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, 2026

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.)**
3000 Pegasus Park Drive, Suite 1640 Dallas, Texas	**75247**
(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 6, 2026, the registrant had 88,202,473 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)

Assets	March 31, 2026 (unaudited)	December 31, 2025
Current assets:		
Cash and cash equivalents	$ 33,700	$ 32,490
Marketable securities	1,042,542	709,665
Inventory	1,493	1,565
Accounts receivable, net	1,275	688
Prepaid expenses and other current assets	23,133	15,067
Total current assets	1,102,143	759,475
Property and equipment, net	15,074	15,596
Operating lease right-of-use assets	4,512	3,971
Intangible assets, net	560	575
Goodwill	10,297	10,297
Other assets	2,676	1,678
Total assets	$ 1,135,262	$ 791,592
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,236	$ 5,714
Operating lease liabilities, current portion	1,066	915
Accrued expenses and other current liabilities	25,914	24,207
Total current liabilities	35,216	30,836
Long-term debt	3,000	3,000
Operating lease liabilities, net of current portion	3,509	3,106
Deferred tax liability	307	307
Other liabilities	1,451	1,741
Total liabilities	43,483	38,990
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, $0.0001 par value per share; 700,000,000 and 700,000,000 shares authorized as of March 31, 2026 and December 31, 2025, respectively; 88,007,761 and 80,689,128 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	9	8
Additional paid-in capital	1,530,948	1,131,570
Accumulated deficit	(439,178)	(378,976)
Total stockholders' equity	1,091,779	752,602
Total liabilities and stockholders' equity	$ 1,135,262	$ 791,592

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,	
	2026	2025
Revenues		
Commercial and development revenue	$ 1,069	$ —
License and collaboration revenue	14	52
Total revenues	1,083	52
Operating costs and expenses		
Cost of sales	2,962	—
Research and development	43,730	27,467
General and administrative	20,780	14,789
Total operating costs and expenses	67,472	42,256
Loss from operations	(66,389)	(42,204)
Other income (expense), net:		
Interest income, net	6,288	7,747
Other (expense) income, net	(101)	5
Total other income, net	6,187	7,752
Net loss and comprehensive loss	$ (60,202)	$ (34,452)
Net loss per share, basic and diluted	$ (0.71)	$ (0.45)
Weighted average shares of common stock outstanding, basic and diluted	84,518,512	76,187,621

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

CG ONCOLOGY, INC.

Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
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
Balance as of December 31, 2025	80,689,128	$ 8	$ 1,131,570	$ (378,976)	$ 752,602
Issuance of common stock in connection with a public offering, net of issuance costs	6,941,407	1	391,409	—	391,410
Issuance of common stock	377,226	—	1,495	—	1,495
Stock-based compensation expense	—	—	6,474	—	6,474
Net loss	—	—	—	(60,202)	(60,202)
Balance as of March 31, 2026	88,007,761	$ 9	$ 1,530,948	$ (439,178)	$ 1,091,779

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,	
	2026	**2025**
Operating Activities		
Net loss	$ (60,202)	$ (34,452)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	841	24
Stock-based compensation expense	6,474	5,151
Unrealized losses (gains) on short-term investments	1,664	(279)
Non-cash interest expense (income)	46	(176)
Non-cash lease expense	13	(14)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(8,066)	(546)
Accounts receivable, net	(587)	—
Inventory	72	—
Other assets	(998)	(35)
Accounts payable	2,522	214
Accrued expenses and other current liabilities	1,607	836
Other liabilities	(329)	—
Net cash used in operating activities	(56,943)	(29,277)
Investing Activities		
Proceeds from sales and maturities of investments	252,853	200,139
Purchases of investments	(587,394)	(361,892)
Issuance of note receivable	—	(25,000)
Purchases of property and equipment	(304)	(16)
Net cash used in investing activities	(334,845)	(186,769)
Financing Activities		
Proceeds from follow-on public offerings, net of issuance costs	391,550	—
Proceeds from exercise of common stock options	1,669	682
Withholding taxes paid on net exercise of stock options	(174)	—
Stock issuance costs	(47)	(232)
Net cash provided by financing activities	392,998	450
Net increase (decrease) in cash and cash equivalents	1,210	(215,596)
Cash and cash equivalents at beginning of period	32,490	257,068
Cash and cash equivalents at end of period	$ 33,700	$ 41,472
Supplemental Disclosure of Cash Flow Information		
Cash paid for interest	$ 47	$ —
Cash paid for taxes	$ —	$ —
Non-cash Investing and Financing Activities:		
Stock issuance costs, unpaid and accrued	$ 139	$ 215
Operating lease right-of-use asset obtained in exchange for lease liabilities	$ 791	$ 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 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, shares of the Company's common stock. As of March 31, 2026, the Company has completed the Jefferies Sales Agreement, having received gross proceeds of $550.0 million and net aggregate proceeds of $538.5 million under the Jefferies Sales Agreement, after deducting discounts and commissions and other offering expenses. During the three months ended March 31, 2026, 6,941,407 shares were sold under the Jefferies Sales Agreement, at a weighted-average price of $57.56 per share, and the Company received net proceeds of $391.4 million, after deducting discounts and commissions and other offering expenses.

