UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2025

OR

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

For the transition period from _____ to _____

Commission File Number: 001-41925

CG Oncology, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**37-1611499**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
400 Spectrum Center Drive, Suite 2040 Irvine, CA	**92618**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (949) 409-3700

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, par value $0.0001 per share	CGON	The 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, 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards 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 ☒

As of May 9, 2025, the registrant had 76,225,308 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

CG ONCOLOGY, INC.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 41,472	$ 257,068
Marketable securities	646,962	484,930
Prepaid expenses and other current assets	12,413	11,431
Accounts receivable - other	345	781
Total current assets	701,192	754,210
Property and equipment, net	264	272
Note receivable, net	25,176	—
Operating lease right-of-use assets	1,033	221
Other assets	516	94
Total assets	$ 728,181	$ 754,797
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,731	$ 6,517
Operating lease liabilities, current portion	255	186
Accrued expenses and other current liabilities	15,656	14,665
Total current liabilities	22,642	21,368
Operating lease liabilities, net of current portion	781	52
Total liabilities	23,423	21,420
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Common stock, $0.0001 par value per share; 700,000,000 and 700,000,000 shares authorized as of March 31, 2025 and December 31, 2024, respectively; 76,221,289 and 76,154,783 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	8	8
Additional paid-in capital	957,183	951,350
Accumulated deficit	(252,433)	(217,981)
Total stockholders' equity	704,758	733,377
Total liabilities and stockholders' equity	$ 728,181	$ 754,797

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

CG ONCOLOGY, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2025	2024
Revenues		
License and collaboration revenue	$ 52	$ 529
Operating expenses		
Research and development	27,467	17,210
General and administrative	14,789	5,788
Total operating expenses	42,256	22,998
Loss from operations	(42,204)	(22,469)
Other income (expense), net:		
Interest income, net	7,747	5,544
Other income (expense), net	5	(9)
Total other income, net	7,752	5,535
Net loss and comprehensive loss	$ (34,452)	$ (16,934)
Net loss per share, basic and diluted	$ (0.45)	$ (0.36)
Weighted average shares of common stock outstanding, basic and diluted	76,187,621	47,064,768

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

CG ONCOLOGY, INC.

Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share amounts)
(unaudited)

	Series A-1 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Series E Redeemable Convertible Preferred Stock		Series F Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance as of December 31, 2023	5,075,000	$ 3,570	11,973,000	$ 10,000	73,598,283	$ 22,000	53,271,754	$ 47,300	112,422,700	$ 120,000	81,587,937	$ 105,020	5,222,283	$ —	$ 6,842	$ (129,942)	$ (123,100)
Conversion of redeemable convertible preferred stock	(5,075,000)	(3,570)	(11,973,000)	(10,000)	(73,598,283)	(22,000)	(53,271,754)	(47,300)	(112,422,700)	(120,000)	(81,587,937)	(105,020)	38,413,909	4	307,886	—	307,890
Issuance of common stock in connection with an initial public offering, net of issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	23,000,000	3	399,562	—	399,565
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	60	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1,517	—	1,517
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(16,934)	(16,934)
Balance as of March 31, 2024	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	66,636,252	$ 7	$ 715,807	$ (146,876)	$ 568,938
Balance as of December 31, 2024	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	76,154,783	$ 8	$ 951,350	$ (217,981)	$ 733,377
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	66,506	—	682	—	682
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	5,151	—	5,151
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(34,452)	(34,452)
Balance as of March 31, 2025	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	76,221,289	$ 8	$ 957,183	$ (252,433)	$ 704,758

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

CG ONCOLOGY, INC.

Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Three Months Ended March 31,	
	2025	2024
Operating Activities		
Net loss	$ (34,452)	$ (16,934)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	24	4
Stock-based compensation expense	5,151	1,517
Accretion of discount on short-term investments	(279)	(2,199)
Non-cash interest income	(176)	—
Non-cash lease expense	(14)	(3)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(982)	(5,654)
Accounts receivable - other	436	—
Other assets	(35)	(33)
Accounts payable	214	1,417
Accrued expenses and other current liabilities	836	(4,127)
Net cash used in operating activities	(29,277)	(26,012)
Investing Activities		
Proceeds from sales and maturities of short-term investments	200,139	145,865
Purchases of short-term investments	(361,892)	(453,297)
Issuance of note receivable	(25,000)	—
Purchases of property and equipment	(16)	(12)
Net cash used in investing activities	(186,769)	(307,444)
Financing Activities		
Proceeds from initial public offering, net of issuance costs	—	406,410
Payments of success fee or long-term debt	—	(365)
Proceeds from exercise of common stock options and issuance of common stock under the employee stock purchase plan	682	—
Deferred offering costs	(232)	(3,387)
Net cash provided by financing activities	450	402,658
Net (decrease) increase in cash and cash equivalents	(215,596)	69,202
Cash and cash equivalents at beginning of period	257,068	8,266
Cash and cash equivalents at end of period	$ 41,472	$ 77,468
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Reclassification of 38,413,909 redeemable convertible preferred stock to 38,413,909 shares of common stock	$ —	$ 307,890
Conversion of deferred offering costs	$ —	$ 6,845
Deferred offering costs, unpaid and accrued	$ 215	$ —
Operating lease right-of-use asset obtained in exchange for lease liabilities	$ 859	$ —

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

1. Description of Business and Basis of Presentation

Description of Business

CG Oncology, Inc. (the Company) is a late-stage clinical biopharmaceutical company focused on developing and commercializing its product candidate, cretostimogene grenadenorepvec, for patients with bladder cancer. The Company is at a clinical stage and does not project to generate significant revenues if and until the U.S. Food and Drug Administration (FDA) approves its product candidate, cretostimogene, and the Company is able to commercialize this product candidate.

On January 11, 2024, the Company's board of directors approved a 1-for-9.535 reverse stock split of its issued and outstanding common stock and stock option awards which was effected on January 16, 2024. All issued and outstanding shares of common stock, stock option awards and per share data have been adjusted in these condensed consolidated financial statements, on a retrospective basis, to reflect the reverse stock split for all periods presented. The par value of the common stock and preferred stock was not adjusted as a result of the reverse stock split.

On January 29, 2024, the Company completed the closing of its initial public offering (IPO) of 23,000,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 3,000,000 additional shares, at a price of $19.00 per share. The common stock began trading on the Nasdaq Global Market on January 25, 2024, under the symbol "CGON". The Company received net proceeds of $399.6 million, after deducting discounts and commissions and other offering expenses. In addition, as a result of its IPO, the Company's redeemable convertible preferred stock converted into common stock concurrently with the IPO. In December 2024, we completed a follow-on offering of 8,500,000 shares of common stock at a price of $28.00 per share, including the exercise in full by the underwriters of their option to purchase an additional 1,200,000 shares of common stock. We received net proceeds of $223.1 million, after deducting discounts, commissions and other offering expenses.

In February 2025, the Company's wholly owned subsidiary, SafeGuard Healthcare, LLC, established a note receivable in the principal amount of $25.0 million through a convertible promissory note (Note) from SP Healthcare SPV I, LLC (SPV). The SPV used the proceeds from the Note to make an investment in Biovire, Inc. for the purpose of Biovire acquiring substantially all of the assets of a contract manufacturing organization that provides clinical supply of cretostimogene to the Company. See footnote 4 for more information on the accounting for the Note.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements as of March 31, 2025 and for the three months ended March 31, 2025 and 2024 have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) for interim financial information and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2024 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 (2024 Annual Report). In the opinion of management, the unaudited condensed consolidated financial statements reflect all adjustments, which include only normal and recurring adjustments, considered necessary for a fair statement of the interim periods.

