ —</u>	<u>\$ (658,423)</u>	<u>\$ 36,302</u>	
<b>Balance at December 31, 2023</b>	26,448,678	\$ 26	\$ 739,443	\$ —	\$ (722,807)	\$ 16,662	
Vesting of restricted stock units	329,532	1	(1)	—	—	—	
Issuance of shares under Employee Stock Purchase Plan	26,247	—	115	—	—	115	
Issuance of restricted stock awards	28,000	—	—	—	—	—	
Stock-based compensation expense	—	—	5,531	—	—	5,531	
Net loss	—	—	—	—	(33,431)	(33,431)	
<b>Balance at September 30, 2024</b>	<u>26,832,457</u>	<u>\$ 27</u>	<u>\$ 745,088</u>	<u>\$ —</u>	<u>\$ (756,238)</u>	<u>\$ (11,123)</u>	

See accompanying notes to unaudited condensed consolidated financial statements.

**SYROS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)  
(unaudited)

	Nine Months Ended September 30,	
	2024	2023
<b>Operating activities</b>		
Net loss	\$ (33,431 )	\$ (100,190 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	990	1,900
Impairment	—	373
Gain on disposal of property and equipment	(125 )	—
Non-cash lease expense	—	73
Stock-based compensation expense	5,531	8,714
Change in fair value of warrant liabilities	(51,663 )	77
Net amortization of premiums and discounts on marketable securities	(302 )	(1,314 )
Amortization of debt-discount and accretion of deferred debt costs	420	424
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(202 )	463
Unbilled receivable	—	29
Other long-term assets	226	3,235
Accounts payable	(1,898 )	(3,556 )
Accrued expenses and other current liabilities	(207 )	3,523
Deferred revenue	—	(4,191 )
Operating lease right-of-use-asset and liabilities	(793 )	(705 )
Net cash used in operating activities	(81,454 )	(91,145 )
<b>Investing activities</b>		
Purchases of property and equipment	—	(234 )
Proceeds from the disposition of asset-held-for-sale	125	—
Purchases of marketable securities	(30,591 )	(50,968 )
Proceeds from the sale or maturities of marketable securities	30,893	87,017
Net cash provided by investing activities	427	35,815
<b>Financing activities</b>		
Payments on financing lease obligations	—	(62 )
Proceeds from the issuance of common stock through Employee Stock Purchase Plan	115	144
Payment of issuance cost related to underwritten registered direct offering and at-the-market facility	(339 )	—
Net cash (used in) provided by financing activities	(224 )	82
Net decrease in cash, cash equivalents and restricted cash	(81,251 )	(55,248 )
<b>Cash, cash equivalents and restricted cash</b> (See reconciliation in Note 6)		
Beginning of period	141,645	170,553
End of period	60,394	115,305
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 4,052	\$ 3,323

See accompanying notes to unaudited condensed consolidated financial statements.

**SYROS PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**1. Nature of Business**

Syros Pharmaceuticals, Inc. (the “Company”), a Delaware corporation formed in November 2011, is a biopharmaceutical company committed to developing new standards of care for the frontline treatment of patients with hematologic malignancies.

On April 6, 2023, the Company filed a universal shelf registration statement on Form S-3 (the “2023 Registration Statement”), with the Securities and Exchange Commission (the “SEC”) to register for sale from time to time up to \$250.0 million of common stock, preferred stock, debt securities, warrants and/or units in one or more registered offerings. The 2023 Registration Statement was declared effective on April 28, 2023. Further, in April 2023, the Company entered into an at-the-market sales agreement (the “2023 Sales Agreement”) with Cowen and Company, LLC (“Cowen”) pursuant to which the Company may offer and sell shares of its common stock having an aggregate offering price of up to \$50.0 million through Cowen pursuant to the 2023 Registration Statement.

On October 2, 2023, the Company announced a strategic realignment to prioritize key development and pre-launch activities to advance tamibarotene for the treatment of newly diagnosed higher-risk myelodysplastic syndrome and newly diagnosed acute myeloid leukemia, and to stop further investment in the clinical development of SY-2101 (oral arsenic trioxide) for the treatment of newly diagnosed acute promyelocytic leukemia, as well as in the Company’s preclinical and discovery-stage programs. In connection with these decisions, the Company instituted certain expense reduction measures (the “Restructuring”), including a reduction of approximately 35% of the Company’s employee base excluding members of the Company’s drug discovery organization whose employment ended concurrently with the termination, effective October 16, 2023, of its collaboration with Pfizer, Inc. (“Pfizer”) related to the discovery, development and commercialization of novel therapies for sickle cell disease and beta thalassemia. The Restructuring was completed by February 2024.

The Company is subject to a number of risks similar to those of other late-stage clinical companies, including dependence on key individuals; risks inherent in the development and commercialization of medicines to treat human disease; competition from other companies, many of which are larger and better capitalized; risks relating to obtaining and maintaining necessary intellectual property protection; and the need to obtain adequate additional financing to fund the development of its product candidates. If the Company is unable to raise capital when needed or on favorable terms, it would be forced to delay, reduce, eliminate or out-license certain of its research and development programs or future commercialization rights to its product candidates.

The Company has incurred significant net operating losses in every year since its inception. It expects to continue to incur significant and increasing net operating losses for at least the next several years. As of September 30, 2024, the Company had an accumulated deficit of \$756.2 million. The Company has not generated any revenues from product sales, has not completed the development of any product candidate and may never have a product candidate approved for commercialization. The Company has financed its operations to date primarily through a credit facility, the issuance of equity securities and through license and collaboration agreements. The Company has devoted substantially all of its financial resources and efforts to research and development and general and administrative activities to support such research and development. The Company’s net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on the Company’s stockholders’ equity and working capital.

Under ASC Topic 205-40, *Presentation of Financial Statements - Going Concern*, management is required at each reporting period to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity’s ability to continue as a going concern within one year after the date that the financial statements are issued. When substantial doubt exists, management evaluates whether the mitigating effect of its plans sufficiently alleviates the substantial doubt about the Company’s ability to continue as a going concern.

Successful completion of the Company’s development programs and, ultimately, the attainment of profitable operations are dependent upon future events, including obtaining adequate financing to support the Company’s cost structure and operating plan. Management’s plans to alleviate its financing requirements include, among other things, pursuing one or more of the following steps, none of which can be guaranteed or is entirely within the Company’s control:

- raise funding through the issuance of the Company’s common or preferred stock;
- raise funding through debt financing; and

- raise funding through business development activities, including the potential sale of SY-2101-related assets.

If the Company is unable to raise capital when needed or on acceptable terms, or if it is unable to procure collaboration arrangements to advance its programs, the Company would be forced to discontinue some of its operations or develop and implement a plan to further extend payables, reduce overhead or scale back its current operating plan until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan would be successful.

The Company's history of significant losses, its negative cash flows from operations, its limited liquidity resources currently on hand, and its dependence on its ability to obtain additional financing to fund its operations after the current resources are exhausted, about which there can be no certainty, have resulted in management's assessment that there is substantial doubt about the Company's ability to continue as a going concern for a period of at least 12 months from the issuance date of this Quarterly Report on Form 10-Q. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments that may result from the outcome of this uncertainty.

## **2. Summary of Significant Accounting Policies**

### **Basis of Presentation**

The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments that are necessary to present fairly the Company's financial position as of September 30, 2024, the results of its operations for the three and nine months ended September 30, 2024 and 2023, statements of stockholders' equity (deficit) for the three and nine months ended September 30, 2024 and 2023, and statements of cash flows for the nine months ended September 30, 2024 and 2023. Such adjustments are of a normal and recurring nature. The results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results for the year ending December 31, 2024 or for any future period.

### **Principles of Consolidation**

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, (i) Syros Securities Corporation, a Massachusetts corporation formed by the Company in December 2014 to exclusively engage in buying, selling and holding securities on its own behalf, (ii) Syros Pharmaceuticals (Ireland) Limited, an Irish limited liability company formed by the Company in January 2019, and (iii) Tyme Technologies, Inc., a Delaware corporation. All intercompany transactions and balances have been eliminated in consolidation.

### **Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Management considers many factors in selecting appropriate financial accounting policies and in developing these estimates, which include, but are not limited to, expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates and whether historical trends are expected to be representative of future trends. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, estimates related to revenue recognition, valuation of warrant liabilities, stock-based compensation expense, accrued expenses, income taxes and the evaluation of the existence of conditions and events that raise substantial doubt regarding the Company's ability to continue as a going concern. Actual results may differ from those estimates or assumptions.

## Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is its chief executive officer. The Company and the chief operating decision maker view the Company's operations and manage its business in one operating segment. The Company operates only in the United States.

## Cash and Cash Equivalents

The Company considers all highly liquid instruments that have original maturities of three months or less when acquired to be cash equivalents. Cash equivalents, which consist of money market funds that invest in U.S. Treasury obligations, as well as overnight repurchase agreements, are stated at fair value. The Company maintains its bank accounts in two major financial institutions.

## Off-Balance Sheet Risk and Concentrations of Credit Risk

The Company has no financial instruments with off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash equivalents and marketable securities. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. The Company is not exposed to any significant concentrations of credit risk from these financial instruments. The goals of the Company's investment policy, in order of priority, are safety and preservation of principal and liquidity of investments sufficient to meet cash flow requirements.

## Fair Value of Financial Instruments

ASC 820, *Fair Value Measurement* ("ASC 820"), established a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumption about the inputs that market participants would use in pricing the asset or liability. These are developed based on the best information available under the circumstances.

ASC 820 identified fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 established a three-tier fair value hierarchy that distinguishes between the following:

Level 1—Quoted market prices (unadjusted) in active markets for identical assets or liabilities.

Level 2—Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

Level 3—Unobservable inputs developed using estimates or assumptions developed by the Company, which reflect those that a market participant would use.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts reflected in the condensed consolidated balance sheets for cash and cash equivalents, prepaid expenses, other current assets, restricted cash, accounts payable and accrued expenses approximate their respective fair values due to their short-term nature.