In February 2025, SafeGuard Healthcare, LLC (SafeGuard), a wholly owned subsidiary of the Company, purchased a $26.8 million convertible note, including accrued interest, from SP Healthcare SPV I, LLC (the SPV). The SPV used the proceeds from the Note to invest and acquire substantially all of the assets of Biovire, Inc. (Biovire), a contract manufacturing organization that produces cretostimogene for the Company. In July 2025, SafeGuard converted the Note (the Conversion Event) and obtained control of both the SPV and Biovire. Refer to Note 15 for additional details on the Conversion Event.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements as of March 31, 2026 and for the three months ended March 31, 2026 and 2025 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, 2025 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 (2025 Annual Report), filed with the SEC on February 27, 2026. 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, 2026, the Company had approximately $1,076.2 million of cash, cash equivalents and marketable securities and working capital of approximately $1,066.9 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, 2026, the Company had an accumulated deficit of $439.2 million. During the three months ended March 31, 2026, the Company incurred a net loss of $60.2 million and had negative cash flows from operations of $56.9 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.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements in its 2025 Annual Report.

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 unaudited condensed consolidated 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.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*, which clarifies and modernizes the accounting for costs related to internal-use software. The amendments remove all references to project stages and clarify the threshold entities apply to begin capitalizing costs. The amendments are effective for fiscal years beginning after December 15, 2027 and interim reporting periods within those annual reporting periods, with early adoption permitted. The Company is currently evaluating the provisions of the amendments and the effect on its future consolidated financial statements.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow Scope Improvements*, which clarifies required interim disclosures under Topic 270 by providing a comprehensive list of required interim disclosures, and clarifies the applicability of Topic 270. This update is effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within annual reporting periods beginning after December 15, 2028, with early adoption permitted. ASU 2025-11 may be adopted on a prospective or retrospective basis. The Company is currently evaluating the impact of this guidance 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, 2026 and December 31, 2025, respectively, in accordance with the ASC 820, *Fair Value Measurement* (ASC 820) hierarchy (in thousands):

	Fair Value Measurements at March 31, 2026			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 18,445	$ —	$ —	$ 18,445
Marketable securities	$ —	$ 1,042,542	$ —	$ 1,042,542

	Fair Value Measurements at December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 16,639	$ 10,056	$ —	$ 26,695
Marketable securities	$ —	$ 709,665	$ —	$ 709,665

The Company's cash equivalents represent deposits in a short-term U.S. Treasury money market fund quoted in an active market, which were classified as a Level 1 fair value measurement, and fixed income securities (U.S. treasury bills) with original maturities of 90 days or less. Marketable securities consist primarily of fixed income securities (U.S. treasury bills and notes) and corporate bonds with original maturities greater than 90 days. All fixed income securities and corporate bonds were classified as a Level 2 fair value measurement.

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the three months ended March 31, 2026 and the year ended December 31, 2025.

4. Property and Equipment, Net

The components of property and equipment, net as of March 31, 2026 and December 31, 2025 were as follows (in thousands):

	March 31, 2026	December 31, 2025
Leasehold Improvements	$ 10,553	$ 10,499
Manufacturing and lab equipment	6,065	5,982
Machinery and Equipment	589	589
Construction in Progress	161	—
Total property and equipment, cost	17,368	17,070
Less: Accumulated depreciation	(2,294)	(1,474)
Property and equipment, net	$ 15,074	$ 15,596

Depreciation expense for the three months ended March 31, 2026 and 2025 was $0.8 million and less than $0.1 million, respectively.

5. Goodwill

Goodwill

In connection with the Conversion Event in July 2025, the Company recognized goodwill of $10.3 million. See Note 15 for additional information on this transaction.

The Company annually assesses goodwill for impairment in the fourth quarter of each calendar year and at an interim date if indicators of impairment exist. During the three months ended March 31, 2026, no goodwill impairment was recognized.

6. Accrued Expenses and Other Current Liabilities

The components of accrued expenses and other current liabilities as of March 31, 2026 and December 31, 2025 were as follows (in thousands):

	March 31, 2026	December 31, 2025
External research and development expenses	$ 18,976	$ 13,936
Personnel-related expenses	3,007	8,216
Professional fees	1,972	967
Deferred revenue	254	286
Other	1,705	802
Total accrued expenses and other current liabilities	$ 25,914	$ 24,207

7. Commitments and Contingencies

Operating Leases

The Company has entered into non-cancellable operating leases with remaining lease terms expiring between 2026 and 2034. Of the four operating leases that have commenced as of March 31, 2026, three are leases in which the Company is the lessee for office space. The remaining operating lease was acquired in connection with the Conversion Event and includes office, manufacturing, and warehouse space. In the fourth quarter of 2025, the Company entered into an additional non-cancelable operating lease for office space with a term of approximately eight years, which, along with rent payments, is expected to commence in the third quarter of 2026. The Company had no finance leases as of March 31, 2026 and December 31, 2025.