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenue and expenses during the reporting period.

Liquidity and Management's Plans

As of March 31, 2025, the Company had approximately $688.4 million of cash, cash equivalents and marketable securities and working capital of approximately $678.6 million. The Company has a relatively limited operating history, and the revenue and income potential of the Company's business and market are unproven. The Company has experienced net losses and negative cash flows from operations since its inception and, as of March 31, 2025, the Company had an accumulated deficit of $252.4 million. During the three months ended March 31, 2025, the Company incurred a net loss of $34.5 million and negative cash flows from operations of $29.3 million. The Company will continue to incur significant costs and expenses related to its ongoing operations until it successfully develops, obtains regulatory approval, and gains market acceptance of a product candidate and achieves a level of revenues adequate to support the Company's operations.

At-the-Market Offering

On March 28, 2025, the Company entered into an Open Market Sale Agreement℠ (Jefferies Sales Agreement) with Jefferies LLC, as agent, pursuant to which the Company may offer and sell, from time to time through Jefferies, up to $250 million of shares of the Company's common stock. As of March 31, 2025, no sales have been made under the Jefferies Sales Agreement.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements appearing in its 2024 Annual Report.

Deferred Offering Costs

The Company capitalizes as deferred offering costs all direct and incremental legal, professional, accounting and other third-party fees incurred in connection with the filing of a registration statement on Form S-3. As of March 31, 2025 and December 31, 2024, the Company had $0.4 million and zero, respectively, in deferred offering costs, of which $0.2 million and zero were in accrued expenses, respectively. Deferred offering costs are included in Other assets in the Company's condensed consolidated balance sheets.

Recently Issued Accounting Standards

Accounting standards not listed below were assessed and determined not to be applicable or are expected to have minimal impact on the Company's condensed consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The guidance includes the requirement that public business entities, on an annual basis, disclose specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5% of the amount computed by multiplying pretax income (or loss) by the applicable statutory income tax rate). It also requires that all entities disclose, on an annual basis, the amount of income taxes paid (net of refunds received) disaggregated by federal (national), state, and foreign taxes and the amount of income taxes paid (net of refunds received) disaggregated by individual jurisdictions in which income taxes paid (net of refunds received) is equal to or greater than 5% of total income taxes paid (net of refunds received) and requires that all entities disclose income (or loss) from continuing operations before income tax expense (or benefit) disaggregated between domestic and foreign and income tax expense (or benefit) from continuing operations disaggregated by federal (national), state, and foreign. Lastly, the guidance eliminates the requirement for all entities to disclose the nature and estimate of the range of the reasonably possible change in the unrecognized tax benefits balance in the next 12 months or make a statement that an estimate of the range cannot be made. The guidance is effective for the Company for annual periods beginning after December 15, 2025. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The guidance should be applied on a prospective basis. Retrospective application is permitted. The Company is currently evaluating the impact that this guidance may have on its financial statements.

In November 2024, the FASB issued ASU No. 2024-03, *Comprehensive Income - Expense Disaggregation Disclosures*, which will improve the disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types of expenses in commonly presented expense captions such as cost of sales, selling, general and administrative, and research and development. The amendments are effective for fiscal years beginning after December 15, 2026. Early adoption is permitted for annual financial statements that have not yet been issued or made available. The amendments should be applied on either (1) prospectively to financial statements issued for reporting periods after the effective date or (2) retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the provisions of the amendments and the effect on its future consolidated financial statements.

3. Fair Value Measurements

The following tables present the financial instruments carried at fair value on a recurring basis as of March 31, 2025 and December 31, 2024, respectively, in accordance with the ASC 820, *Fair Value Measurement* (ASC 820) hierarchy (in thousands):

	Fair Value Measurements at March 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 41,057	$ —	$ —	$ 41,057
Marketable securities	$ —	$ 646,962	$ —	$ 646,962

	Fair Value Measurements at December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 256,204	$ —	$ —	$ 256,204
Marketable securities	$ —	$ 484,930	$ —	$ 484,930

The Company’s cash equivalents represent deposits in a short-term U.S. Treasury money market fund quoted in an active market and were classified as a Level 1 fair value measurement. Marketable securities represent fixed income securities (U.S. treasury bills) with original maturities greater than 90 days and were classified as a Level 2 fair value measurement. As of March 31, 2025 and December 31, 2024, the amortized cost of the Company's available for sale marketable securities approximated their fair value. There was no material realized or unrealized gains or losses, either individually or in the aggregate.

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the three months ended March 31, 2025 and the year ended December 31, 2024.

4. Note Receivable

The Company has a note receivable from SPV totaling $25.0 million, which was established in February 2025. The note carries an interest rate of 8% and is due on February 3, 2029. As of March 31, 2025, no payments have been made, and the outstanding principal balance is $25.0 million. The note is recognized on an amortized cost basis, which is equal to the principal amount, adjusted for accrued interest. The Company assesses the collectability of this note on an ongoing basis and has determined that it is fully collectible as of the reporting date.

5. Accrued Expenses and Other Current Liabilities

The components of accrued expenses and other current liabilities as of March 31, 2025 and as of December 31, 2024 were as follows (in thousands):

	March 31, 2025	December 31, 2024
External research and development expenses	$ 10,861	$ 7,181
Personnel-related expenses	2,336	5,793
Professional fees	1,978	1,255
Deferred offering costs	215	—
Other	266	436
Total accrued expenses and other current liabilities	$ 15,656	$ 14,665

6. Commitments and Contingencies

Operating Leases

As of March 31, 2025 and December 31, 2024, the Company had three and two operating leases, respectively, in which the Company was the lessee for office space. As of March 31, 2025, the leases have varying terms expiring between 2026 and 2030. The Company had no finance leases as of March 31, 2025 and December 31, 2024.

The components of lease expense as of March 31, 2025 and 2024 were as follows (in thousands):

	Three Months Ended March 31, 2025	2024
Lease cost		
Operating lease cost	$ 67	$ 61
Total lease cost	$ 67	$ 61
Other information		
Operating lease right-of-use asset obtained in exchange for new operating lease liabilities	$ 859	$ —
Cash paid for amounts included in the measurement of lease liabilities, included in operating cash flows	$ 75	$ 58
Weighted-average remaining lease term	3.94	1.92
Weighted-average discount rate	6.77%	1.63%

Maturities of lease liabilities as of March 31, 2025 were as follows (in thousands):

2025	$ 230
2026	324
2027	274
2028	227
2029	123
Thereafter	10
Total lease payment	1,188
Less: amount representing imputed interest	(152)
Total future minimum lease obligations	$ 1,036

Legal Proceedings

A liability for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources is recorded in the condensed consolidated financial statements if it is determined that it is probable that a loss has been incurred, and that the amount (or range) of the loss can be reasonably estimated.

On March 4, 2024, a complaint was filed against the Company in the Superior Court of the State of Delaware by ANI Pharmaceuticals, Inc. seeking a declaratory judgment that an assignment and technology transfer agreement between the Company and ANI, dated November 15, 2010, obligates the Company to pay ANI a royalty on certain "net sales" of cretostimogene. The court set a trial date for July 21, 2025. The Company disputes the allegations and is vigorously defending the matter.

Indemnification

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with officers and members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. As of March 31, 2025, the Company had not experienced any losses related to these indemnification obligations, and no claims with respect thereto were outstanding.