## Property and Equipment

Property and equipment consists of computer equipment, furniture and fixtures and leasehold improvements, all of which are stated at cost, less accumulated depreciation. Expenditures for maintenance and repairs that do not improve or extend the lives of the respective assets are recorded to expense as incurred. Major betterments are capitalized as

additions to property and equipment. Depreciation and amortization are recognized over the estimated useful lives of the assets using the straight-line method.

#### **Impairment of Long-Lived Assets**

The Company evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the carrying values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying values of the assets exceed their fair value.

The Company did not record any impairment losses during the three and nine months ended September 30, 2024. In connection with the Restructuring, the Company entered into an exclusive auction agreement in October 2023 to sell all of its laboratory equipment by public auction. The Company concluded that the assets met the held for sale criteria and has written the assets down to their fair value less cost to sell of \$1.7 million which resulted in an impairment charge of \$0.4 million during the three and nine months ended September 30, 2023. These assets held for sale are recorded in prepaid and other current assets in the Company's condensed consolidated balance sheet as of September 30, 2023.

#### **Revenue Recognition**

The Company has not generated any revenue from product sales and does not expect to generate any revenue from product sales for the foreseeable future.

The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps:

- (i) identify the contract(s) with a customer;
- (ii) identify the performance obligations in the contract;
- (iii) determine the transaction price;
- (iv) allocate the transaction price to the performance obligations in the contract; and
- (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. If a contract is determined to be within the scope of ASC 606 at inception, the Company assesses the goods or services promised within such contract, determines which of those goods and services are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

If the Company performs by transferring goods or services to a customer before the customer pays consideration or before payment is due, the Company records a contract asset, excluding any amounts presented as accounts receivable. The Company includes contract assets as unbilled accounts receivable on its consolidated balance sheets. The Company records accounts receivable for amounts billed to the customer for which the Company has an unconditional right to consideration. The Company assesses contract assets and accounts receivable for impairment and, to date, no impairment losses have been recorded.

From time to time, the Company may enter into agreements that are within the scope of ASC 606. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees or prepaid research and development services; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products. Each of these payments results in license and collaboration revenues, except for revenues from royalties on net sales of licensed products, which will be classified as royalty revenues.

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* (“ASC 808”), to determine whether such arrangements 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. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above.

#### **Research and Development**

Expenditures relating to research and development are expensed in the period incurred. Research and development expenses consist of both internal and external costs associated with the development of the Company’s product candidates. Research and development costs include salaries and benefits, materials and supplies, external research, preclinical and clinical development expenses, stock-based compensation expense and facilities costs. Facilities costs primarily include the allocation of rent, utilities, depreciation and amortization.

In certain circumstances, the Company is required to make nonrefundable advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the nonrefundable advance payments are deferred and capitalized, even when there is no alternative future use for the research and development, until related goods or services are provided.

The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the work being performed, including the phase or completion of the event, invoices received and costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company’s estimates.

The Company may in-license the rights to develop and commercialize product candidates. For each in-license transaction, the Company evaluates whether it has acquired processes or activities along with inputs that would be sufficient to constitute a “business” as defined under U.S. GAAP. A “business” as defined under U.S. GAAP consists of inputs and processes applied to those inputs that have the ability to create outputs. Although businesses usually have outputs, outputs are not required for an integrated set of activities to qualify as a business. When the Company determines that it has not acquired sufficient processes or activities to constitute a business, any up-front payments, as well as milestone payments, are immediately expensed as acquired research and development in the period in which they are incurred.

#### **Warrants**

The Company accounts for issued warrants either as a liability or equity in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (“ASC 480-10”) or ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock* (“ASC 815-40”). Under ASC 480-10, warrants are considered liabilities if they are mandatorily redeemable and they require settlement in cash, other assets, or a variable number of shares. If warrants do not meet liability classification under ASC 480-10, the Company considers the requirements of ASC 815-40 to determine whether the warrants should be classified as liability or equity. Under ASC 815-40, contracts that may require settlement for cash are liabilities, regardless of the probability of the occurrence of the triggering event. Liability-classified warrants are measured at fair value on the issuance date and at the end of each reporting period. Any change in the fair value of the warrants after the issuance date is recorded in the consolidated statements of operations as a gain or loss. If warrants do not require liability classification under ASC 815-40, in order to conclude warrants should be classified as equity, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP standard. Equity-classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

#### **Stock-Based Compensation Expense**

The Company accounts for its stock-based compensation awards in accordance with ASC 718, *Compensation—Stock Compensation* (“ASC 718”). ASC 718 requires all stock-based payments to employees and directors, including grants of restricted stock units and stock option awards, to be recognized as expense in the consolidated statements of operations based on their grant date fair values. The Company estimates the fair value of stock options granted using the

Black-Scholes option-pricing model. The Company estimates its expected stock volatility based on its historical volatility. The expected term of the Company's stock options granted to employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The Company uses the contractual term in determining the expected term of the stock options granted to non-employees. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The Company uses the value of its common stock at the grant date to determine the fair value of restricted stock awards.

The Company expenses the fair value of its stock-based awards to employees and non-employees on a straight-line basis over the associated service period, which is generally the vesting period. The Company accounts for forfeitures as they occur instead of estimating forfeitures at the time of grant. Ultimately, the actual expense recognized over the vesting period will be for only those options that vest.

Compensation expense for discounted purchases under the employee stock purchase plan is measured using the Black-Scholes model to compute the fair value of the lookback provision plus the purchase discount and is recognized as compensation expense over the offering period.

For stock-based awards that contain performance-based milestones, the Company records stock-based compensation expense in accordance with the accelerated attribution model. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions as of the reporting date.

#### Income Taxes

The Company accounts for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in the law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity, and changes in facts or circumstances related to a tax position.

#### Net Loss per Share

Basic net earnings per share applicable to common stockholders is calculated by dividing net earnings applicable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net earnings per share applicable to common stockholders is calculated by adjusting the weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method and the if-converted method. For purposes of the calculation of dilutive net loss per share applicable to common stockholders, stock options, unvested restricted stock units, and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share applicable to common stockholders, as their effect would be anti-dilutive; therefore, basic and diluted net loss per share applicable to common stockholders were the same for all periods presented.

The following outstanding pre-funded warrants as of September 30, 2024 and 2023 were included in the basic and diluted net loss per share calculation (refer to Note 10):

	As of September 30,	
	2024	2023
2020 Pre-Funded Warrants, issued in the 2020 Private Placement	100,000	100,000
2022 Pre-Funded Warrants, issued in the 2022 Private Placement	7,179,819	7,179,819
2023 Pre-Funded Warrants, issued in December 2023 registered direct offering	5,242,588	—
<b>Total</b>	<b>12,522,407</b>	<b>7,279,819</b>



The following common stock equivalents were excluded from the calculation of diluted net loss per share applicable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of September 30,	
	2024	2023
Stock options	940,211	1,746,177
Unvested restricted stock units	3,029,226	2,417,891
Warrants*	14,142,298	14,142,298
<b>Total</b>	<b>18,111,735</b>	<b>18,306,366</b>

\* As of September 30, 2024 and 2023, this is comprised of 2,754 warrants to purchase common stock issued in connection with the execution and first draw of the Company's loan agreement in February 2020 (refer to Note 7), 1,738 warrants to purchase common stock issued in connection with the second draw on this loan agreement in December 2020 (refer to Note 7), 282,809 warrants to purchase common stock issued in connection with the private placement in December 2020 (refer to Note 10), 13,813,912 warrants to purchase common stock issued in connection with the private placement in September 2022 (refer to Note 10), and 41,085 warrants to purchase common stock that were issued upon the assumption and conversion of warrants in connection with the acquisition of Tyme Technologies, Inc.

### 3. Collaboration and Research Arrangements

During the three and nine months ended September 30, 2023, the Company recognized revenue of \$3.8 million and \$9.6 million, respectively, under a license and collaboration agreement with Global Therapeutics, Inc, now a subsidiary of Pfizer. As the agreement was terminated in October 2023, no revenue was recognized during the three and nine month periods ended September 30, 2024.

### 4. Cash and Cash Equivalents

Cash equivalents are highly liquid investments that are readily convertible into cash with original maturities of three months or less when purchased. Unrealized gains or losses are included in accumulated other comprehensive loss. Premiums or discounts from par value are amortized to interest income over the life of the underlying security.

Cash and cash equivalents consisted of the following as of September 30, 2024 and December 31, 2023 (in thousands):

September 30, 2024	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash and money market funds	\$ 58,275	\$ —	\$ —	\$ 58,275
<b>Total:</b>	<b>\$ 58,275</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 58,275</b>

December 31, 2023	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash and money market funds	\$ 139,526	\$ —	\$ —	\$ 139,526
<b>Total</b>	<b>\$ 139,526</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 139,526</b>

## 5. Fair Value Measurements

Assets and liabilities measured at fair value on a recurring basis as of September 30, 2024 and December 31, 2023 were as follows (in thousands):

Description	September 30, 2024	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents:				
Cash and money market funds	\$ 58,275	\$ 58,275	\$ —	\$ —
Total	\$ 58,275	\$ 58,275	\$ —	\$ —
Liabilities:				
Warrant liabilities	\$ 10,084	\$ —	\$ —	\$ 10,084
Total	\$ 10,084	\$ —	\$ —	\$ 10,084

Description	December 31, 2023	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents:				
Cash and money market funds	\$ 139,526	\$ 139,526	\$ —	\$ —
Total	\$ 139,526	\$ 139,526	\$ —	\$ —
Liabilities:				
Warrant liabilities	\$ 61,747	\$ —	\$ —	\$ 61,747
Total	\$ 61,747	\$ —	\$ —	\$ 61,747

### Assumptions Used in Determining Fair Value of Warrants

The Company issued warrants to purchase an aggregate of up to 13,813,912 shares of common stock in connection with a private placement in September 2022 (the "2022 Warrants") and warrants to purchase an aggregate of up to 282,809 shares of common stock in connection with a private placement in December 2020 (the "2020 Warrants"). The Company accounted for the 2022 Warrants and 2020 Warrants as liabilities. The Company recorded the fair value of these warrants upon issuance using the Black-Scholes valuation model and is required to revalue these warrants at each reporting date with any changes in fair value recorded on the Company's statement of operations. The valuation of the 2022 Warrants and 2020 Warrants is considered under Level 3 of the fair value hierarchy and influenced by the fair value of the underlying common stock of the Company.