The components of lease expense for the periods ended March 31, 2026 and 2025 were as follows (in thousands):

	Three Months Ended March 31,	
	2026	2025
Lease cost		
Operating lease cost	$ 338	$ 67
Total lease cost	$ 338	$ 67
Other information		
Operating lease right-of-use asset obtained in exchange for new operating lease liabilities	$ 791	$ 859
Cash paid for amounts included in the measurement of lease liabilities, included in operating cash flows	$ 310	$ 75
Weighted-average remaining lease term (years)	3.82	3.94
Weighted-average discount rate	6.90%	6.77%

Maturities of lease liabilities as of March 31, 2026 were as follows (in thousands):

2026	1,008
2027	1,368
2028	1,354
2029	1,285
2030	205
Total lease payment	5,220
Less: amount representing imputed interest	(645)
Total future minimum lease obligations	$ 4,575

Legal Proceedings

A liability for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources is recorded in the unaudited 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 a provision in an assignment and technology transfer agreement between the Company and ANI, dated November 15, 2010 (the ANI Agreement), obligates the Company to pay ANI a royalty on certain “net sales” of cretostimogene, and (ii) compensatory damages alleging the Company was unjustly enriched by obtaining the benefit of certain non-patent assets under the ANI Agreement without paying adequate consideration to ANI. On July 16, 2025, the Superior Court granted the Company’s motion for summary judgment with respect to ANI’s request for a declaratory judgment to receive royalty payments from the potential sale of cretostimogene but denied the Company’s motion for summary judgment with respect to ANI’s unjust enrichment claim. On July 29, 2025, a jury entered a verdict in favor of the Company, unanimously rejecting all of ANI's claims for unjust enrichment damages. As a result, the Company will not owe ANI a future royalty of 5% on commercial sales of cretostimogene, no damages have been awarded to ANI, and there are no further payments due to ANI under the ANI Agreement. On April 10, 2026, the Superior Court heard oral arguments from ANI and the Company on pending post-trial motions submitted by the Company and ANI, which included (i) ANI’s Motion for Judgment as a Matter of Law; (ii) ANI’s Motion to Unseal Trial Exhibits; and (iii) CG’s Motion for Costs. As of the filing of this Quarterly Report on Form 10-Q, the Superior Court has not issued a ruling on these post-trial motions. The Company will continue to vigorously defend the post-trial motions and any appeals brought by ANI.

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, 2026, the Company had not experienced any losses related to these indemnification obligations, and no claims with respect thereto were outstanding.

8. License and Collaboration Agreements

Lepu Biotech Co., Ltd.

In March 2019, the Company entered into a development and license agreement with Lepu Biotech Co., Ltd. (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 n-Dodecyl-beta-Maltoside (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 constrained 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 recognized no license and collaboration revenue during the three months ended March 31, 2026 and 2025.

Kissei Pharmaceutical Co., Ltd.

In March 2020, and amended as of September 2022, the Company entered into a license and collaboration agreement with Kissei Pharmaceutical Co., Ltd. (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 License 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 License 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 License 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 License 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 has the right to terminate the Kissei License Agreement in the event that Kissei commences a legal action challenging the validity, enforceability or scope of any licensed patents under the Kissei License Agreement. Kissei may terminate the Kissei License Agreement at will upon specified written notice. Additionally, Kissei may terminate the Kissei License 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 License Agreement for any other reason all rights and licenses granted to Kissei to develop and commercialize the product under the Kissei License Agreement will terminate, subject to certain rights to sell existing inventory of Licensed Products by Kissei and its sublicensees. Upon termination of the Kissei License Agreement for Kissei’s breach, any sublicenses granted by Kissei may, upon the Company’s discretion, continue.

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

The Company determined the Kissei License 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 License 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 License 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 a 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 recognized less than $0.1 million in license and collaboration revenue for each of the three months ended March 31, 2026 and 2025.

9. 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, 2026 and 2025:

	Three Months Ended March 31,	
	2026	2025
Revenues		
Commercial and development revenue	$ 1,069	$ —
License and collaboration revenue	14	52
Total revenues	1,083	52
Less:		
Cost of sales	2,962	—
Research and development		
Clinical and manufacturing	39,126	23,065
Other research and development[(1)]	4,604	4,402
Total research and development	43,730	27,467
General and administrative	20,780	14,789
Total costs and operating expenses	67,472	42,256
Loss from operations	(66,389)	(42,204)
Other income, net	6,187	7,752
Net loss	$ (60,202)	$ (34,452)

(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.

10. Common Stock

The Company is authorized to issue up to 700,000,000 shares of common stock at March 31, 2026 and December 31, 2025, of which 88,007,761 and 80,689,128 shares were issued and outstanding at March 31, 2026 and December 31, 2025, 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, of which there are none as of March 31, 2026 and December 31, 2025.

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, 2026, the Company reserved the following shares of common stock for issuance:

	March 31, 2026
Stock options and awards outstanding	7,754,214
Reserved for future stock award issuances	7,309,118
Reserved for future ESPP issuances	1,481,534
Total	16,544,866

11. 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, 2026, there were 437,361 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, 2026, there were 3,096,076 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 January 24, 2024. 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 its initial public offering. However, the 2015 and 2022 Plans 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 and 2022 Plans 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, 2026, there were 4,220,777 shares of common stock subject to outstanding awards and 7,309,113 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 summarizes stock option activity for the three months ended March 31, 2026 (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, 2025	7,958,219	$ 16.59	7.96	$ 198,545
Granted	36,000	$ 61.15		
Exercised	(355,634)	$ 5.70		
Forfeited/Expired	(49,744)	$ 29.77		
Balance at March 31, 2026	7,588,841	$ 17.23	7.79	$ 382,892
Vested and expected to vest at March 31, 2026	7,588,841	$ 17.23	7.79	$ 382,892
Exercisable at March 31, 2026	3,583,396	$ 12.61	7.20	$ 197,350

The aggregate intrinsic value is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock. The aggregate intrinsic value of options exercised during the three months ended March 31, 2026 and 2025 was $19.6 million and $0.9 million, respectively.