7. License and Collaboration Agreements

Lepu Biotech Co., Ltd.

In March 2019, the Company entered into a development and license agreement with Lepu for cretostimogene (the Lepu License Agreement). Under the terms of the Lepu License Agreement, the Company granted to Lepu an exclusive license to develop, manufacture and commercialize cretostimogene and/or DDM to treat and/or prevent cancer in mainland China, including Hong Kong and Macau (the Lepu Territory). The Company is obligated to use commercially reasonable efforts to supply Lepu with its requirements of cretostimogene and DDM for its development activities at Lepu's cost and to periodically provide Lepu with manufacturing documentation and, at Lepu's cost, reasonably requested assistance related to the manufacture of clinical and, if applicable, commercial supplies of cretostimogene and DDM. The Company determined that control of the license was transferred to Lepu on March 2019 upon execution of the contract.

Lepu paid to the Company a one-time upfront payment of $4.5 million and is obligated to make regulatory milestone payments of up to $2.5 million and commercial milestone payments of up to $57.5 million. The Company is entitled to receive a high single-digit royalty on net sales of cretostimogene and/or DDM sold in the Lepu Territory, subject to a specified reduction. Lepu's royalty obligations will expire upon termination of the Lepu License Agreement.

The Company assessed the Lepu License Agreement in accordance with ASC 606, *Revenue Recognition* (ASC 606) and determined that the performance obligation is comprised solely of the license grant to Lepu. The Company determined the transaction price was $4.5 million and recorded the entire amount upon transfer of control of the functional intellectual property license rights in 2019. The Company evaluated the provision of manufacturing activities related to clinical and commercial supply of the licensed products and concluded that the manufacturing activities were not performance obligations as the terms do not provide a material right to Lepu.

Future milestone payments are fully contingent as the risk of significant revenue reversal will only be resolved depending on future regulatory approval and sales level outcomes. The Company will re-evaluate the likelihood of achieving future milestones at the end of each reporting period.

The sales-based royalty fee is considered variable consideration and will be recognized as revenue as such sales occur. The sales-based royalty fee qualifies for the royalty constraint exception and does not require an estimate of the future transaction price.

The Company recorded zero and $0.5 million in license and collaboration revenue for the three months ended March 31, 2025 and 2024, respectively.

Kissei Pharmaceutical Co., Ltd.

In March 2020, and amended as of September 2022, the Company entered into a license and collaboration agreement with Kissei (the Kissei License Agreement). Under the terms of the Kissei License Agreement, the Company granted to Kissei an exclusive license to certain intellectual property rights in Bangladesh, Bhutan, Brunei, Cambodia, India, Indonesia, Japan, South Korea, Laos, Malaysia, Myanmar, Nepal, Pakistan, Palau, Philippines, Singapore, Sri Lanka, Taiwan, Thailand and Vietnam (the Kissei Territory), for Kissei to develop and commercialize, but not manufacture, cretostimogene in combination with DDM (the Licensed Product) for all uses in oncology indications for which marketing approval is being sought. Under the Kissei Agreement, the Company and Kissei agree to use commercially reasonable efforts to collaborate on clinical development activities in the Kissei Territory and each party is responsible for conducting the applicable activities pursuant to an agreed development plan. Kissei is responsible for the costs of developing the Licensed Product in the Kissei Territory, and the Company is responsible for the costs of developing the Licensed Product outside the Kissei Territory (Global Development), provided that Kissei is responsible for a low-double digit percentage and the Company is responsible for a high-double digit percentage of the cost of development activities that cannot be attributed solely to the Kissei Territory or outside the Kissei Territory. The Company is obligated to supply and Kissei will exclusively purchase its clinical and commercial requirements of Licensed Product from the Company. Kissei is responsible for commercializing the Licensed Product in the Kissei Territory and is obligated to use commercially reasonable efforts to seek regulatory approval for and commercialize at least one Licensed Product in a specified indication. Until a certain period of time has passed after the first regulatory approval of the Licensed Product, the Company is prohibited from commercializing certain competing products worldwide and Kissei is prohibited from researching, developing or commercializing certain competing products worldwide.

Under the terms of the Kissei License Agreement, the Company received a $10.0 million one-time upfront payment and, in connection with entry into this agreement, Kissei purchased $30.0 million worth of Series D redeemable convertible preferred stock as part of the Company's Series D financing. Kissei is obligated to make development and regulatory milestone payments to the Company of up to $33.0 million and commercial milestone payments of up to $67.0 million. The Company has agreed to pay Kissei a royalty on net sales of Licensed Product outside the Kissei Territory and outside the Lepu Territory (as described above), including on any U.S. sales, in a low-single digit percentage, subject to certain capped reductions. The Company is entitled to receive a royalty on net sales of Licensed Product in the Kissei Territory in the mid-twenties percentage, subject to certain capped reductions. Also, Kissei has the right to offset the royalty payments due to the Company with respect to the cost for the supply of Licensed Product sold by the Company to Kissei, and to indefinitely carryforward credits for any excess supply amounts paid over royalty amounts owed in a given quarter. The Company is entitled to receive a specified minimum percentage of royalties on net sales of a given Licensed Product in a given country and a given quarter, unless, if for such Licensed Product in such country and such quarter, Kissei has taken the maximum allowable reductions and the ratio of the cost for the supply of Licensed Product to the sales price for Licensed Product exceeds a low-double digit percentage threshold, then the Company shall receive no royalties on the net sales of such Licensed Product in such country and such quarter. Kissei's and the Company's royalty obligations will expire on a Licensed Product-by-Licensed Product and country-by-country basis on the later of twelve years from the date of first commercial sale of such Licensed Product in such country or when there is no longer a valid patent claim covering such Licensed Product in such country.

The Kissei Agreement will expire on a Licensed Product-by-Licensed Product and country-by-country basis when there is no remaining royalty or milestone payment obligation due to a party with respect to such Licensed Product in such country. Following expiration of the Kissei Agreement in its entirety, the licenses the Company granted to Kissei will become non-exclusive, fully-paid royalty-free and irrevocable and Kissei will have the right to negotiate directly with the Company's product suppliers for the direct supply of Licensed Product to Kissei. The Kissei Agreement may be terminated either by Kissei or by the Company in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, insolvency or similar circumstances. In addition, the Company have the right to terminate the Kissei Agreement in the event that Kissei commences a legal action challenging the validity, enforceability or scope of any licensed patents under the Kissei Agreement. Kissei may terminate the Kissei Agreement at will upon specified written notice. Additionally, Kissei may terminate the Kissei Agreement for the Company's willful and malicious misconduct that results in substantial and irreparable harm to the commercial value of the Licensed Products in the Kissei Territory and upon any such termination, the licenses the Company granted to Kissei will become royalty-free and fully paid-up and Kissei will have the right to negotiate directly with the Company's contract manufacturing organizations for the supply of Licensed Product. Upon termination of the Kissei Agreement for any other reason all rights and licenses granted to Kissei to develop and commercialize the product under the Kissei Agreement will terminate, subject to certain rights to sell existing inventory of Licensed Products by Kissei and its sublicensees. Upon termination of the Kissei Agreement for Kissei's breach, any sublicenses granted by Kissei may, upon the Company's discretion, continue.

The Company evaluated the Kissei Agreement to determine whether it is a collaborative arrangement in the scope of ASC 808, *Collaborative Arrangements* (ASC 808). The Company concluded the Kissei Agreement is a collaborative agreement under ASC 808, as the Kissei Agreement involves a joint operating activity, each party is an active participant in the activities related to the Kissei Agreement, and both parties are exposed to significant risks and rewards dependent upon the commercial success of the activities related to the Kissei Agreement.