A summary of the Black Scholes pricing model assumptions used to record the fair value of the warrants is as follows:

	September 30, 2024	December 31, 2023
Stock price	\$ 2.15	\$ 7.79
Average risk-free interest rate	3.59 %	3.96 %
Dividend yield	0.00 %	0.00 %
Average expected life (in years)	2.92	3.67
Average expected volatility	103.93 %	87.63 %

### Changes in Level 3 Liabilities Measured at Fair Value on a Recurring Basis

The following table reflects the change in the Company's Level 3 warrant liabilities for the nine months ended September 30, 2024 and the year ended December 31, 2023 (in thousands):

	September 30, 2024	December 31, 2023
Fair value of warrant liabilities as of beginning of period	\$ 61,747	\$ 24,472
Change in fair value	(51,663 )	37,275
Fair value of warrant liabilities as of end of period	\$ 10,084	\$ 61,747

## 6. Restricted Cash

As of each of September 30, 2024 and December 31, 2023, the Company had \$2.1 million in restricted cash, which was classified as long-term on the Company's condensed consolidated balance sheets, and all of which was attributable to the lease with respect to the Company's corporate headquarters (the "HQ Lease").

In connection with the execution of the HQ Lease, the Company was required to provide the landlord with a letter of credit in the amount of \$3.1 million that will expire 95 days after expiration or early termination of the HQ Lease. Pursuant to the HQ Lease, the Company exercised its right to reduce the amount of the letter of credit to \$2.1 million during the year ended December 31, 2023.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the amounts shown in the Company's condensed consolidated statement of cash flows as of September 30, 2024 and 2023 (in thousands):

	September 30, 2024	September 30, 2023
Cash and cash equivalents	\$ 58,275	\$ 112,219
Restricted cash	\$ 2,119	3,086
Total cash, cash equivalents and restricted cash	<u>\$ 60,394</u>	<u>\$ 115,305</u>

## 7. Oxford Finance Loan Agreement

On February 12, 2020, the Company entered into a Loan and Security Agreement (as subsequently amended, the "Loan Agreement") with Oxford Finance LLC (the "Lender"). Pursuant to the terms of an amendment dated May 9, 2024 (the "Fourth Loan Amendment"), the Loan Agreement was modified to increase the aggregate amount of term loans available to the Company from \$60.0 million to \$100.0 million. A \$20.0 million term loan was funded on February 12, 2020 (Term A) and another \$20.0 million term loan was funded on December 23, 2020 (Term B). Two additional \$20.0 million term loans (Term C and Term D) will become available upon achievement of certain clinical development, regulatory and equity-raising milestones, and another \$20.0 million term loan (Term E) remains available solely at the discretion of the Lender.

The floating annual rate for each term loan is equal to the greater of (i) 7.75% and (ii) the sum of (a) the 1-month CME Term SOFR reference rate, (b) 0.10%, and (c) 5.98%. Pursuant to the terms of the Fourth Loan Amendment, the Lender agreed to extend the interest-only period from September 1, 2024 to November 1, 2025, with further extensions to as late as November 1, 2026 upon the achievement of certain milestones and the payment of certain fees, and to provide for the repayment of the aggregate outstanding principal balance of the term loan in monthly installments starting on November 1, 2025 through February 1, 2028 (the "Maturity Date"), subject to the potential further extension of the interest-only period.

The Company paid a facility fee of \$0.1 million upon the issuance of the Term A loan, paid a facility fee of \$75,000 upon the issuance of the Term B loan, and must pay a \$50,000 facility fee if and when each of the Term C loan, the Term D loan, and the Term E loan is issued. In connection with prior extensions of the interest-only period, the Company paid fees of \$300,000 in September 2022 and agreed to pay fees of \$300,000 upon the first to occur of the Maturity Date or the acceleration or prepayment of any term loan. In connection with the Fourth Loan Amendment, the Company agreed to pay an additional fee of \$1,050,000 upon the first to occur of the Maturity Date or the acceleration or prepayment of any term loan. The Company is required to make a final payment equal to 5.00% of the amount of the term loan drawn payable on the earlier of (i) the prepayment of the term loan or (ii) the Maturity Date. At the Company's option, the Company may elect to prepay the loans subject to a prepayment fee equal to the following percentage of the principal amount being prepaid: 2% if an advance is prepaid during the first 12 months following the applicable advance date, 1% if an advance is prepaid after 12 months but prior to 24 months following the applicable advance date, and 0.5% if an advance is prepaid any time after 24 months following the applicable advance date but prior to the Maturity Date.

In connection with the Loan Agreement, the Company granted the Lender a security interest in all of the Company's personal property now owned or hereafter acquired, excluding intellectual property (but including the right to payments and proceeds of intellectual property), and a negative pledge on intellectual property. The Loan Agreement also contains certain events of default, representations, warranties and covenants of the Company. In consideration of the Fourth Loan Amendment, the Company has agreed to, among other things, certain cash covenants, which requires an unrestricted cash balance in an aggregate amount of not less than (i) for May 31, 2024 and at all times thereafter through

and including January 31, 2025, seventy-five percent (75.00%) of the aggregate principal amount of the outstanding obligations, and (ii) for February 1, 2025 and at all times thereafter through and including May 31, 2026, one hundred twenty percent (120.00%) of the aggregate principal amount of the outstanding obligations, and revenue performance covenants, and that the failure to satisfy the primary endpoint for the SELECT-MDS-1 trial, the termination of the Company's SELECT-MDS-1 trial for safety reasons, or the failure to obtain United States Food and Drug Administration ("FDA") approval for tamibarotene for the treatment of newly diagnosed HR-MDS patients with *RARA* overexpression by May 31, 2026, would each constitute events of default under the Loan Agreement. In addition, upon drawing any further loans under the Loan Agreement the Company has agreed to grant the Lender, to the extent permitted under existing agreements and applicable law, a security interest in all intellectual property owned by the Company. As of September 30, 2024, the Company was in compliance with all covenants under the Loan Agreement.

In connection with the issuance of the Term A loan, the Company issued the Lender warrants to purchase 2,754 shares of the Company's common stock at an exercise price per share of \$72.60 in February 2020. In connection with the issuance of the Term B loan, the Company issued the Lender warrants to purchase 1,738 shares of the Company's common stock at an exercise price of \$115.00 per share in December 2020 (collectively, the "Oxford Warrants"). The Oxford Warrants are exercisable within five years from the respective dates of issuance.

The Oxford Warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the Oxford Warrants do not provide any guarantee of value or return.

The Company has the following minimum aggregate future loan payments as of September 30, 2024 (in thousands):

Three months ending December 31, 2024	—
Year ending December 31, 2025	2,857
Year ending December 31, 2026	17,143
Year ending December 31, 2027	17,143
Year ending December 31, 2028	2,857
Total minimum payments	40,000
Less unamortized debt discount	(800 )
Plus accumulated accretion of final fees	1,881
Long-term debt	<u>\$ 41,081</u>

For the three and nine months ended September 30, 2024, interest expense related to the Loan Agreement was approximately \$1.3 million and \$4.0 million, respectively. For the three and nine months ended September 30, 2023, interest expense related to the Loan Agreement was approximately \$1.3 million and \$3.7 million, respectively.

#### 8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024	December 31, 2023
External research and preclinical development	\$ 9,984	\$ 8,001
Employee compensation and benefits	4,788	6,993
Professional fees	707	1,015
Facilities and other	683	137
Accrued expenses and other current liabilities	<u>\$ 16,162</u>	<u>\$ 16,146</u>

## 9. Commitments and Contingencies

There have been no significant changes to the Company's commitments and contingencies as discussed in its Annual Report on Form 10-K for the year ended December 31, 2023.

The Company has a supply management agreement with TMRC Co. Ltd. under which the Company agreed to pay TMRC a fee for each kilogram of tamibarotene that is produced. The Company incurred fees of \$1.3 million under this supply management agreement during both the three and nine months ended September 30, 2024. The Company incurred fees of \$1.8 million under this supply management agreement during both the three and nine months ended September 30, 2023.

## 10. Stockholders' Equity (Deficit)

### Increase of Authorized Shares

On June 5, 2024, the Company's stockholders approved an amendment to the Company's Restated Certificate of Incorporation to (i) increase the number of authorized shares of the Company's capital stock from 80,000,000 shares to 150,000,000 shares, and (ii) increase the number of authorized shares of the Company's common stock from 70,000,000 shares to 140,000,000 shares. The Company filed a Certificate of Amendment of Restated Certificate of Incorporation with the Secretary of State of the State of Delaware on the same day to effect the increase in the Company's authorized shares.

### Issuance of Securities through an Underwritten Registered Direct Offering

In December 2023, the Company issued 4.9 million shares of common stock and, in lieu of its common stock to certain investors who so chose, pre-funded warrants (the "2023 Pre-Funded Warrants") to purchase an aggregate of 5,242,588 shares of common stock, pursuant to the 2023 Registration Statement, in an underwritten registered direct offering for gross proceeds of \$45.0 million, before deducting underwriting fees and other transaction costs of \$3.4 million.