The weighted-average grant-date fair value of the options granted was $39.90 and $27.30 per share for the three months ended March 31, 2026 and 2025, respectively. The aggregate grant-date fair value of options vested during the three months ended March 31, 2026 and 2025 was $6.8 million and $5.6 million, respectively.

The following table provides the assumptions used in determining the fair value of option awards for the three months ended March 31, 2026 and 2025:

	Three Months Ended March 31,	
	2026	2025
Expected volatility	68.24% - 69.97%	73.39% - 74.09%
Risk-free interest rate	3.725% - 3.97%	4.05% - 4.5%
Expected dividend yield	0%	0%
Expected term (in years)	6.1	6.0 - 6.1

The Company recorded stock-based compensation expense related to stock options of $6.0 million and $4.4 million for the three months ended March 31, 2026 and 2025, respectively. As of March 31, 2026, the Company had an aggregate $57.5 million of gross unrecognized stock-based compensation expense related to unvested options to be recognized over a weighted average period of 2.7 years.

Performance-Based Restricted Stock Units

A Performance Stock Unit (PSU) represents one equivalent share of the Company's common stock to be issued after achievement of the performance metrics specified in the grant. The following table summarizes the Company's PSU activity for three months ended March 31, 2026:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2025	166,342	$ 39.40
Granted	—	$ —
Vested	—	$ —
Forfeited	(969)	$ 43.25
Nonvested at March 31, 2026	165,373	$ 39.38
Expected to vest at March 31, 2026	165,373	$ 39.38

The Company estimates the fair value of a PSU based upon the expected achievement of the performance metrics specified in the grant and the closing market price of the Company's common stock on the date of grant.

Stock-based compensation expense associated with these PSUs is recognized if achievement of the underlying performance condition is considered probable of achievement based on the Company's best estimates. No stock-based compensation expense related to PSUs was recorded during the three months ended March 31, 2026 and 2025. As of March 31, 2026, the Company had an aggregate $6.5 million of gross unrecognized stock-based compensation expense related to unvested PSUs to be recognized over a weighted average period of 1.2 years, including the expense attributable to PSUs for which achievement is not considered probable and no current expense is being recognized.

Stock-based compensation expense related to stock awards and the 2024 Employee Stock Purchase Plan (see Note 12) recorded in the accompanying statements of operations for the three months ended March 31, 2026 and 2025 was as follows (in thousands):

	Three Months Ended March 31,	
	2026	2025
Research and development	$ 2,559	$ 1,652
General and administrative	3,915	3,499
Total stock-based compensation expense	$ 6,474	$ 5,151

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.

12. 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 January 24, 2024. 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 39,060 shares purchased under the ESPP during the three months ended March 31, 2026, and 32,019 shares purchased under the ESPP during the three months ended March 31, 2025. As of March 31, 2026, there were approximately 1.5 million shares available for issuance under the ESPP.

The Company recorded stock-based compensation expense under the ESPP of approximately $0.5 million and $0.7 million for the three months ended March 31, 2026 and 2025, respectively. As of March 31, 2026, the Company had $1.3 million of gross unrecognized stock-based compensation expense under the ESPP to be recognized over a weighted average period of 1.6 years.

13. Debt

In connection with the Conversion Event, the Company assumed an unsecured promissory note held by Biovire (the Biovire Note) with an outstanding principal balance of $3.0 million. The Company determined that the carrying amount of the Biovire Note represented its fair value. The Biovire Note is due and payable on February 28, 2028 (Maturity Date) and accrues interest at the lesser of (i) the daily term SOFR rate plus 2.60% and (ii) 25.0%, or the highest rate permitted by applicable law, and is payable monthly. The Company has the ability to repay the Biovire Note in full prior to the Maturity Date without penalty.

14. 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,	
	2026	2025
Numerator:		
Net loss and comprehensive loss	$ (60,202)	$ (34,452)
Denominator:		
Weighted-average common stock outstanding, basic and diluted	84,518,512	76,187,621
Net loss per share attributable to common stockholders, basic and diluted	$ (0.71)	$ (0.45)

The Company's potentially dilutive securities, which include stock options and awards, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share.

The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders at March 31, 2026 and 2025 because including them would have had an anti-dilutive effect:

	March 31,	
	2026	2025
Stock options outstanding	7,588,841	6,607,154
Total	7,588,841	6,607,154

15. Acquisition of Biovire

On July 20, 2025, the Company obtained control of the SPV through the Conversion Event, resulting in SafeGuard owning 100% of the membership interest of the SPV. As a result of the Conversion Event, the Company also indirectly obtained control of Biovire as the SPV owns 99.96% of the capital stock of Biovire. As a result of this change in control, purchase accounting was applied by the Company and the operations of Biovire are consolidated as of the effective date of the conversion. See footnote 1 for more information on the Note.