The Company determined the Kissei Agreement contained two material components: (i) an exclusive license granted to Kissei to certain intellectual property rights in the Kissei Territory, for Kissei to develop and commercialize, but not manufacture, the Licensed Product for all uses in oncology; and (ii) the parties' participation in the Global Development of the Licensed Product. The Company used the criteria specified in ASC 606 to determine which of the components of the Kissei Agreement are performance obligations with a customer and concluded Kissei is the Company's customer for the license and related activities in the Kissei Territory under ASC 606. The Global Development activities under the agreement does not present a transaction with a customer and the payments received by the Company for Global Development activities, including manufacturing, will be accounted for as a reduction of related expenses.

The Company evaluated the Kissei Territory specific license and related activities under ASC 606, as these transactions are considered transactions with a customer, and identified two material promises at the outset of the Kissei License Agreement, which consists of the following: (1) the exclusive license and (2) the manufacturing activities related to development and commercial supply of the Licensed Product in the Kissei Territory. The Company further evaluated the material promise associated with manufacturing activities related to development and commercial supply of the Licensed Products in the Kissei Territory. Given Kissei is not obligated to purchase any minimum amount or quantities of the development and commercial supply from the Company, the Company concluded, for the purpose of ASC 606, the provision of manufacturing activities related to development and commercial supply of the Licensed Product in the Kissei Territory was an option but not a performance obligation of the Company at the inception of the Kissei Agreement and will be accounted for if and when exercised. The Company also concluded there is no separate material right in connection with the development and commercial supply of the licensed product, as the expected pricing was not issued at a significant and incremental discount. Therefore, the manufacturing activities were excluded as performance obligation at the outset of the arrangement.

The Company evaluated the license under ASC 606 and concluded the license is a functional intellectual property license. The Company determined Kissei benefited from the license at the time of grant and, therefore, the related performance obligation was satisfied at a point in time. Additionally, the Company is entitled to development and regulatory milestones as well as sales milestones and royalties from Kissei upon future sales of the Licensed Product in the Kissei Territory. Future milestone payments are fully contingent as the risk of significant reversal will only be resolved depending on future development milestones, regulatory approval and sales level outcomes. The Company re-evaluates the likelihood of achieving future milestones at the end of each reporting period. The royalties are considered variable consideration and will be recognized as revenue as such sales occur. The sales-based royalties qualify for the royalty constrain exception and do not require an estimate of the future transaction price.

The Company recorded less than $0.1 million and zero in license and collaboration revenue for the three months ended March 31, 2025 and 2024, respectively.

8. Segment Disclosures

The Company operates as a single operating segment. The Company's chief operating decision maker (CODM) is its chief executive officer, who reviews financial information presented on a consolidated basis. The CODM uses consolidated net income (loss) to assess financial performance and allocate resources. The CODM does not review assets in evaluating the results of the single segment and therefore, such information is not presented.

The following table presents selected financial information with respect to the Company's single operating segment for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
	2025	2024
Revenue	$ 52	$ 529
Less:		
Research and development		
Clinical and manufacturing	23,065	14,226
Other research and development[(1)]	4,402	2,984
Total research and development	27,467	17,210
General and administrative	14,789	5,788
Total operating expenses	42,256	22,998
Loss from operations	(42,204)	(22,469)
Other income, net	7,752	5,535
Net loss	$ (34,452)	$ (16,934)

(1) Other research and development consists of indirect costs incurred for the benefit of the research and development efforts, including certain personnel, supply chain, quality assurance, and regulatory affairs.

9. Common Stock

The Company is authorized to issue up to 700,000,000 shares of common stock at March 31, 2025 and December 31, 2024, of which 76,221,289 and 76,154,783 shares were issued and outstanding at March 31, 2025 and December 31, 2024, respectively.

Voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers and preferences of the holders of the preferred stock.

Voting

Each holder of outstanding shares of common stock shall be entitled to one vote in respect of each share. The holders of outstanding shares of common stock, voting together as a single class, shall be entitled to elect one director. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of a majority of the outstanding shares of common stock and preferred stock voting together as a single class.

Dividends

The holders of common stock shall be entitled to receive dividends out of funds legally available therefore at such times and in such amounts as the board of directors may determine in its sole discretion.

Liquidation Rights

Upon any voluntary or involuntary liquidation, dissolution or winding-up of the Company or deemed liquidation event of the Company, all of the remaining assets of the Company available for distribution to the stockholders shall be distributed among the holders of the common stock, pro rata based on the number of shares held by each such holder.

Reserved Shares

As of March 31, 2025, the Company reserved the following shares of common stock for issuance:

	March 31, 2025
Stock options outstanding	6,607,154
Reserved for future stock option issuances	6,155,929
Reserved for future ESPP issuances	751,077
Total	13,514,160

10. Stock-Based Compensation

In 2015, the Company established the 2015 Plan, under which the Company may grant options and restricted stock to its employees and certain non-employees. As of March 31, 2025, there were 905,885 shares of common stock subject to outstanding awards under the 2015 Plan. In 2022, the Company established the 2022 Plan, under which the Company may grant options, restricted stock units, restricted stock, stock appreciation rights, dividend equivalents and other stock and cash-based awards to its employees and certain non-employees. As of March 31, 2025, there were 3,337,431 shares of common stock subject to outstanding awards under the 2022 Plan.

On January 11, 2024, the Company's board of directors and stockholders approved the 2024 Equity Incentive Plan (the 2024 Plan), which became effective on the date immediately preceding the date on which the Company's registration statement was declared effective by the SEC. The 2024 Plan replaced the 2022 Plan, as the Company's board of directors has determined to not make additional grants under the 2022 Plan following the closing of the offering. However, the 2015 and 2022 Plan will continue to govern outstanding equity awards granted under the 2015 and 2022 Plans. The 2024 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors and consultants. The number of shares initially available for issuance under awards granted pursuant to the 2024 Plan is (1) 8,246,565 shares, plus (2) any shares subject to outstanding awards under the 2015 Plan and 2022 Plan as of the effective date of the 2024 Plan that become available for issuance under the 2024 Plan thereafter in accordance with its terms. As of March 31, 2025, there were 2,363,838 shares of common stock subject to outstanding awards and 6,155,924 shares of common stock remaining and available for issuance under the 2024 Plan.

The Company may grant options to purchase authorized but unissued shares of the Company's common stock. Options granted under the 2015 Plan, 2022 Plan and 2024 Plan include incentive stock options that can be granted only to the Company's employees and non-statutory stock options that can be granted to the Company's employees, consultants, advisors and directors.

The exercise prices, vesting and other restrictions of the awards granted under the 2015 Plan, 2022 Plan and 2024 Plan are determined by the Board, except that no stock option may be issued with an exercise price less than the fair market value of the common stock at the date of the grant or have a term in excess of ten years. Options granted under the 2015 Plan, 2022 Plan and 2024 Plan are exercisable in whole or in part at any time subsequent to vesting.

Stock Options

The following table provides the assumptions used in determining the fair value of option awards for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
	2025	2024
Expected volatility	73.39% - 74.09%	84.5%
Risk-free interest rate	4.05% - 4.5%	3.93%
Expected dividend yield	0%	0%
Expected term (in years)	6.0 - 6.1	6.05

The weighted average grant-date fair value of the options granted was $27.30 and $13.94 per share for the three months ended March 31, 2025 and 2024, respectively. The fair value of shares vested during the three months ended March 31, 2025 and 2024 was $16.61 and $3.40 per share, respectively. The fair value of shares exercised during the three months ended March 31, 2025 and 2024 was $2.84 and $1.82 per share, respectively.