The Company determined that the 2023 Pre-Funded Warrants are freestanding financial instruments because they are both legally detachable and separately exercisable from the common stock sold in the offering. As such, the Company evaluated the 2023 Pre-Funded Warrants to determine whether they represent instruments that require liability classification pursuant to the guidance in ASC 480. However, the Company concluded that the 2023 Pre-Funded Warrants are not a liability within the scope of ASC 480 due to their characteristics. Further, the Company determined that the 2023 Pre-Funded Warrants do not meet the definition of a derivative under ASC 815 because they do not meet the criteria regarding no or little initial net investment. Accordingly, the Company assessed the 2023 Pre-Funded Warrants relative to the guidance in ASC No. 815-40, Contracts in Entity's Own Equity, to determine the appropriate treatment. The Company concluded that the 2023 Pre-Funded Warrants are both indexed to its own stock and meet all other conditions for equity classification. Accordingly, the Company has classified the 2023 Pre-Funded Warrants as permanent equity.

### Issuance of Securities through a Private Placement

On September 16, 2022, the Company issued in a private placement (the "2022 Private Placement") 6,387,173 shares of common stock, and, in lieu of shares of common stock, the pre-funded warrants to purchase an aggregate of 7,426,739 shares of common stock (the "2022 Pre-Funded Warrants"), and, in each case, the accompanying 2022 Warrants to purchase an aggregate of up to 13,813,912 additional shares of common stock (or 2022 Pre-Funded Warrants to purchase common stock in lieu thereof) at a price of \$10.34 per share and accompanying 2022 Warrant (or \$10.33 per 2022 Pre-Funded Warrant and accompanying 2022 Warrant). The 2022 Private Placement resulted in aggregate gross proceeds of \$129.9 million, before \$10.1 million of transaction costs.

On December 8, 2020, through a private placement (the "2020 Private Placement"), the Company issued 1,031,250 shares of common stock, and, in lieu of shares of common stock, pre-funded warrants to purchase an aggregate of 100,000 shares of common stock (the "2020 Pre-Funded Warrants"), and, in each case, accompanying 2020 Warrants to purchase an aggregate of up to 282,809 additional shares of common stock (or 2020 Pre-Funded Warrants to purchase common stock in lieu thereof) at a price of \$80.00 per share and accompanying 2020 Warrant (or \$79.90 per

2020 Pre-Funded Warrant and accompanying 2020 Warrant). The 2020 Private Placement resulted in aggregate gross proceeds of \$90.5 million, before \$0.4 million of transaction costs.

In the event of certain fundamental transactions involving the Company, the holders of the 2022 Warrants and 2020 Warrants may require the Company to make a payment based on a Black-Scholes valuation, using specified inputs. The holders of 2022 Pre-Funded Warrants and 2020 Pre-Funded Warrants do not have similar rights. Therefore, the Company accounted for the 2022 Warrants and 2020 Warrants as liabilities, while the 2022 Pre-Funded Warrants and 2020 Pre-Funded Warrants met the permanent equity criteria classification. The 2022 Pre-Funded Warrants and 2020 Pre-Funded Warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the 2022 Pre-Funded Warrants and 2020 Pre-Funded Warrants do not provide any guarantee of value or return. The initial fair value of the 2022 Warrants and the 2020 Warrants at issuance was \$64.7 million and \$19.3 million, respectively, determined using the Black-Scholes valuation model. For the three and nine months ended September 30, 2024, the Company recorded a gain for the remeasurement of the aggregate fair value of the 2022 Warrants and the 2020 Warrants in its condensed statement of operations of \$20.3 million and \$51.7 million, respectively. For the three and nine months ended September 30, 2023, the Company recorded a loss for the remeasurement of the aggregate fair value of the 2022 Warrants and the 2020 Warrants in its condensed statement of operations of \$5.8 million and \$0.1 million, respectively. As of September 30, 2024 and December 31, 2023, the aggregate fair value of the 2022 Warrants and the 2020 Warrants included in the Company's condensed balance sheet was \$10.1 million and \$61.7 million, respectively.

## **11. Stock-Based Payments**

### ***2016 Employee Stock Purchase Plan***

The 2016 Employee Stock Purchase Plan (the "2016 ESPP") was adopted by the board of directors on December 15, 2015, approved by the stockholders on June 17, 2016, and became effective on July 6, 2016 upon the closing of the IPO. The number of shares of the Company's common stock reserved for issuance under the 2016 ESPP automatically increases on the first day of each calendar year through the 2025 calendar year, in an amount equal to the least of (i) 117,333 shares of the Company's common stock, (ii) 1.0% of the total number of shares of the Company's common stock outstanding on the first day of the applicable year, and (iii) an amount determined by the Company's board of directors. For the calendar year beginning January 1, 2024, the number of shares reserved for issuance under the 2016 ESPP was increased by 117,333 shares. As of September 30, 2024, 349,590 shares remained available for future issuance under the 2016 ESPP.

### ***2022 Inducement Stock Incentive Plan***

On January 25, 2022, the Company's board of directors adopted the 2022 Inducement Stock Incentive Plan (the "2022 Plan"), pursuant to which the Company may grant non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards. Awards under the 2022 Plan may only be granted to persons who (i) were not previously an employee or director of the Company or (ii) are commencing employment with the Company following a bona fide period of non-employment, in either case as an inducement material to the individual's entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). In January 2023, the Company's board of directors amended the 2022 Plan to increase the aggregate number of shares that can be granted by 750,000 shares of common stock. As of September 30, 2024, 702,555 shares remained available for future issuance under the 2022 Plan.

### ***2022 Equity Incentive Plan***

The 2022 Equity Incentive Plan (the "2022 EIP") was adopted by the board of directors on July 14, 2022, approved by the stockholders and became effective on September 15, 2022. The 2022 EIP replaced the 2016 Stock Incentive Plan (the "2016 Plan"). Any options or awards outstanding under the 2016 Plan remained outstanding and effective. Under the 2022 EIP, the Company may grant incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards. Under the 2022 EIP, stock options may not be granted at less than fair value on the date of grant. On June 5, 2024, the Company's stockholders approved an amendment to the 2022 EIP to increase the number of shares of the Company's common stock available for

issuance thereunder by 1,750,000 shares. As of September 30, 2024, 1,910,549 shares remained available for future issuance under the 2022 EIP.

### Stock Options

Terms of stock option agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the applicable plan. Stock option awards granted by the Company generally vest over four years, with 25% vesting on the first anniversary of the vesting commencement date and 75% vesting ratably, on a monthly basis, over the remaining three years. Such awards have a contractual term of ten years from the grant date.

A summary of the status of stock options as of December 31, 2023 and September 30, 2024 and changes during the nine months ended September 30, 2024 is presented below:

	Shares	Weighted Average Exercise Price	Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	1,548,642	\$ 34.80	4.5	\$ 646
Granted	54,000	5.30		
Cancelled	(662,431 )	31.45		
Outstanding at September 30, 2024	<u>940,211</u>	32.00	7.0	\$ —
Exercisable at September 30, 2024	<u>632,615</u>	40.21	6.5	\$ —

There were no stock options exercised during the nine months ended September 30, 2024.

As of September 30, 2024, there was \$1.8 million of total unrecognized compensation cost related to unvested stock options granted to employees, which is expected to be recognized over a weighted-average period of less than one year.

### Restricted Stock Units and Restricted Stock Awards

From time to time, upon approval by the Company's board of directors, certain employees have been granted restricted stock units with time-based vesting criteria. The majority of these restricted stock units vest annually over a three-year or four-year term. In addition, pursuant to the Company's director compensation policy, members of the Company's board of directors have been granted, at their election, either restricted stock units or restricted stock awards, which awards vest annually over a three-year term with 33.33% vesting on each anniversary of the grant date. The fair value of restricted stock units and restricted stock awards are calculated based on the closing sale price of the Company's common stock on the date of grant.

The Company has granted performance-based restricted stock units for which vesting occurs upon the achievement of certain clinical development milestones. Stock-based compensation expense associated with these performance-based restricted stock units is recognized when the achievement of the vesting conditions becomes probable. The Company did not recognize any stock-based compensation expense relating to the achievement of performance-based milestones during the three and nine months ended September 30, 2024 and 2023.

A summary of the status of restricted stock units and restricted stock awards as of December 31, 2023 and September 30, 2024 and changes during the nine months ended September 30, 2024 is presented below:

	Shares Subject to Restricted Stock Units and Restricted Stock Awards	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2023	1,778,614	\$ 6.29
Granted	1,726,278	6.43
Vested	(385,530 )	8.32
Forfeited	(46,134 )	7.36
Outstanding at September 30, 2024	<u>3,073,228</u>	<u>\$ 6.13</u>

As of September 30, 2024, there was \$15.5 million of unrecognized stock-based compensation expense related to outstanding restricted stock units and restricted stock awards, with an expected recognition period of approximately one year.

***Stock-based Compensation Expense***

The following table summarizes the stock-based compensation expense for stock options, restricted stock units and restricted common stock granted to employees and non-employees and from the 2016 ESPP recorded in the Company's condensed consolidated statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 518	\$ 1,586	\$ 2,227	\$ 4,236
General and administrative	1,107	1,501	3,304	4,310
Restructuring	—	168	—	168
Total stock-based compensation expense	<u>\$ 1,625</u>	<u>\$ 3,255</u>	<u>\$ 5,531</u>	<u>\$ 8,714</u>

**12. Restructuring**

As a result of the Restructuring, the Company incurred \$2.4 million in costs for the three and nine months ended September 30, 2023. Restructuring costs were comprised of \$2.0 million of severance, post employment benefits, stock-based compensation and outplacement services, and \$0.4 million of asset impairment charges related to the laboratory equipment that was classified as assets held for sale.



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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2023 that we filed with the Securities and Exchange Commission, or SEC, on March 27, 2024, or the 2023 10-K. Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.*

*The following information and any forward-looking statements should also be considered in light of risks identified under the caption "Risk Factors" in the 2023 10-K and in this Quarterly Report. We caution you not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.*

### Overview

We are a biopharmaceutical company committed to developing new standards of care for the frontline treatment of patients with hematologic malignancies. Driven by the motivation to help patients with blood disorders that have largely eluded other targeted approaches, we are advancing tamibarotene, a selective retinoic acid receptor alpha, or RAR $\alpha$ , agonist for which we are conducting SELECT-MDS-1, a Phase 3 clinical trial evaluating tamibarotene in combination with azacitidine in a genomically defined subset of patients with higher-risk myelodysplastic syndrome, or HR-MDS.