Biovire is a contract manufacturer specializing in the fill and finish of novel drugs and medical devices for pharmaceutical and biotech companies. Prior to becoming a majority-owned subsidiary, Biovire was a vendor to the Company and continues to provide clinical supply of cretostimogene used in the Company's clinical trials. The acquisition provides the Company the ability to supply its requirements of cretostimogene during the remainder of its clinical trials.

Consideration was determined to be the fair value of the note receivable that was exchanged for the majority of shares of the SPV and Biovire. The acquisition was accounted for as a business combination using the acquisition method of accounting, under which the acquired assets, including intangible assets, and assumed liabilities were recognized at their estimated fair values as of July 20, 2025, with the excess of the fair value of consideration transferred over the fair value of the net assets acquired recognized as goodwill. The Company's unaudited condensed consolidated financial statements include the operating results of the SPV and Biovire from the date of acquisition through March 31, 2026.

The purchase price allocation is set forth in the table below and represents the Company's fair value estimates related to the acquisition as of July 20, 2025.

	Estimated fair value
Identifiable assets acquired	
Cash	$ 4,033
Current assets	2,565
Operating lease right-of-use assets	3,413
Property and equipment, net	16,610
Intangible assets	600
Total identifiable assets acquired	27,221
Liabilities assumed	
Current liabilities	2,410
Operating lease liabilities, non-current portion	2,800
Long-term debt	3,000
Deferred tax liability	307
Other long-term liabilities	2,157
Total liabilities assumed	10,674
Net identifiable assets acquired	16,547
Goodwill	10,297
Total fair value of consideration paid	$ 26,844

The purchase price was allocated to the tangible assets and identifiable intangible assets acquired and liabilities assumed based on their acquisition date estimated fair values. The carrying amount of accounts receivable and inventory acquired represented their fair value. Property and equipment were assigned a fair value of $16.6 million and will be amortized over a weighted average of 5.5 years. The identifiable intangible assets consist of trade names and trademarks and customer relationships which were each assigned fair values of approximately $0.3 million and will be amortized on a straight-line basis over their estimated useful lives of 10 years. The acquired property and equipment and intangible assets were valued utilizing either the relief from royalty method or the multi-period excess earnings method as deemed most applicable. These approaches require judgment, including those related to projected net cash flows, revenue growth rates, and the weighted average cost of capital used to discount the cash flows.

Goodwill represents the excess of the purchase price over the identifiable tangible and intangible assets acquired in addition to liabilities assumed arising from the business combination. The Company believes the goodwill related to the acquisition was attributable to the expected synergies, value of the assembled workforce, and the collective experience of the management team with regards to its operations, customers, and industry.

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 (Quarterly Report) is provided as a supplement to, and should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2025 and the related "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" of the Annual Report on Form 10-K for the year ended December 31, 2025 (the 2025 Annual Report).

Forward-Looking Statements

This Quarterly Report 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 2025 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 cretostimogene grenadenorepvec (cretostimogene), an investigational oncolytic immunotherapy with a dual mechanism of action designed both to eliminate cancer cells directly by selective replication and indirectly by activating an anti-tumor immune response, as a potential backbone therapy in a broad range of patients afflicted with bladder cancer. Cretostimogene is currently in clinical development for the treatment of patients with high-risk and intermediate-risk non-muscle invasive bladder cancer (NMIBC), which potentially represents up to 150,000 addressable patients.

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 Bacillus Calmette-Guérin (BCG)-unresponsive NMIBC with carcinoma in situ (CIS), with or without Ta/T1 disease. Given the limitations of currently approved therapies, the next course of treatment for these patients with BCG-unresponsive tumors is radical cystectomy, which is the complete removal of the bladder. This surgery carries a significant social, functional and emotional burden for patients. As such, there is a significant unmet need for effective bladder-sparing treatments. We have completed enrollment for this cohort and reported potentially best-in-disease data in September 2025. This trial served as the basis for our Biologics License Application (BLA) submission for our initial indication to the U.S. Food and Drug Administration (FDA), which we initiated in the fourth quarter of 2025 and expect to complete in the fourth quarter of 2026. 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 papillary tumors. Additionally, 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 potentially best-in-disease data reported at the Society of Urologic Oncology (SUO) 26th Annual Meeting in December 2025. Based on internal research derived from the National Cancer Institute Surveillance, Epidemiology, and End Results Program's (NIH SEER) database, secondary claims data analytics and management assumptions, the high-risk BCG-unresponsive NMIBC segment may represent up to 25,000 addressable patients.

We are also conducting a Phase 3 clinical trial, PIVOT-006, the first randomized registrational trial to evaluate an investigational therapy in intermediate-risk NMIBC assessing adjuvant cretostimogene following transurethral resection of the bladder tumor (TURBT), with enrollment completed in the third quarter of 2025. These patients with intermediate-risk NMIBC are encumbered by frequent tumor recurrence that requires repeat resection of the bladder tumors. Moreover, intravesical BCG is no longer recommended by guidelines for this patient population due to the continuous BCG shortage. We believe cretostimogene, if approved in intermediate-risk NMIBC, has the potential to serve as a first-in-class backbone therapy in this frontline adjuvant setting, for which there are currently no U.S. FDA approved options. Based on internal research derived from NIH SEER database, secondary claims data analytics and management assumptions, the intermediate-risk NMIBC segment may represent up to 50,000 addressable patients.