The following table summarizes stock option activity for the three months ended March 31, 2025 (in thousands, except share and per share amounts):

	Number of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2024	6,574,580	$ 14.19	8.20	$ 108,155
Granted	67,134	$ 27.30		
Exercised	(34,487)	$ 2.84		
Forfeited/Expired	(73)	$ 36.63		
Balance at March 31, 2025	6,607,154	$ 14.38	7.99	$ 87,311
Vested and expected to vest at March 31, 2025	6,607,154	$ 14.38	7.99	$ 87,311
Exercisable at March 31, 2025	2,494,428	$ 6.88	6.79	$ 46,115

The Company recorded stock-based compensation expense related to stock options of $4.4 million and $1.5 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, the Company had an aggregate $52.3 million of gross unrecognized stock-based compensation expense related to unvested options to be recognized over a weighted average period of 3.1 years.

Stock-based compensation expense related to stock options and the 2024 Employee Stock Purchase Plan (see Note 9) recorded in the accompanying statements of operations for the three months ended March 31, 2025 and 2024 was as follows (in thousands):

	For the Three Months Ended March 31, 2025	2024
Research and development	$ 1,652	$ 543
General and administrative	3,499	974
Total stock-based compensation expense	$ 5,151	$ 1,517

The Company has not recognized and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance related to its net deferred tax assets.

11. Employee Stock Purchase Plan

On January 11, 2024, the Company's board of directors and stockholders approved the 2024 Employee Stock Purchase Plan (the ESPP), which became effective on the date on which the Company's registration statement was declared effective by the SEC. The number of shares initially available for issuance pursuant to the ESPP is 812,242 shares. The ESPP provides for the sale of the Company's common stock to eligible employees at 85% of the fair market value of the Company's common stock at the commencement date of each offering period or the relevant date of purchase, whichever is lower. Payroll deductions are limited to 15% of the employee's eligible compensation, subject to IRS limits. In addition, employees may not buy more than 100,000 shares during any purchase period or offering period. There were 32,019 shares purchased under the ESPP during the three months ended March 31, 2025. On March 31, 2025, there were approximately 0.8 million shares available for issuance under the ESPP.

The Company recorded stock-based compensation expense under the ESPP of approximately $0.7 million for the three months ended March 31, 2025. As of March 31, 2025, the Company had $2.7 million of gross unrecognized stock-based compensation expense under the ESPP to be recognized over a weighted average period of 1.19 years.

12. Debt

In January 2021, the Company entered into a loan agreement with SVB (the "Loan Agreement") for a term loan in three tranches. In 2021, the Company drew down on two of the tranches in the aggregate principal amount of $15.0 million. On May 12, 2023, the Company repaid all outstanding principal and accrued and unpaid interest on the funds received under the Loan Agreement and all other outstanding obligations with respect to the funds received under the Loan Agreement and made a final payment.

In connection with the Loan Agreement, the Company entered into a Success Fee Agreement (the Success Fee Agreement) with SVB in January 2021. In accordance with the Success Fee Agreement, the Company agreed to pay to SVB an amount equal to (a) the quotient of (i) the aggregate original principal amount of all Term Loan Advances made by SVB to the Company divided by (ii) $5 million, multiplied by (b) $125,000 (the Success Fee), upon the closing of a success fee event (the Success Fee Event) and, in the event of an IPO, within five business days of closing such IPO. In connection with the Company's IPO, it became obligated to pay SVB the Success Fee.

On March 5, 2024, the Company paid $0.4 million for the Success Fee under the Success Fee Agreement. As of March 31, 2025, the Company has no further obligations in connection with the Loan Agreement.

13. Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2025	2024
Numerator:		
Net loss and comprehensive loss	$ (34,452)	$ (16,934)
Denominator:		
Weighted-average common stock outstanding, basic and diluted	76,187,621	47,064,768
Net loss per share attributable to common stockholders, basic and diluted	$ (0.45)	$ (0.36)

The Company's potentially dilutive securities, which include redeemable convertible preferred stock and stock options, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Basic and diluted net loss per share attributable to common stockholders is computed in conformity with the two-class method required for participating securities. The Company considers all series of its redeemable convertible preferred stock to be participating securities as the holders of such stock have the right to receive dividends on a pari passu basis in the event that a dividend is paid on common stock. Under the two-class method, the net loss attributable to common stockholders is not allocated to the redeemable convertible preferred stock as the preferred stockholders do not have a contractual obligation to share in the Company's losses.

The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders at March 31, 2025 and 2024 because including them would have had an anti-dilutive effect:

	March 31,	
	2025	2024
Stock options outstanding	6,607,154	5,998,420
Total	6,607,154	5,998,420

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

The following discussion and analysis and the unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2024 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Annual Report on Form 10-K for the year ended December 31, 2024 (the 2024 Annual Report).

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our ongoing and planned clinical trials and preclinical studies for cretostimogene and any future product candidates, the timing and likelihood of regulatory filings and approvals for cretostimogene and any future product candidates, our ability to commercialize cretostimogene and any future product candidates, if approved, the pricing and reimbursement of cretostimogene and any future product candidates, if approved, the potential to develop future product candidates, the potential benefits of strategic collaborations and potential to enter into any future strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "contemplate," "continue" "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target" or "will" or the negative of these terms or other similar expressions. These forward-looking statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial and other trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties, and assumptions, including, without limitation, the risk factors described in Part I, Item 1A, "Risk Factors" of the 2024 Annual Report. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Overview

We are a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients afflicted with bladder cancer. Our goal is to develop cretostimogene grenadenorepvec (cretostimogene), our product candidate, as an alternative to Bacillus Calmette-Guérin (BCG) in treating a broad range of bladder cancer indications. Cretostimogene is in clinical development for the treatment of patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) who are unresponsive to BCG therapy, the current standard-of-care for high-risk NMIBC. Given the limitations of currently approved therapies, the next course of treatment for these BCG-unresponsive patients is radical cystectomy, or the complete removal of the bladder, which is associated with significant social, functional and emotional burden. As such, there is a significant unmet need for effective treatments in these patients.

In anticipation of potential FDA approval, we are actively building our commercial operations, marketing, market access and patient access and field force capabilities. This includes pre-launch activities currently being executed, including scientific communication activities and engagements by our field medical organization. We are also implementing strategic initiatives to build seamless product distribution and patient support. Our efforts are focused on ensuring that we are fully prepared to launch and deliver cretostimogene to patients and healthcare providers, if approved. We are evaluating the safety and efficacy of cretostimogene as a monotherapy in BOND-003 Cohort C, our ongoing Phase 3 clinical trial in high-risk BCG-unresponsive NMIBC with carcinoma *in situ* (CIS) and with or without Ta/T1 disease. We have completed enrollment for this cohort and reported interim data at the American Urological Association's (AUA) 2024 Annual Meeting in May 2024, and topline data at the 2024 Society of Urologic Oncology (SUO) Annual Meeting in December 2024, which was updated at the 40th Annual European Association of Urology (EAU) Congress in March 2025, and at the 2025 AUA Annual Meeting in April 2025. We believe that this trial could serve as the basis for a BLA submission to the U.S. FDA, which we expect to initiate in the second half of 2025. Cretostimogene has received both Fast Track and Breakthrough Therapy designations from the FDA for the treatment of High-Risk BCG-unresponsive NMIBC with CIS with or without Ta or T1 tumors.