At the 62nd American Society of Hematology Annual Meeting and Exposition held in December 2020, or ASH 2020, we presented data from our fully enrolled Phase 2 clinical trial assessing the safety and efficacy of tamibarotene in combination with azacitidine in newly diagnosed patients with acute myeloid leukemia, or AML, who are not suitable candidates for standard intensive chemotherapy, as well as in relapsed or refractory AML patients who have been prospectively selected using our proprietary *RARA*, the gene that codes for RAR $\alpha$ , biomarker. As of an October 1, 2020 data cut-off, 51 newly diagnosed unfit AML patients, including patients with and without *RARA* gene overexpression, were eligible for a safety analysis. Among these patients, tamibarotene in combination with azacitidine was generally well-tolerated, with no evidence of increased toxicity relative to either as a single agent, including rates of myelosuppression that were comparable to single agent azacitidine. As of the data cut-off, of the 18 patients with *RARA* overexpression that were evaluable for clinical response, 50% of patients achieved complete response, or CR, and 11% achieved a complete response with incomplete blood count recovery, or CRi, for a total CR/CRi rate of 61%. The median time to initial CR/CRi response was 1.2 months, the median duration of CR/CRi response was 10.8 months, and the median overall survival, or OS, among patients who achieved a CR or CRi was 18.0 months. As of the data cut-off, of the 28 patients without *RARA* overexpression that were evaluable for clinical response, the overall response rate was 43%, with a CR/CRi rate of 32%, with 25% of patients achieving CR and 7% achieving CRi. The median time to initial CR/CRi response was 3.0 months, and the median duration of CR/CRi response was 10.3 months.

HR-MDS is a hematologic malignancy for which disease-related cytopenias result in significant morbidity and mortality, with more than half of HR-MDS patients progressing to AML, and we believe that approximately 50% of HR-MDS patients overexpress *RARA*. Based on the data presented at ASH 2020 and our assessment of ongoing areas of high unmet need, we advanced tamibarotene in combination with azacitidine into a registration-enabling Phase 3 clinical trial in newly diagnosed HR-MDS patients with *RARA* overexpression, which we refer to as SELECT-MDS-1. We believe that approximately 9,000 HR-MDS patients are diagnosed in the United States each year. We expect that the total market opportunity for HR-MDS therapeutics in the United States will be approximately \$1.6 billion by 2029, and that the total United States market opportunity for tamibarotene in HR-MDS patients with *RARA* overexpression will be over \$800 million by 2029. The SELECT-MDS-1 trial is evaluating newly diagnosed HR-MDS patients with *RARA* overexpression in a double-blind placebo-controlled study design, randomized 2:1 to receive tamibarotene in combination with azacitidine, or placebo in combination with azacitidine, respectively. The primary efficacy endpoint is based on 190 patients to provide over 90% power to detect a difference in CR rates between the experimental and

control arms with a one-sided alpha of 0.025. The United States Food and Drug Administration, or FDA, has expressed that the CR rate is an acceptable efficacy endpoint for either full or accelerated approval for treatment of newly diagnosed HR-MDS with supporting data on durability of remission. Informed by feedback from the FDA, we amended the SELECT-MDS-1 clinical trial protocol in March 2023 to include a total of approximately 550 patients to enable us to assess OS as a key secondary endpoint, which could allow the trial to serve as a confirmatory study if needed to convert an accelerated approval to a full approval in the future. The amended clinical trial protocol is designed with 80% power to detect a difference in OS rates for the key secondary endpoint between the experimental and control arms, also with a one-sided alpha of 0.025. In January 2023, the FDA granted Fast Track Designation to tamibarotene in combination with azacitidine for the treatment of adults with newly diagnosed HR-MDS who are positive for *RARA* overexpression. In the first quarter of 2024, we completed enrollment of the 190 patients necessary to support the CR primary endpoint analysis. In addition, the SELECT-MDS-1 trial passed a pre-specified interim futility analysis of the primary endpoint based on an analysis, blinded to us, in the initial 50% of the enrolled patients. The analysis was conducted by an independent data monitoring committee, who also noted that there were no concerning safety signals and recommended that the trial continue without modification. We expect to report pivotal CR data from the SELECT-MDS-1 trial in mid-November of 2024.

In August 2024, we announced our decision to discontinue enrollment in the SELECT-AML-1 Phase 2 clinical trial evaluating the triplet regimen of tamibarotene in combination with venetoclax and azacitidine compared to the doublet regimen of venetoclax and azacitidine in newly diagnosed, unfit patients with AML and *RARA* gene overexpression, based on the results of a prespecified interim analysis of the trial.

As part of our launch preparation activities for tamibarotene, we have engaged a leading provider of testing services to develop and validate a laboratory-developed test based on our existing clinical trial assay to provide *RARA* overexpression testing at launch, and we continue to evaluate multiple approaches to the development of a commercial companion diagnostic. We are also partnered with Qiagen Manchester Limited to develop a kit-based testing solution for future commercialization.

### ***Financings***

On December 21, 2023, we issued and sold an aggregate of 4,939,591 shares of our common stock at a price of \$4.42 per share, and, in lieu of our common stock to certain investors who so chose, pre-funded warrants to purchase an aggregate of 5,242,588 shares of our common stock at a price of \$4.419 per pre-funded warrant, in an underwritten offering resulting in gross proceeds of approximately \$45.0 million, before deducting underwriting fees and other transaction costs of approximately \$3.2 million. The offering was made pursuant to an underwriting agreement between us and Cowen and Company, LLC, or Cowen, and Piper Sandler & Co. on December 18, 2023. Pursuant to the underwriting agreement, the underwriters purchased the shares of common stock from us at a price of \$4.1548 per share and the pre-funded warrants from us at a price of \$4.15386 per share underlying each pre-funded warrant. The shares of common stock and the pre-funded warrants were issued, and any shares of common stock issuable upon exercise of the pre-funded warrants will be issued, pursuant to a shelf registration statement on Form S-3 that was filed with the SEC on April 6, 2023 and declared effective by the SEC on April 28, 2023.

### **Financial Operations Overview**

#### ***Revenue***

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future. We did not recognize any revenue during the three and nine months ended September 30, 2024. For the three and nine months ended September 30, 2023, we recognized revenue of \$3.8 million and \$9.6 million, respectively, related to our collaboration with Global Blood Therapeutics, or GBT. The collaboration with GBT was terminated in October 2023 and we do not expect to recognize collaboration revenue from GBT following that date.

#### ***Expenses***

##### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred for our research activities, including the preclinical and clinical development of our product candidates, which include:

- employee-related expenses, including salaries and benefits;

- stock-based compensation expense;
- external costs of funding activities performed by third parties that conduct research and development on our behalf and of purchasing supplies used in designing, developing and manufacturing preclinical study and clinical trial materials;
- consulting, licensing and professional fees related to research and development activities; and
- facilities costs, depreciation and amortization and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other operating costs.

Research and development costs are expensed as incurred. Nonrefundable advance payments made to vendors for goods or services that will be received in the future for use in research and development activities are deferred and capitalized, even when there is no alternative future use for the research and development, until related goods or services are provided.

We typically use our employee, consultant and infrastructure resources across our research and development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or certain external consultant costs to specific product candidates or development programs.

The following table summarizes our external research and development expenses by program, as well as expenses not allocated to programs, for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Tamibarotene external costs	\$ 13,763	\$ 14,435	\$ 44,977	\$ 42,771
SY-5609 program external costs	1	173	70	2,516
SY-2101 program external costs	(62)	999	718	4,007
Other research program external costs	491	2,507	1,435	6,239
Employee-related expenses, excluding stock-based compensation	4,531	6,865	13,858	21,644
Stock-based compensation	518	1,586	2,227	4,236
Facilities and other expenses	1,285	1,715	3,849	5,237
Total research and development expenses	<u>\$ 20,527</u>	<u>\$ 28,280</u>	<u>\$ 67,134</u>	<u>\$ 86,650</u>

We expect to incur significant research and development expenses for the foreseeable future as we seek to advance the clinical development of tamibarotene. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of tamibarotene or any future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of any product candidates. This is due to the numerous risks and uncertainties associated with developing such product candidates, including the uncertainty of:

- approval of investigational new drug applications, or INDs, to commence any future clinical trials;
- successful enrollment in, and completion of, clinical trials;
- successful data from our clinical programs that support an acceptable benefit-risk profile of our product candidates in the intended populations;
- successful development, and subsequent clearance or approval, of diagnostic tests for use in identifying potential patients;
- receipt of regulatory approvals from applicable regulatory authorities;
- establishment of arrangements with third-party manufacturers for clinical supply and commercial manufacturing and, where applicable, commercial manufacturing capabilities;

- establishment and maintenance of patent and trade secret protection or regulatory exclusivity for our product candidates;
- commercial launch of our product candidates, if and when approved, whether alone or in collaboration with others;
- enforcement and defense of intellectual property rights and claims;
- maintenance of a continued acceptable safety profile of the product candidates following approval;
- retention of key personnel;
- the impact of public health crises, including epidemics and pandemics; and
- general economic conditions, including inflation and recession risk.

Any changes in the outcome of any of these variables with respect to the development of our product candidates could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of our product candidates.

#### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, information technology and administrative functions. Other significant costs include corporate facility costs not otherwise included in research and development expenses, legal fees related to patent and corporate matters, and fees for accounting and consulting services.

#### *Restructuring Costs*

Restructuring costs consist primarily of severance, post-employment benefit, outplacement services, impairment charges and any other expenses that we incur related to the realignment of our strategy and cost reduction measures.

#### *Interest Income*

Interest income consists of interest income on our cash, cash equivalents and investments in marketable securities, including the related amortization of premiums and discounts.

#### *Interest Expense*

Interest expense consists of interest, amortization of debt discount, and amortization of deferred financing costs associated with our loans payable, and interest on finance lease arrangements.