Additionally, we have multiple ongoing Phase 2 trials designed to generate data in high-risk BCG-exposed and BCG-naïve patients. In October 2024, we initiated CORE-008 Cohort A, a 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. Initial data from this Cohort were reported at the SUO Annual Meeting in December 2025. Based on internal research derived from NIH SEER database, secondary claims data analytics and management assumptions, the high-risk BCG-naïve NMIBC segment may represent up to 25,000 addressable patients. In March 2025, we expanded CORE-008 evaluating cretostimogene as a monotherapy in 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 both the high-risk BCG-exposed and BCG-unresponsive population. Based on internal research derived from NIH SEER database, secondary claims data analytics and management assumptions, the high-risk BCG-exposed NMIBC segment may represent up to 50,000 addressable patients. Notably, cretostimogene's potential for combination with other therapies was assessed in a Phase 2 CORE-001 clinical trial evaluating cretostimogene in combination with the checkpoint inhibitor (CPI) pembrolizumab in high-risk BCG-unresponsive NMIBC patients.

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 $60.2 million and $34.5 million for the three months ended March 31, 2026 and 2025, respectively. As of March 31, 2026, we had an accumulated deficit of $439.2 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. In January 2024, we completed our initial public offering of 23,000,000 common shares at a price of $19.00 per share, including the exercise in full by the underwriters of their option to purchase an additional 3,000,000 shares of common stock. We received net proceeds of $399.6 million, after deducting discounts, commissions and other offering expenses. In addition, as a result of our initial public offering, our convertible preferred stock converted into common stock concurrently with the initial public offering. In December 2024, we completed a follow-on offering of 8,500,000 common shares 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. 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, 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, which we subsequently amended on January 13, 2026, covering the offering, issuance and sale of up to a maximum aggregate offering of $550 million of our common stock that may be issued and sold from time to time under the Jefferies Sales Agreement. As of March 31, 2026, we have completed the Jefferies Sales Agreement and have received gross proceeds of $550.0 million and net aggregate proceeds of $538.5 million under the Jefferies Sales Agreement, after deducting discounts and commissions and other offering expenses.

Through March 31, 2026, we have received aggregate gross proceeds of approximately $1,532.9 million from the sale of shares of our common stock from our initial public offering, our follow-on offering in December 2024, and our at-the-market facility, and sales of redeemable convertible preferred stock. In addition, through March 31, 2026, we have recognized $26.9 million in license and collaboration revenue pursuant to our license and collaboration agreements. As of March 31, 2026, we had cash, cash equivalents and marketable securities of $1,076.2 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.

In February 2025, the Company's wholly owned subsidiary, SafeGuard Healthcare, LLC (SafeGuard), purchased a $26.8 million convertible note, including accrued interest, from SP Healthcare SPV I, LLC (the SPV). The SPV used the proceeds from the Note to invest and acquire substantially all of the assets of Biovire, Inc. (Biovire), a contract manufacturing organization that produces cretostimogene for the Company. In July 2025, SafeGuard converted the Note (the Conversion Event) and obtained control of both the SPV and Biovire. As a result of this change in control, the operations of Biovire were consolidated as of the effective date of the conversion.

We believe, based on our current operating plan, that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations for at least the next twelve months from the date of this Quarterly Report. 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 of cretostimogene or any future product candidates unless and until we successfully complete clinical development and obtain regulatory approval, 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.

Other than Biovire, which manufactures and conducts release testing of our cretostimogene drug product, we do not own or operate any manufacturing facilities. We rely, and expect to continue to rely, on Biovire and 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.

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 2025 Annual Report.

Lepu License Agreement

In March 2019, we entered into a development and license agreement (the Lepu License Agreement) with Lepu Biotech Co., Ltd. (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, 2026 and 2025, we did not recognize any license and collaboration revenue related to the Lepu License Agreement.

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 Pharmaceutical Co., Ltd. (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 each of the three months ended March 31, 2026 and 2025, less than $0.1 million in license and collaboration revenue was recorded related to the Kissei License Agreement.

Components of Our Results of Operations

Revenue

License and Collaboration Revenue

Through March 31, 2026, we have recognized $26.9 million in license and collaboration revenue through our license and collaboration agreements. We have not generated any revenue from the sale of our cretostimogene products, however, and do not expect to generate any revenue from the sale of our cretostimogene 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.

Commercial and Development Revenue

In connection with the Conversion Event, we obtained control of the SPV and its subsidiary, Biovire, a contract manufacturer specializing in the fill and finish of novel drugs and medical devices for pharmaceutical and biotech companies. Our commercial and development revenue consists of Biovire's fill and finish of novel drugs and medical devices.

Operating Costs and Expenses

Our operating costs and expenses consist of (i) cost of sales, (ii) research and development expenses and (iii) general and administrative expenses.

Cost of Sales

Cost of sales reflects the direct cost of labor and other overhead, which includes direct manufacturing, production, and packaging materials for commercial and development product sales.

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 allocated facilities 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

Other income (expense), net consists primarily of interest income related to interest earned on our invested cash equivalents and marketable securities balances. It also includes other miscellaneous items, such as interest expense and other items not related to our core operations. We expect our interest income will increase as we invest the cash received from the net proceeds from our public offerings.