In April 2024, we initiated BOND-003 Cohort P, an exploratory study evaluating cretostimogene monotherapy in high-risk BCG-unresponsive NMIBC with only Ta/T1 disease. Initial data from this Cohort was reported at the 2025 AUA Annual Meeting, with updated data expected in the second half of 2025. In October 2024, we initiated CORE-008 Cohort A, our Phase 2 clinical trial in high-risk NMIBC patients who are naïve to BCG treatment, including patients with CIS and with or without Ta/T1 disease and patients with only Ta/T1 disease. In March 2025, we expanded CORE-008 into the high-risk BCG-exposed population (Cohort B). In addition, in April 2025, we initiated a third Cohort (Cohort CX), evaluating cretostimogene in combination with gemcitabine in the high-risk BCG-exposed population. We have completed and published the results for CORE-001, our Phase 2 clinical trial of cretostimogene in combination with pembrolizumab in high-risk BCG-unresponsive NMIBC patients that have CIS. Additionally, in NMIBC that is not categorized as high-risk, we have launched our second Phase 3 clinical trial, PIVOT-006, evaluating adjuvant cretostimogene in intermediate-risk NMIBC following transurethral resection of the bladder tumor (TURBT). We believe cretostimogene, if approved in intermediate-risk NMIBC, has the potential to serve as backbone therapy, thereby alleviating the current need to prioritize treatment recipients and ration administration of BCG given its significant market shortage.

Since our inception in 2010, we have focused substantially all of our resources on organizing and staffing our company, business planning, raising capital, establishing and maintaining our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of cretostimogene, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales.

We have incurred significant operating losses and negative cash flows from operations since our inception. Our net losses were $34.5 million and $16.9 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of $252.4 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and, to a lesser extent, from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses in the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for, and potentially commercialize cretostimogene and potentially seek to discover and develop additional product candidates, utilize third parties to manufacture cretostimogene, hire additional personnel, expand and protect our intellectual property, and incur additional costs associated with being a public company. If we obtain regulatory approval for cretostimogene, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we do not become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce or terminate our operations.

To date, we have primarily funded our operations with proceeds from the sale of shares of our common stock through public offerings and our redeemable convertible preferred stock, as well as through previously outstanding term debt. From inception through March 31, 2025, we have received aggregate gross proceeds of approximately $982.9 million from the sale of shares of our common stock from our IPO, a follow-on offering in December 2024, and sales of redeemable convertible preferred stock. In addition, from inception through March 31, 2025, we have recognized $26.2 million in license and collaboration revenue pursuant to our license and collaboration agreements. As of March 31, 2025, we had cash, cash equivalents and marketable securities of $688.4 million. Our ability to generate any product revenue and, in particular, our ability to generate product revenue sufficient to achieve profitability, will depend on the successful development and eventual commercialization of cretostimogene and any future product candidates.

Based on our current operating plan, we estimate that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations into the first half of 2028. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, we could utilize our available capital resources sooner than we expect.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for cretostimogene or any future product candidates, which we expect will take a number of years and may never occur. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through equity offerings, debt financings, or other capital sources, including current or potential future collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements or arrangements as, and when needed, we may 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, or even cease operations.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of cretostimogene for clinical testing, as well as for commercial manufacture if we obtain marketing approval. In addition, we rely on third parties to package, label, store, and distribute cretostimogene, and we intend to rely on third parties for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the development of cretostimogene.

License and Collaboration Agreements

Below is a summary of the key terms for certain of our license and collaboration agreements. For a more detailed description of these agreements, see the section titled "Business—License and Collaboration Agreements" in our 2024 Annual Report.

Lepu License Agreement

In March 2019, we entered into a development and license agreement (the Lepu License Agreement) with Lepu, under which we granted an exclusive license to Lepu to develop, manufacture and commercialize cretostimogene and/or DDM to treat and/or prevent cancer in the Lepu Territory. Lepu paid to us a one-time upfront payment of $4.5 million and is obligated to make regulatory milestone payments of up to $2.5 million and commercial milestone payments of up to $57.5 million. We are entitled to receive a high single-digit royalty on net sales of cretostimogene and/or DDM sold in the Lepu Territory, subject to a specified reduction. During the three months ended March 31, 2025 and 2024, zero and $0.5 million in license and collaboration revenue was recorded related to the Lepu License Agreement, respectively.

Kissei License Agreement

In March 2020, and as amended September 2022, we entered into a license and collaboration agreement (the Kissei License Agreement) with Kissei, under which we granted to Kissei an exclusive license to certain intellectual property rights in Bangladesh, Bhutan, Brunei, Cambodia, India, Indonesia, Japan, South Korea, Laos, Malaysia, Myanmar, Nepal, Pakistan, Palau, Philippines, Singapore, Sri Lanka, Taiwan, Thailand and Vietnam (the Kissei Territory), for Kissei to develop and commercialize, but not manufacture, cretostimogene in combination with DDM (the Licensed Product) for all uses in oncology. Kissei paid to us a one-time upfront payment of $10.0 million under the agreement. Kissei is obligated to pay development milestone payments of up to $33.0 million and commercial milestone payments of up to $67.0 million. We have also agreed to pay Kissei a royalty on net sales of Licensed Product outside the Kissei Territory and outside the Lepu Territory, including on any U.S. sales, in a low-single digit percentage, subject to certain capped reductions. We are entitled to receive a royalty on net sales of Licensed Product in the Kissei Territory in the mid-twenties percentage, subject to certain capped reductions and offset rights. We are obligated to supply and Kissei will exclusively purchase its clinical and commercial requirements of Licensed Product from us. During the three months ended March 31, 2025, all license and collaboration revenue recorded was related to the Kissei License Agreement, with no license and collaboration revenue related to the Kissei License Agreement recorded during the three months ended March 31, 2024.

Components of Our Results of Operations

Revenue

From inception through March 31, 2025, we have recognized $26.2 million in license and collaboration revenue through our license and collaboration agreements. We have not generated any revenue from the sale of products, however, and do not expect to generate any revenue from the sale of products in the foreseeable future, if at all. If our or our collaborators' development efforts for cretostimogene and any future product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales, payments from existing or potential future collaboration or license agreements with third parties, or any combination thereof.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development Expenses

Research and development (R&D) expenses consist primarily of external and internal costs incurred in performing clinical and preclinical development activities.

Our R&D expenses consist of:

- external costs incurred under agreements with contract research organizations (CROs), contract manufacturers, consultants and other third parties to conduct and support our clinical trials and preclinical studies; and
- internal costs, including R&D personnel-related expenses such as salaries, stock-based compensation and benefits, as well as allocated facilities costs and dues and subscriptions.

We expense R&D costs as incurred. We currently only have one product candidate, cretostimogene. Therefore, since our inception, substantially all of our R&D costs were related to the development of cretostimogene. We track R&D expenses on an aggregate basis and not on an indication-by-indication or treatment setting-by-treatment setting basis.

Although R&D activities are central to our business model, the successful development of cretostimogene and any future product candidates is highly uncertain. There are numerous factors associated with the successful development of any product candidate such as cretostimogene, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our R&D expenses will increase substantially in connection with our ongoing and planned clinical and preclinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of cretostimogene and any future product candidates. Our future R&D expenses may vary significantly based on a wide variety of factors such as:

- the number and scope, rate of progress, expense and results of our clinical trials and preclinical studies of cretostimogene and any future product candidates we may choose to pursue, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing cretostimogene and any future product candidates;
- the costs, if any, of obtaining third-party drugs for use in our combination trials;
- the extent of changes in government regulation and regulatory guidance;
- the efficacy and safety profile of cretostimogene and any future product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities; and
- the extent to which we establish additional collaboration, license, or other arrangements.