#### *Change in Fair Value of Warrant Liabilities*

Change in fair value of warrant liabilities is the result of the remeasurement of the fair value of our warrant liabilities at each reporting period end.

#### *Critical Accounting Policies and Estimates*

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors

that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the financial statements prospectively from the date of the change in estimates.

We believe that our most critical accounting policies are those relating to revenue recognition, accrued research and development expenses and stock-based compensation. There have been no significant changes to our critical accounting policies as discussed in our 2023 10-K.

## Results of Operations

### Comparison of three months ended September 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023, together with the changes in those items in dollars (in thousands):

	Three Months Ended September 30,		Dollar Change	% Change
	2024	2023		
<b>Statements of Operations Data:</b>				
Revenue	\$ —	\$ 3,762	\$ (3,762)	(100) %
Operating expenses:				
Research and development	20,527	28,280	(7,753)	(27) %
General and administrative	5,655	7,764	(2,109)	(27) %
Restructuring costs	—	—	—	—
		2,354	(2,354)	(100) %
Total operating expenses	26,182	38,398	(12,216)	(32) %
Loss from operations	(26,182)	(34,636)	8,454	(24) %
Interest income	793	1,633	(840)	(51) %
Interest expense	(1,312)	(1,303)	(9)	1 %
Change in fair value of warrant liabilities	20,305	(5,837)	26,142	(448) %
Net loss	\$ (6,396)	\$ (40,143)	\$ 33,747	(84) %

### Revenue

We did not recognize any revenue during the three months ended September 30, 2024. For the three months ended September 30, 2023, we recognized \$3.8 million of revenue, all of which was attributable to our collaboration with GBT.

### Research and Development Expense

Research and development expense decreased by approximately \$7.8 million, or 27%, from \$28.3 million for the three months ended September 30, 2023 to \$20.5 million for the three months ended September 30, 2024. The following table summarizes our research and development expenses for the three months ended September 30, 2024 and 2023, together with the changes to those items in dollars (in thousands):

	Three Months Ended September 30,		Dollar Change	% Change
	2024	2023		
External research and development	\$ 13,175	\$ 16,730	\$ (3,555)	(21) %
Employee-related expenses, excluding stock-based compensation	4,531	6,865	(2,334)	(34) %
Stock-based compensation	518	1,586	(1,068)	(67) %
Consulting, licensing and professional fees	1,018	1,384	(366)	(26) %
Facilities and other expenses	—	—	—	—
	1,285	1,715	(430)	(25) %
Total research and development expenses	\$ 20,527	\$ 28,280	\$ (7,753)	(27) %

The change in research and development expense was primarily attributable to activities associated with advancing our clinical programs, including the following:

- a decrease of approximately \$3.6 million, or 21%, for external research and development costs, primarily attributable to a decrease in costs associated with our clinical trial of SY-2101 and the elimination of costs associated with our discovery programs following the restructuring of our operations in the fourth quarter of 2023;
- a decrease of approximately \$2.3 million, or 34%, for employee-related expenses, primarily due to a reduction of headcount associated with the restructuring of our operations in the fourth quarter of 2023;
- a decrease of approximately \$1.1 million, or 67%, for stock-based compensation, primarily due to a reduction of headcount associated with the restructuring of our operations in the fourth quarter of 2023, and because the stock-based awards granted to employees in 2024 have performance-based vesting conditions for which no related expenses were recognized during the period;
- a decrease of approximately \$0.4 million, or 26%, for consulting, licensing and professional fees, primarily related to a decrease in costs associated with our clinical trials and elimination of costs associated with our discovery programs following the restructuring of our operations in the fourth quarter of 2023; and
- a decrease of approximately \$0.4 million, or 25%, for facilities and other expenses, primarily due to the closure of our laboratory facilities as part of the restructuring of our operations in the fourth quarter of 2023.

#### *General and Administrative Expense*

General and administrative expense decreased by approximately \$2.1 million, or 27%, from \$7.8 million for the three months ended September 30, 2023 to \$5.7 million for the three months ended September 30, 2024. The change in general and administrative expense was primarily attributable to a decrease in facilities expenses, consulting and a reduction of headcount associated with the restructuring of our operations in the fourth quarter of 2023.

#### *Restructuring Costs*

Restructuring costs for the three months ended September 30, 2023 consist primarily of severance, post-employment benefit, outplacement services, impairment charges and any other expenses that we incur related to the realignment of our strategy and cost reduction measures.

#### *Interest Income*

Interest income was derived generally from our investments in cash, cash equivalents, and marketable securities. The decrease in interest income during the three months ended September 30, 2024 as compared to the three months ended September 30, 2023 was due to a lower average cash balance during the three months ended September 30, 2024 compared to the same period in 2023.

#### *Interest Expense*

Interest expense was related to our credit facility with Oxford Finance LLC, or Oxford. Interest expense increased slightly during the three months ended September 30, 2024 compared to the three months ended September 30, 2023 due to a higher effective interest rate during the three month period ended September 30, 2024 compared to the same period in 2023.

#### *Change in Fair Value of Warrant Liabilities*

The gain from the change in fair value of warrant liabilities during the three months ended September 30, 2024 was primarily driven by the decrease in the price of our common stock from June 30, 2024 to September 30, 2024. The loss from the change in fair value of warrant liabilities during the three months ended September 30, 2023 was primarily driven by the increase in the price of our common stock from June 30, 2023 to September 30, 2023.

**Comparison of nine months ended September 30, 2024 and 2023**

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023, together with the changes in those items in dollars (in thousands):

	Nine Months Ended September 30,		Dollar Change	% Change
	2024	2023		
<b>Statements of Operations Data:</b>				
Revenue	\$ —	\$ 9,550	\$ (9,550)	(100) %
Operating expenses:				
Research and development	67,134	86,650	(19,516)	(23) %
General and administrative	17,383	22,394	(5,011)	(22) %
Restructuring costs	—	2,354	(2,354)	(100) %
Total operating expenses	84,517	111,398	(26,881)	(24) %
Loss from operations	(84,517)	(101,848)	17,331	(17) %
Interest income	3,424	5,533	(2,109)	(38) %
Interest expense	(4,001)	(3,798)	(203)	5 %
Change in fair value of warrant liabilities	51,663	(77)	51,740	(67,195) %
Net loss	<u>\$ (33,431)</u>	<u>\$ (100,190)</u>	<u>\$ 66,759</u>	<u>\$ (67) %</u>

*Revenue*

We did not recognize any revenue during the nine months ended September 30, 2024. For the nine months ended September 30, 2023, we recognized \$9.6 million of revenue, all of which was attributable to our collaboration with GBT.

*Research and Development Expense*

Research and development expense decreased by approximately \$(19.5) million, or 23%, from \$86.7 million for the nine months ended September 30, 2023 to \$67.1 for the nine months ended September 30, 2024. The following table summarizes our research and development expenses for the nine months ended September 30, 2024 and 2023, together with the changes to those items in dollars (in thousands):

	Nine Months Ended September 30,		Dollar Change	% Change
	2024	2023		
External research and development	\$ 43,659	\$ 49,186	\$ (5,527)	(11) %
Employee-related expenses, excluding stock-based compensation	13,858	21,644	(7,786)	(36) %
Stock-based compensation	2,227	4,236	(2,009)	(47) %
Consulting, licensing and professional fees	3,541	6,347	(2,806)	(44) %
Facilities and other expenses	3,849	5,237	(1,388)	(27) %
Total research and development expenses	<u>\$ 67,134</u>	<u>\$ 86,650</u>	<u>\$ (19,516)</u>	<u>(23) %</u>

The change in research and development expense was primarily attributable to activities associated with advancing our clinical programs, including the following:

- a decrease of approximately \$5.5 million, or 11%, for external research and development costs, primarily attributable to the decrease in costs associated with our clinical trials of prior programs related to SY-5609 and SY-2101 and the elimination of costs associated with our discovery programs following the restructuring of our operations in the fourth quarter of 2023, partially offset by an increase in costs associated with the clinical development of tamibarotene;
- a decrease of approximately \$7.8 million, or 36%, for employee-related expenses, primarily due to a reduction of headcount associated with the restructuring of our operations in the fourth quarter of 2023;
- a decrease of approximately \$2.0 million, or 47%, for stock-based compensation, primarily due to a reduction of headcount associated with the restructuring of our operations in the fourth quarter of 2023,

and because the stock-based awards granted to employees in 2024 have performance-based vesting conditions for which no related expenses were recognized during the period;

- a decrease of approximately \$2.8 million, or 44%, for consulting, licensing and professional fees, primarily related to a decrease in costs associated with our clinical trials; and

- a decrease of approximately \$1.4 million, or 27%, for facilities and other expenses, primarily due to the closure of our laboratory facilities as part of the restructuring of our operations in the fourth quarter of 2023.

#### *General and Administrative Expense*

General and administrative expense decreased by approximately \$5.0 million, or 22%, from \$22.4 million for the nine months ended September 30, 2023 to \$17.4 million for the nine months ended September 30, 2024. The change in general and administrative expense was primarily attributable to a decrease in facilities expenses, consulting and professional fees and a reduction of headcount associated with the restructuring of our operations in the fourth quarter of 2023.

#### *Interest Income*

Interest income was derived generally from our investments in cash, cash equivalents and marketable securities. The decrease in interest income during the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 was due to a lower average cash balance during the nine months ended September 30, 2024 compared to the same period in 2023.

#### *Interest Expense*

Interest expense was related to our credit facility with Oxford. Interest expense increased from the nine months ended September 30, 2023 to the nine months ended September 30, 2024 due to a higher effective interest rate during the nine months ended September 30, 2024 compared to the same period in 2023.

#### *Change in Fair Value of Warrant Liabilities*

The gain from the change in fair value of warrant liabilities during the nine months ended September 30, 2024 was primarily driven by the decrease in the price of our common stock from December 31, 2023 to September 30, 2024. The loss from the change in fair value of warrant liabilities during the nine months ended September 30, 2023 was primarily driven by the increase in the price of our common stock from December 31, 2022 to September 30, 2023.