Results of Operations

Comparison of the Three Months Ended March 31, 2026 and 2025

The following table summarizes our results of operations for the three months ended March 31, 2026 and 2025 (in thousands):

	Three Months Ended March 31,		
	2026	2025	Change
Revenue:			
Commercial and development revenue	$ 1,069	$ —	$ 1,069
License and collaboration revenue	14	52	(38)
Total revenues	1,083	52	1,031
Operating costs and expenses			
Cost of sales	2,962	—	2,962
Research and development	43,730	27,467	16,263
General and administrative	20,780	14,789	5,991
Total operating costs and expenses	67,472	42,256	25,216
Loss from operations	(66,389)	(42,204)	(24,185)
Other income (expense), net:			
Interest income, net	6,288	7,747	(1,459)
Other income (expense), net	(101)	5	(106)
Total other income, net	6,187	7,752	(1,565)
Net loss and comprehensive loss	$ (60,202)	$ (34,452)	$ (25,750)

Commercial and Development Revenue

Commercial and development revenue was $1.1 million for the three months ended March 31, 2026 compared to zero for the three months ended March 31, 2025. As the Conversion Event occurred in July 2025, there was no corresponding commercial and development revenue in the prior period.

License and Collaboration Revenue

License and collaboration revenue was less than $0.1 million for the three months ended March 31, 2026 and the three months ended March 31, 2025. All revenue recognized during both periods was related to the Kissei License Agreement.

Cost of Sales

Cost of sales was $3.0 million for the three months ended March 31, 2026 compared to zero for the three months ended March 31, 2025. As the Conversion Event occurred in July 2025, there was no corresponding costs in the prior period.

Research and Development Expenses

The following table summarizes our R&D expenses for the three months ended March 31, 2026 and 2025 (in thousands):

	Three Months Ended March 31,		
	2026	2025	Change
External clinical trial expenses	$ 32,823	$ 18,301	$ 14,522
Personnel-related expenses	9,744	7,673	2,071
Other research and development	1,163	1,493	(330)
Total research and development expenses	$ 43,730	$ 27,467	$ 16,263

R&D expenses were $43.7 million for the three months ended March 31, 2026 compared to $27.5 million for the three months ended March 31, 2025. The increase of $16.3 million in R&D expenses for the three months ended March 31, 2026 was primarily due to an increase of $14.5 million in external clinical trial expenses related to higher Chemistry, Manufacturing, and Controls (CMC) costs, as well as an increase of $2.1 million in compensation costs due to increased headcount, including a $0.9 million increase in stock-based compensation, partially offset by a decrease in other research and development costs of $0.3 million.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2026 and 2025 (in thousands):

	Three Months Ended March 31,		
	2026	2025	Change
Personnel-related expenses	$ 11,148	$ 8,441	$ 2,707
Professional and consultant fees	5,771	3,222	2,549
Other general and administrative	3,861	3,126	735
Total general and administrative expenses	$ 20,780	$ 14,789	$ 5,991

General and administrative expenses were $20.8 million for the three months ended March 31, 2026 compared to $14.8 million for the three months ended March 31, 2025. The increase of $6.0 million in general and administrative expenses for the three months ended March 31, 2026 was primarily due to an increase in compensation costs of $2.7 million due to increased headcount, including a $0.4 million increase in stock-based compensation, an increase in professional and consultant fees of $2.5 million, and an increase in other general fees and costs of $1.1 million, partially offset by a decrease in marketing-related costs of $0.4 million.

Other Income (Expense), Net

Other income, net, for the three months ended March 31, 2026 was an other income, net of $6.2 million compared to an other income, net of $7.8 million for the three months ended March 31, 2025. The $1.6 million decrease was driven primarily by a decrease in interest income earned related to cash equivalents and marketable securities balances, as well as interest expense in the current period related to debt acquired through SPV and Biovire, with no corresponding interest expense in the prior period.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales of cretostimogene 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, 2026, we have received aggregate gross proceeds of $1,532.9 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, 2026, we have recognized $26.9 million in license and collaboration revenue through our license and collaboration agreements. As of March 31, 2026, we had cash, cash equivalents and marketable securities of $1,076.2 million.

At-the-Market Offering

On March 28, 2025, we entered into the Jefferies Sales Agreement with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time through Jefferies, 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, which we subsequently amended on January 13, 2026, covering the offering, issuance and sale of up to a maximum aggregate offering of $550 million of our common stock that may be issued and sold from time to time under the Jefferies Sales Agreement. During the three months ended March 31, 2026, 6,941,407 shares were sold under the Jefferies Sales Agreement, at a weighted-average price of $57.56 per share, and the Company received net proceeds of $391.4 million, after deducting discounts and commissions and other offering expenses.

Effects of Inflation

Inflation could affect us by increasing our cost of labor and R&D costs. We do not believe inflation has had a material effect on our business, financial condition or results of operations, or on our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

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, engage in potential strategic transactions, 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 or businesses that we may in-license or acquire.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations for at least the next twelve months from the date of this Quarterly Report. 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.