A change in the outcome of any of these variables with respect to the development of cretostimogene or any future product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses such as salaries, stock-based compensation and benefits, for our personnel in executive, legal, finance and accounting, human resources and other administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters and professional fees paid for accounting, auditing, consulting and tax services, as well as facilities-related costs not otherwise included in R&D expenses and other costs such as insurance costs and travel expenses.

We anticipate our general and administrative expenses will increase substantially in the future as we expand our operations, including increasing our headcount to support our continued R&D activities and preparing for potential commercialization of cretostimogene. We also anticipate we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance, and investor and public relations expenses associated with operating as a public company.

Other Income (Expense), Net

Interest Income, Net

Interest income, net, consists of interest income related to interest earned on our invested cash and cash equivalents and marketable securities balances and expenses related to our previously outstanding term debt. We expect our interest income will increase as we invest the cash received from the net proceeds from our IPO.

Other Income (Expense)

Other income (expense) consists of miscellaneous items, such as success fees and final payment amortization and other items not related to our core operations.

Results of Operations

Comparison of the Three Months Ended March 31, 2025 and 2024

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,		
	2025	2024	Change
Revenue:			
License and collaboration revenue	$ 52	$ 529	$ (477)
Operating expenses:			
Research and development	27,467	17,210	10,257
General and administrative	14,789	5,788	9,001
Total operating expenses	42,256	22,998	19,258
Loss from operations	(42,204)	(22,469)	(19,735)
Other income (expense), net:			
Interest income, net	7,747	5,544	2,203
Other income (expense), net	5	(9)	14
Total other income, net	7,752	5,535	2,217
Net loss and comprehensive loss	$ (34,452)	$ (16,934)	$ (17,518)

License and Collaboration Revenue

License and collaboration revenue was $0.1 million for the three months ended March 31, 2025 compared to $0.5 million for the three months ended March 31, 2024. We recorded zero and $0.5 million in revenue for the three months ended March 31, 2025 and 2024, respectively, related to the Lepu License Agreement, and $0.1 million and zero in revenue related to the Kissei License Agreement for the three months ended March 31, 2025 and 2024, respectively.

Research and Development Expenses

The following table summarizes our R&D expenses for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,		
	2025	2024	Change
External clinical trial expenses	$ 18,301	$ 12,731	$ 5,570
Personnel-related expenses	7,673	4,113	3,560
Other research and development	1,493	366	1,127
Total research and development expenses	$ 27,467	$ 17,210	$ 10,257

R&D expenses were $27.5 million for the three months ended March 31, 2025 compared to $17.2 million for the three months ended March 31, 2024. The increase of $10.3 million in R&D expenses for the three months ended March 31, 2025 was primarily due to an increase of $5.6 million in external clinical trial expenses related to higher CRO fees as patient enrollment increased, as well as an increase of $3.6 million in compensation costs due to increased headcount, including a $1.1 million increase in stock-based compensation, and an increase in other fees and costs of $1.1 million.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,		
	2025	2024	Change
Personnel-related expenses	$ 8,441	$ 3,142	$ 5,299
Professional and consultant fees	3,222	1,781	1,441
Other general and administrative	3,126	865	2,261
Total general and administrative expenses	$ 14,789	$ 5,788	$ 9,001

General and administrative expenses were $14.8 million for the three months ended March 31, 2025 compared to $5.8 million for the three months ended March 31, 2024. The increase of $9.0 million in general and administrative expenses for the three months ended March 31, 2025 was primarily due to an increase in compensation costs of $5.3 million due to increased headcount, including a $2.5 million increase in stock-based compensation, as well as increased professional and consultant fees of $1.4 million related to legal, accounting and consulting fees, an increase in marketing-related costs of $1.1 million, and an increase in insurance, fees, and other costs of $1.2 million.

Other Income (Expense), Net

Other income (expense), net, for the three months ended March 31, 2025 was an other income, net of $7.8 million compared to an other income, net of $5.5 million for the three months ended March 31, 2024. For the three months ended March 31, 2025 and 2024, other income (expense), net primarily consisted of $7.7 million and $5.5 million, respectively, in interest income related to marketable securities balances.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We expect to incur significant expenses and operating losses in the foreseeable future as we advance the clinical development of cretostimogene and any future product candidates. To date, we have primarily funded our operations with proceeds from the sale of shares of our common stock through public offerings and our redeemable convertible preferred stock, as well as through previously outstanding term debt. Through March 31, 2025, we have received aggregate gross proceeds of $982.9 million from the sale of shares of our common stock through our public offerings and our redeemable convertible preferred stock. In addition, through March 31, 2025, we have recognized $26.2 million in license and collaboration revenue through our license and collaboration agreements. As of March 31, 2025, we had cash, cash equivalents and marketable securities of $688.4 million. On January 29, 2024, we closed our initial public offering of common stock for aggregate net proceeds of $399.6 million, after deducting discounts and commissions and other offering expenses. In December 2024, we closed a follow-on public offering of common stock for aggregated net proceeds of $223.1 million, after deducting discounts and commissions and other offering expenses.

At-the-Market Offering

On March 28, 2025, we entered into an Open Market Sale Agreement℠ (Jefferies Sales Agreement) with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time through Jefferies, up to $250 million of shares of our common stock. On the same day, we filed a shelf registration statement on Form S-3ASR with the SEC, which contains a base prospectus, covering an unlimited amount of our common stock, preferred stock, debt securities and warrants to purchase any of such securities, and a sales agreement prospectus, covering the offering, issuance and sale of up to a maximum aggregate offering price of $250 million of our common stock that may be issued and sold from time to time under the Jefferies Sales Agreement. As of the filing of this Quarterly Report, no sales have been made under the shelf registration statement or the Jefferies Sales Agreement.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue our development of, seek regulatory approval for, and potentially commercialize cretostimogene and potentially seek to discover and develop additional product candidates, conduct our ongoing and planned clinical trials and preclinical studies, continue our R&D activities, utilize third parties to manufacture cretostimogene, hire additional personnel, expand and protect our intellectual property, and incur additional costs associated with being a public company.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses, and prepaid expenses. The timing and amount of our funding requirements will depend on many factors, including:

- the initiation, type, number, scope, progress, expansions, results, costs and timing of clinical trials and preclinical studies of cretostimogene and any future product candidates we may choose to pursue, including the costs of modification to clinical development plans based on feedback that we may receive from regulatory authorities and any third-party products used as combination agents in our clinical trials
- the costs, timing and outcome of regulatory meetings and reviews of cretostimogene or any future product candidates, including requirements of regulatory authorities in any additional jurisdictions in which we may seek approval for cretostimogene and any future product candidates;
- the costs of obtaining, maintaining, enforcing and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, CMC quality and commercial personnel;
- the timing and payment of milestone, royalty or other payments we must make pursuant to our existing and potential future license or collaboration agreements with third parties;
- the costs and timing of establishing or securing sales and marketing capabilities if cretostimogene or any future product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage, and adequate reimbursement from third- party payors and adequate market share and revenue for any approved products;
- our ability and strategic decision to develop future product candidates other than cretostimogene, and the timing of such development, if any;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Based upon our current operating plan, we estimate that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations into the first half of 2028. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, we could utilize our available capital resources sooner than we expect.