### **Liquidity and Capital Resources**

#### *Sources of Liquidity*

We funded our operations from inception through September 30, 2024, primarily through the issuance of equity securities, through license and collaboration agreements, and through the credit facility with Oxford.

On February 12, 2020, we entered into a Loan and Security Agreement with Oxford. Pursuant to the Loan Agreement, term loans of up to an aggregate principal amount of \$60.0 million were originally made available to us. A \$20.0 million term loan was funded on February 12, 2020, and another \$20.0 million term loan was funded on December 23, 2020. On July 3, 2022, we entered into an amendment to the Loan Agreement with Oxford, or the First Loan Amendment. Pursuant to the First Loan Amendment, Oxford agreed to modify the Loan Agreement in order to, among other things, extend the interest only period from March 1, 2023 to March 1, 2024 and extend the maturity date from February 1, 2025 to February 1, 2026, and upon the achievement of certain milestones and subject to the payment of certain fees, further extend the interest only period to September 1, 2024 and maturity date to August 1, 2026. On May 9, 2024, we entered into a further amendment to the Loan Agreement with Oxford, or the Fourth Loan Amendment. Under the Fourth Loan Amendment, Oxford agreed to modify the Loan Agreement in order to, among other things, (i) increase the aggregate amount of term loans available to us to from \$40.0 million to \$100.0 million, with term loans totaling \$40.0 million in the aggregate becoming available to us upon achievement of certain clinical development, regulatory and equity-raising milestones, and \$20.0 million becoming available at Oxford's discretion; (ii) extend the interest only period from September 1, 2024 to November 1, 2025 with further extensions to as late as November 1,



2026 upon achievement of certain milestones; and (iii) extend the maturity date from August 1, 2026 to February 1, 2028. In consideration for this Fourth Loan Amendment, we have agreed to, among other things, certain cash covenants and revenue performance covenants, and that the failure to satisfy the primary endpoint for the SELECT-MDS-1 trial, the termination of the SELECT-MDS-1 trial for safety reasons, or the failure to obtain FDA approval for tamibarotene for the treatment of newly diagnosed HR-MDS patients with *RARA* overexpression by May 31, 2026, would each constitute events of default under the Loan Agreement. In addition, upon drawing any further loans under the Loan Agreement we have agreed to grant Oxford, to the extent permitted under existing agreements and applicable law, a security interest in all intellectual property owned by us. As of September 30, 2024, term loans totaling \$40.0 million in the aggregate remain available under the Loan Agreement upon the achievement of certain clinical development, regulatory and equity-raising milestones, and a \$20.0 million term loan remains available under the Loan Agreement at the sole discretion of Oxford.

On April 6, 2023, we filed a universal shelf registration statement on Form S-3, or the 2023 Registration Statement, with the SEC to register for sale from time to time up to \$250.0 million of common stock, preferred stock, debt securities, warrants and/or units in one or more registered offerings. The 2023 Registration Statement was declared effective on April 28, 2023. Further, in April 2023, we entered into an at-the-market sales agreement, or the 2023 sales agreement, with Cowen, pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to \$50.0 million through Cowen pursuant to the 2023 Registration Statement. During the year ended December 31, 2023, we issued and sold 350,000 shares of common stock pursuant to the 2023 sales agreement for gross proceeds of \$1.4 million, before deducting underwriting fees.

Upon entry into the 2023 sales agreement, we terminated our prior at-the-market program pursuant to the original sales agreement dated July 12, 2020. At the time of such termination, the entire \$75.0 million available under such agreement remained unsold.

In December 2023, we issued shares of our common stock and, in lieu of common stock to certain investors, pre-funded warrants to purchase our common stock, pursuant to the 2023 Registration Statement, in an underwritten offering resulting in gross proceeds of \$45.0 million, before deducting underwriting fees and other transaction costs of approximately \$3.2 million.

As of September 30, 2024, \$48.6 million of our common stock remained available for future issuance under the 2023 sales agreement.

As of September 30, 2024, \$203.6 million of securities remained available for future issuance under the 2023 Registration Statement.

As of September 30, 2024, we had cash and cash equivalents of approximately \$58.3 million.

#### **Cash Flows**

The following table provides information regarding our cash flows for the nine months ended September 30, 2024 and 2023 (in thousands):

	<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
Net cash (used in) provided by:		
Operating activities	\$ (81,454 )	\$ (91,145 )
Investing activities	427	35,815
Financing activities	(224 )	82
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (81,251 )</u>	<u>\$ (55,248 )</u>

#### **Net Cash Used in Operating Activities**

Net cash used in operating activities for the nine months ended September 30, 2024 and 2023 resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital.

Net cash used in operating activities was \$81.5 million during the nine months ended September 30, 2024 compared to \$91.1 million for the nine months ended September 30, 2023. The decrease in net cash used in operating activities during the nine months ended September 30, 2024 was primarily due to a decrease in the loss from operations of \$17.3 million, partially offset by a decrease in stock-based compensation of \$3.2 million, an increase in the change of net operating assets and liabilities of \$1.7 million, a decrease in depreciation and impairment of property and equipment of \$1.3 million, a decrease in interest income of \$1.1 million (excluding amortization of premiums and discounts), and an increase in interest expense of \$0.2 million.

#### *Net Cash Provided By Investing Activities*

Net cash provided by investing activities was \$0.4 million during the nine months ended September 30, 2024 compared to net cash provided by investing activities of \$35.8 million during the nine months ended September 30, 2023. The net cash provided by investing activities during the nine months ended September 30, 2024 was primarily due to the proceeds from the sale or maturities of marketable securities of \$30.9 million and proceeds from disposal of property and equipment of \$0.1 million, partially offset by the purchase of marketable securities of \$30.6 million during the nine months ended September 30, 2024. In comparison, the net cash provided by investing activities during the nine months ended September 30, 2023 was primarily due to the maturity of marketable securities of \$87.0 million, partially offset by the purchases of marketable securities of \$51.0 million during the nine months ended September 30, 2023.

#### *Net Cash (Used In) Provided By Financing Activities*

Net cash used in financing activities was \$0.2 million during the nine months ended September 30, 2024 compared to the net cash provided by financing activities of \$0.1 million for the nine months ended September 30, 2023. Cash used in financing activities for the nine months ended September 30, 2024 was primarily due to the payments of issuance costs related to our underwritten registered direct offering and our at-the-market facility during the year ended December 31, 2023 of \$0.3 million, partially offset by the proceeds from the issuance of shares of our common stock pursuant to our employee stock purchase plan. In comparison, the cash provided by financing activities for the nine months ended September 30, 2023 was primarily due to proceeds from the issuance of shares of our common stock pursuant to our employee stock purchase plan.

#### **Funding Requirements and Going Concern**

We expect to incur significant expenses in connection with our ongoing activities, particularly as we continue to advance the clinical development of tamibarotene, seek to develop diagnostic tests for use with tamibarotene, and seek marketing approval for tamibarotene or any future product candidates that we successfully develop. In addition, if we obtain marketing approval for tamibarotene or any other product candidate, we expect to incur significant commercialization expenses related to establishing sales, marketing, distribution and other commercial infrastructure to commercialize such products. We will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on favorable terms, we would be forced to delay, reduce, eliminate, or out-license our development programs or future commercialization rights to our product candidates.

We believe that our cash and cash equivalents as of September 30, 2024, will enable us to fund our planned operating expense and capital expenditure requirements into the third quarter of 2025. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of the clinical development of tamibarotene and associated diagnostic tests;
- our ability to satisfy the representations, warranties and covenants contained in the Loan Agreement with Oxford and to avoid the occurrence of any specified events of default thereunder;
- development efforts for any future product candidates that we may develop;
- the number of future product candidates that we pursue and their development requirements;
- our ability to enter into, and the terms and timing of, any collaborations, licensing agreements or other arrangements;

- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for tamibarotene or any other product candidate that receives marketing approval to the extent such costs are not the responsibility of any collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- the costs of acquiring potential new product candidates or technology;
- the costs of any physician education programs relating to selecting and treating genomically defined patient populations;
- the timing and amount of milestone and other payments due to TMRC Co. Ltd. associated with the development, manufacture and commercialization of tamibarotene;
- revenue received from commercial sales, if any, of our current and future product candidates;
- our employment-related costs as we advance our clinical pipeline and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the impact of public health crises, including epidemics and pandemics.

Identifying potential product candidates and conducting clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, tamibarotene or any future product candidate, if approved, may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the issuance of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have incurred significant net operating losses in every year since our inception. We expect to continue to incur significant and increasing net operating losses for at least the next several years. As of September 30, 2024, we had cash and cash equivalents of \$58.3 million and an accumulated deficit of \$756.2 million. We have not generated any revenues from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We have financed our operations to date primarily through a credit facility, the issuance of equity securities and through license and collaboration agreements. We have devoted substantially all of our financial resources and efforts to research and development and general and administrative activities to support such research and development. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

As discussed in Note 1 of the Notes to the Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q, under ASC Topic 205-40, *Presentation of Financial Statements - Going Concern*, management is

required at each reporting period to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued.

Based on our current operating plan, we anticipate that our cash and cash equivalents of \$58.3 million as of September 30, 2024 will allow us to meet our liquidity requirements into the third quarter of 2025. Our history of significant losses, our negative cash flows from operations, our limited liquidity resources currently on hand, and our dependence on our ability to obtain additional financing to fund our operations after the current resources are exhausted, about which there can be no certainty, have resulted in our assessment that there is substantial doubt about our ability to continue as a going concern for a period of at least 12 months from the issuance date of the condensed consolidated financial statements included in this Quarterly Report. We have plans in place to mitigate this risk, which primarily consist of raising additional capital through a combination of equity or debt financings, business development transactions, including the potential sale of SY-2101-related assets, and reducing cash expenditures. There is no guarantee that we will be successful in any capital raising or business development efforts, in which case we may not be able to continue our development programs as planned.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments, including cash equivalents, are in the form of money market funds and are invested in U.S. treasury or government obligations. However, because of the short-term nature of the duration of our portfolio and the low-risk profile of our investments, we believe an immediate 10% change in market interest rates would not be expected to have a material impact on the fair market value of our investment portfolio or on our financial condition or results of operations.