Contractual Obligations and Other Commitments

During the three months ended March 31, 2026, 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 – Contractual Obligations and Other Commitments" included in the 2025 Annual Report.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2026 and 2025 (in thousands):

	Three Months Ended March 31,	
	2026	2025
Net cash used in operating activities	$ (56,943)	$ (29,277)
Net cash used in investing activities	(334,845)	(186,769)
Net cash provided by financing activities	392,998	450
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 1,210	$ (215,596)

Operating Activities

During the three months ended March 31, 2026, operating activities used $56.9 million of cash, primarily resulting from our net loss of $60.2 million, as well as net cash used by changes in our operating assets and liabilities of $5.8 million, partially offset by non-cash stock-based compensation charges of $6.5 million and other non-cash operating adjustments of $2.6 million.

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, accretion of the discount on short-term investments of $0.3 million, partially offset by $5.2 million of non-cash stock-based compensation charges and net cash used in changes in our operating assets and liabilities of $0.5 million.

Investing Activities

During the three months ended March 31, 2026, net cash used in investing activities was $334.8 million, primarily due to $587.4 million of purchases of marketable securities, partially offset by proceeds from sales and maturities of short-term investments.

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.

Financing Activities

During the three months ended March 31, 2026, net cash provided by financing activities was $393.0 million, consisting primarily of proceeds of $391.4 million from the sale of our common stock pursuant to the Jefferies Sales Agreement, net of issuance costs, and proceeds from exercise of options of $1.7 million.

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.

Critical Accounting Policies and Significant Judgments and Estimates

Our unaudited condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles in the United States. The preparation of our unaudited 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 unaudited 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 2025 Annual Report.

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 unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

For the Company's disclosures about market risk, please see "Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk" in our 2025 Annual Report filed with the SEC. There have been no material changes to the Company's disclosures about market risk in Part II—Item 7A of our 2025 Annual Report.

Item 4. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) 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.

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, 2026, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. 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.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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. Other than the below, there have been no material developments to the legal proceedings previously disclosed in Part II, Item 1, "Legal Proceedings" in our 2025 Annual Report.

On March 4, 2024, ANI Pharmaceuticals, Inc. (ANI) filed a complaint against the Company in the Superior Court of the State of Delaware seeking (i) a declaratory judgment that a provision in an assignment and technology transfer agreement between the Company and ANI, dated November 15, 2010 (the ANI Agreement), obligates the Company to pay ANI a royalty on certain "net sales" of cretostimogene, and (ii) compensatory damages alleging the Company was unjustly enriched by obtaining the benefit of certain non-patent assets under the ANI Agreement without paying adequate consideration to ANI. On July 16, 2025, the Superior Court granted the Company's motion for summary judgment with respect to ANI's request for a declaratory judgment to receive royalty payments from the potential sale of cretostimogene but denied the Company's motion for summary judgment with respect to ANI's unjust enrichment claim. On July 29, 2025, a jury entered a verdict in favor of the Company, unanimously rejecting all of ANI's claims for unjust enrichment damages. As a result and subject to the outcome of any post-trial motions or appeals brought by ANI, the Company will not owe ANI a future royalty of 5% on commercial sales of cretostimogene, no damages have been awarded to ANI, and there are no further payments due to ANI under the ANI Agreement. On April 10, 2026, the Superior Court heard oral arguments from ANI and the Company on pending post-trial motions submitted by the Company and ANI, which included (i) ANI's Motion for Judgment as a Matter of Law; (ii) ANI's Motion to Unseal Trial Exhibits; and (iii) CG's Motion for Costs. As of the filing of this Quarterly Report on Form 10-Q, the Superior Court has not issued a ruling on these post-trial motions. The Company will continue to vigorously defend the post-trial motions and any appeals brought by ANI.

Item 1A. Risk Factors.

There have been no material changes to our risk factors previously disclosed in Part I, Item 1A, "Risk Factors" of our 2025 Annual Report, filed with the SEC on February 27, 2026.

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, 2026, we estimate that we have used approximately $340.2 million of the proceeds from our initial public offering for general corporate purposes, including to fund the research and development of cretostimogene, manufacturing and pre-commercial activities, and to fund a contract manufacturing organization that provides us with clinical supply of cretostimogene. 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, 2026, except for James J. Mulé and Leonard Post, none of our officers or directors adopted, modified or terminated any such trading arrangements.

			Type of Trading Arrangement			
Name and Position	**Action**	**Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares to be Sold**	**Expiration Date**
James J. Mulé, Director	Adoption	March 27, 2026	X		30,713	March 31, 2027
Leonard Post, Director	Adoption	March 5, 2026	X		22,000	May 31, 2027
* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.						
** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.						

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#	Employment Agreement dated April 13, 2026 between the Registrant and Jim DeTore	8-K	04/13/26	10.1	
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 Principal 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 Principal 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)				

# Indicates management contract or compensatory plan.

* 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.

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 8, 2026

By: /s/ Arthur Kuan
Arthur Kuan
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: May 8, 2026

By: /s/ Jim DeTore
Jim DeTore
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Arthur Kuan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CG Oncology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2026

By: /s/ Arthur Kuan
Name: Arthur Kuan
Title: Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jim DeTore, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CG Oncology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    a. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2026

By: /s/ Jim DeTore
Name: Jim DeTore
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of CG Oncology, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 8, 2026

By: /s/ Arthur Kuan
Name: Arthur Kuan
Title: Chairman and Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

Exhibit 32.2

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

In connection with the Quarterly Report of CG Oncology, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 8, 2026

By: /s/ Jim DeTore
Name: Jim DeTore
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.