We have no other committed sources of capital. Until such time, if ever, we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings, or other capital sources, including current or potential future collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments or declaring dividends. If we raise additional funds through collaborations or license agreements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or 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, or even cease operations.

Material Cash Requirements for Known Contractual and Other Obligations

During the three months ended March 31, 2025, there have been no material changes outside of the ordinary course of business in the composition to the material contractual obligations or commitments discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Material Cash Requirements for Known Contractual and Other Obligations" included in the 2024 Annual Report.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,	
	2025	2024
Net cash used in operating activities	$ (29,277)	$ (26,012)
Net cash used in investing activities	(186,769)	(307,444)
Net cash provided by financing activities	450	402,658
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (215,596)	$ 69,202

Operating Activities

During the three months ended March 31, 2025, operating activities used $29.3 million of cash, primarily resulting from our net loss of $34.5 million, as well as accretion of the discount on short-term investments of $0.3 million, partially offset by non-cash stock-based compensation charges of $5.2 million and net cash provided by changes in our operating assets and liabilities of $0.5 million.

During the three months ended March 31, 2024, operating activities used $26.0 million of cash, primarily resulting from our net loss of $16.9 million, accretion of the discount on short-term investments of $2.2 million, and net cash used in changes in our operating assets and liabilities of $8.4 million, partially offset by $1.5 million of non-cash stock-based compensation charges.

Investing Activities

During the three months ended March 31, 2025, net cash used in investing activities was $186.8 million, primarily due to purchases of marketable securities offset by proceeds from sales and maturities of short-term investments and the issuance of a note receivable through a convertible promissory note in the principal amount of $25.0 million to provide SP Healthcare SPV I, LLC with proceeds to make an investment in Biovire, Inc. for the purpose of Biovire's acquisition of substantially all of the assets of a contract manufacturing organization that provides clinical supply of cretostimogene to us.

During the three months ended March 31, 2024, net cash used in investing activities was $307.4 million, primarily due to purchases of marketable securities offset by proceeds from sales and maturities of short-term investments.

Financing Activities

During the three months ended March 31, 2025, net cash provided by financing activities was $0.5 million, consisting primarily of proceeds from exercise of options of $0.7 million, partially offset by deferred offering costs of $0.2 million.

During the three months ended March 31, 2024, net cash provided by financing activities was $402.7 million, consisting primarily of net proceeds from the initial public offering, net of issuance costs and deferred offering costs of $403.0 million, partially offset by the long-term debt success fee payoff of $0.4 million.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates" included in the 2024 Annual Report.

R&D Expenses and Related Prepaid and Accrued Expenses

As part of the process of preparing our condensed consolidated financial statements, we are required to estimate our R&D expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our R&D expenses as of each balance sheet date based on facts and circumstances known to us at that time. The significant estimates in our R&D expenses include the costs incurred for services performed by our vendors in connection with services for which we have not yet been invoiced. We base our expenses related to R&D activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct R&D on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows.

There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the R&D expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future R&D activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Standards

A description of recently issued accounting standards that may potentially impact our financial position, results of operations and cash flows is included in Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

Our exposure to market risk is limited primarily to interest rate sensitivity. As of March 31, 2025, we had cash, cash equivalents and marketable securities of approximately $688.4 million, which consisted primarily of money market funds and marketable securities, comprised of fixed income securities (U.S. Treasury bills).

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Due to the short-term duration of our investment portfolio and the low risk profile of our investment portfolio, we believe that our exposure to interest rate risk is not significant.

Effects of inflation

Inflation has not had a material effect on our business, financial condition, or results of operations as of and for the periods covered by this Quarterly Report on Form 10-Q.

Item 4. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and our principal financial officer, has evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report. Based on such evaluation, our principal executive officer and our principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2025.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the three months ended March 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

On March 4, 2024, a complaint was filed against us in the Superior Court of the State of Delaware by ANI Pharmaceuticals, Inc. seeking a declaratory judgment that an assignment and technology transfer agreement between us and ANI, dated November 15, 2010, obligates us to pay ANI a royalty on certain "net sales" of cretostimogene. The court has most recently set a trial date of July 21, 2025. We dispute the allegations and are vigorously defending the matter.

From time to time, we may be subject to other legal proceedings. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors. There have been no material developments to the legal proceedings disclosed in Part II, Item 1, "Legal Proceedings" in our 2024 Annual Report.

Item 1A. Risk Factors.

There have been no material changes to the risk factors disclosed in Part I, Item 1A, “Risk Factors” of our 2024 Annual Report.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On January 24, 2024, our registration statement on Form S-1 (File No. 333-276350) was declared effective by the SEC for our initial public offering. At the closing of our initial public offering on January 29, 2024, we sold 23,000,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 3,000,000 additional shares, at an initial public offering price of $19.00 per share and received gross proceeds of $437.0 million, which resulted in net proceeds to us of approximately $399.6 million, after deducting underwriting discounts and commissions of approximately $30.6 million and offering-related transaction costs of approximately $6.8 million. As of March 31, 2025, we estimate that we have used approximately $156.0 million of the proceeds from our initial public offering for general corporate purposes, including to fund the research and development of cretostimogene, and manufacturing and pre-commercial activities. There has been no material change in the planned use of proceeds from that described in the final prospectus for our initial public offering filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

From time to time, our Section 16 officers (as defined in Rule 16a–1(f)) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K) for the purchase or sale of our securities. During the three months ended March 31, 2025, none of our officers or directors adopted, modified or terminated any such trading arrangements.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	S-1/A	01/18/24	3.3	
3.2	Amended and Restated Bylaws	S-1	01/02/24	3.4	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1/A	01/18/24	4.1	
4.2	Amended and Restated Investors' Rights Agreement, dated July 28, 2023, as amended, by and among the Registrant and certain of its stockholders	S-1/A	01/18/24	4.2	
10.1**	Convertible Promissory Note between the Registrant's subsidiary, SafeGuard Healthcare, LLC, and SP Healthcare SPV I, LLC dated February 3, 2025				X
10.2#	Amended and Restated Non-Employee Director Compensation Program	10-K	03/28/25	10.5	
10.3#	Amended and Restated Employment Agreement, effective January 9, 2025, between Arthur Kuan and the Registrant	10-K	03/28/25	10.11	
10.4#	Amended and Restated Employment Agreement, effective January 9, 2025, between Ambaw Bellete and the Registrant	10-K	03/28/25	10.12	
10.5#	Amended and Restated Employment Agreement, effective January 9, 2025, between Vijay Kasturi and the Registrant	10-K	03/28/25	10.13	
10.6#	Amended and Restated Employment Agreement, effective January 9, 2025, between Corleen Roche and the Registrant	10-K	03/28/25	10.14	
10.7#	Amended and Restated Employment Agreement, effective January 9, 2025, between Joshua F. Patterson and the Registrant	10-K	03/28/25	10.15	
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* This certification is not being filed for purposes of Section 18 of the Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

** Portions of the exhibit (indicated by "[***]") have been omitted because they are not material and would likely cause competitive harm to us if disclosed.

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.

CG Oncology, Inc.

Date: May 13, 2025

By: /s/ Arthur Kuan
Arthur Kuan
Chairman and Chief Executive Officer

(Principal Executive Officer)

Date: May 13, 2025

By: /s/ Corleen Roche
Corleen Roche
Chief Financial Officer
(Principal Financial and Accounting Officer)