We are also exposed to market risk related to changes in foreign currency exchange rates. We contract with vendors that are located in Asia and Europe and certain invoices are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these arrangements. We do not currently hedge our foreign currency exchange rate risk. As of September 30, 2024, we did not have significant liabilities denominated in foreign currencies.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the nine months ended September 30, 2024 and 2023.

### **Item 4. Controls and Procedures**

#### *Management's Evaluation of our Disclosure Controls and Procedures*

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our Chief Executive Officer, who serves as our Principal Executive Officer, and our Chief Financial Officer, who serves as our Principal Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024, the end of the period covered by this Quarterly Report. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### Item 1A. Risk Factors

*The following information updates, and should be read in conjunction with, the risk factors discussed in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, or the 2023 10-K. Any of the risk factors contained in this Quarterly Report and the 2023 10-K could materially affect our business, financial condition or future results, and such risk factors may not be the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.*

#### **Risks Related to Our Financial Position and Need for Additional Capital**

*We will need substantial additional funding to execute our operating plan and continue to operate as a going concern, and if we are unable to raise capital, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.*

Developing pharmaceutical products, including conducting clinical trials, is a time consuming, expensive and uncertain process. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that our cash and cash equivalents as of September 30, 2024 will enable us to fund our planned operating expense and capital expenditure requirements into the third quarter of 2025. These funds may not be sufficient to fund operations for at least the next 12 months from the date of issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report, which raises substantial doubt about our ability to continue as a going concern. Our future viability beyond one year from the date of issuance of these condensed consolidated financial statements is dependent on our ability to raise additional capital to finance our operations. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. In any event, our existing cash and cash equivalents will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of our product candidates. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Although management plans to pursue additional funding, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, or at all.

Our future funding requirements will depend on many factors, including those discussed in Part I, Item 1A, "Risk Factors" in the 2023 10-K under "Risks Related to Our Financial Position and Need for Additional Capital - We have incurred significant losses since inception, expect to incur significant losses for at least the next several years, and may never achieve or maintain profitability." Our future funding requirements may also depend on:

- the costs of launch activities related to tamibarotene and any future product candidates, including any physician education programs relating to selecting and treating genomically defined patient populations;
- the timing and amount of milestone and other payments due to TMRC Co. Ltd. associated with the development, manufacture and commercialization of tamibarotene; and
- the timing and amount of payments due to parties we have engaged related to the development and commercialization of diagnostic tests for use with tamibarotene.

#### **The terms of our loan and security agreement place restrictions on our operating and financial flexibility.**

In February 2020, we entered into a loan and security agreement with Oxford Finance LLC, or Oxford, which is secured by substantially all of our currently owned or later acquired personal property other than our intellectual property (but including the right to payments and proceeds of intellectual property), which is subject to a negative pledge. We borrowed \$20.0 million upon execution of the loan and security agreement and borrowed an additional \$20.0 million term loan advance in December 2020.

On May 9, 2024, we entered into an amendment, or the Loan Amendment, to the loan and security agreement with Oxford. We refer to the loan and security agreement with Oxford, as amended by the Loan Amendment, as the Loan Agreement. Pursuant to the Loan Amendment, in its capacity as lender and agent, Oxford agreed to modify the terms of the loan and security agreement to, among other things: (i) increase the aggregate amount of term loans available to us from \$40.0 million to \$100.0 million, with tranches totaling \$40.0 million in the aggregate becoming available to us upon achievement of certain clinical development, regulatory and equity-raising milestones, and \$20.0 million becoming available at Oxford's discretion; (ii) extend the interest only period from September 1, 2024 to November 1, 2025 with further extensions to as late as November 1, 2026 upon achievement of certain milestones; and (iii) extend the maturity date from August 1, 2026 to February 1, 2028.

The Loan Agreement contains representations and warranties and affirmative and negative covenants applicable to us and our subsidiaries, as more fully described in the Loan Agreement. The Loan Agreement also includes events of default. In consideration for the Loan Amendment, we agreed that the failure to satisfy the primary endpoint for the SELECT-MDS-1 trial, the termination of the SELECT-MDS-1 trial for safety reasons, or the failure to obtain FDA approval for tamibarotene for the treatment of newly diagnosed HR-MDS patients with *RARA* overexpression by May 31, 2026, would each constitute events of default under the Loan Agreement. If an event of default were to occur in connection with the pivotal complete response data from the SELECT-MDS-1 trial that we expect to report in mid-November of 2024, or if an event of default were otherwise to occur and continue, the Loan Agreement provides Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the loans under the Loan Agreement, including foreclosure against our property securing the Loan Agreement, including our cash, potentially requiring us to renegotiate our agreement on terms less favorable to us, or to immediately cease operations.

Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Oxford could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the Loan Agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by Oxford of an event of default could significantly harm our business, financial condition and prospects and would cause the price of our common stock to decline.

### **Risks Related to the Development and Commercialization of Product Candidates**

*We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.*

We expect that we, and any collaborators, will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to any product candidates that we, or any collaborators, may seek to develop or commercialize in the future. Specifically, there are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of myelodysplastic syndrome, or MDS, the indication targeted in our SELECT-MDS-1 trial involving tamibarotene.

For example, we are aware of two new drugs approved by the U.S. Food and Drug Administration, or the FDA, since 2020 for the treatment of MDS or patient subsets within MDS (decitabine/cedazuridine and ivosidenib). Tamibarotene may also face competition from other agents currently in clinical development for MDS, including those in late-stage development from AbbVie Inc., Roche Holding AG, and Taiho Oncology, Inc.

Our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, have fewer side effects or more tolerable side effects, have greater ease of access, or are less costly than any product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive. In addition, the evolving standard of care for the treatment of patients with acute myeloid leukemia, or AML, may lead to evolution of the standard of care for patient subsets within MDS. Our competitors also may obtain FDA or other marketing approval for their products before we, or any collaborators, are able to obtain approval for ours, which could result in our competitors establishing a strong market position before we, or any collaborators, are able to enter the market.

Many of our existing and potential future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing

approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our product candidates.

#### **Risks Related to Our Dependence on Third Parties**

***Failure of any third-party collaborator to successfully develop or commercialize a diagnostic test for use with tamibarotene to identify patients with RARA overexpression could harm our ability to commercialize tamibarotene.***

We do not plan to internally develop a commercial diagnostic test to identify patients with *RARA* overexpression. As a result, we will be dependent on the efforts of third-party collaborators to successfully develop and commercialize a diagnostic test. As part of our launch preparation activities for tamibarotene, we have engaged a leading provider of testing services to develop and validate a laboratory-developed test based on our existing clinical trial assay to provide *RARA* overexpression testing at launch, and we continue to evaluate multiple approaches to the development of a commercial companion diagnostic. We are also partnered with Qiagen Manchester Limited to develop a kit-based testing solution for future commercialization.

Our third-party collaborators may not perform their obligations as expected or as required under our agreements with those parties, may encounter production difficulties that could constrain the supply of a diagnostic test, may have difficulties gaining acceptance of the use of a diagnostic test in the clinical community, may not pursue commercialization of a diagnostic test even if they receive any required regulatory approvals, may elect not to continue the development of a diagnostic test based on changes in strategic focus or available funding, or external factors such as an acquisition, that divert resources or create competing priorities, may not commit sufficient resources to the marketing and distribution of a diagnostic test, and may terminate their relationships with us.

If a diagnostic test that is developed for use with tamibarotene fails to gain market acceptance, our ability to derive revenues from sales from tamibarotene would be harmed. If the third parties we engage fail to commercialize a diagnostic test, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative test for use with tamibarotene or do so on commercially reasonable terms, which could adversely affect and/or delay commercial launch and cause us to fail to realize the full commercial potential of tamibarotene.

#### **Item 5. Other Information**

(c)

None of our directors or officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the quarterly period covered by this report.



**Item 6. Exhibits**

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
3.1	<a href="#"><u>Restated Certificate of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 (File No. 001-37813) filed on July 31, 2024).</u></a>
3.2	<a href="#"><u>Second Amended and Restated By-Laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 (File No. 001-37813) filed on August 5, 2021).</u></a>
31.1	<a href="#"><u>Certification of principal executive officer pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.</u></a>
31.2	<a href="#"><u>Certification of principal financial officer pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.</u></a>
32.1	<a href="#"><u>Certification of principal executive officer pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.</u></a>
32.2	<a href="#"><u>Certification of principal financial officer pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.</u></a>
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data (formatted as Inline XBRL and contained in Exhibit 101)

**SIGNATURES**

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

**Syros Pharmaceuticals, Inc.**

Date: October 31, 2024

By: /s/ Jason Haas  
Jason Haas  
Chief Financial Officer (Principal Financial Officer)



**Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a)  
and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002**

I, Conley Chee, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Syros Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the 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 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Syros Pharmaceuticals, Inc.

/s/ Conley Chee  
Conley Chee  
President and Chief Executive Officer  
(Principal Executive Officer)

Dated: October 31, 2024

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**Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a)  
and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002**

I, Jason Haas, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Syros Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the 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 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Syros Pharmaceuticals, Inc.

/s/ Jason Haas  
Jason Haas  
Chief Financial Officer  
(Principal Financial Officer)

Dated: October 31, 2024

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**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT  
TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Syros Pharmaceuticals, Inc. (the "Company") for the quarter ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Conley Chee, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 31, 2024

/s/ Conley Chee  
Conley Chee  
President and Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT  
TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Syros Pharmaceuticals, Inc. (the "Company") for the quarter ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Jason Haas, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 31, 2024

/s/ Jason Haas  
Jason Haas  
Chief Financial Officer  
(Principal Financial Officer)

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