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 June 30, 2025

OR

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

For the transition period from _____ to _____

Commission File Number: 001-41925

CG Oncology, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	CGON	The Nasdaq Global Select Market

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

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

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

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

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

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

As of August 6, 2025, the registrant had 76,247,581 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)

	June 30, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 14,624	$ 257,068
Marketable securities	646,428	484,930
Prepaid expenses and other current assets	11,416	11,431
Accounts receivable - other	562	781
Total current assets	673,030	754,210
Property and equipment, net	253	272
Note receivable, net	26,675	—
Operating lease right-of-use assets	965	221
Other assets	522	94
Total assets	$ 701,445	$ 754,797
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,125	$ 6,517
Operating lease liabilities, current portion	288	186
Accrued expenses and other current liabilities	22,968	14,665
Total current liabilities	30,381	21,368
Operating lease liabilities, net of current portion	706	52
Total liabilities	31,087	21,420
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.0001 par value per share; 700,000,000 and 700,000,000 shares authorized as of June 30, 2025 and December 31, 2024, respectively; 76,231,859 and 76,154,783 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	8	8
Additional paid-in capital	964,209	951,350
Accumulated deficit	(293,859)	(217,981)
Total stockholders' equity	670,358	733,377
Total liabilities and stockholders' equity	$ 701,445	$ 754,797

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

CG ONCOLOGY, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenues				
License and collaboration revenue	$ —	$ 111	$ 52	$ 640
Operating expenses				
Research and development	31,331	18,470	58,799	35,680
General and administrative	17,410	7,494	32,198	13,282
Total operating expenses	48,741	25,964	90,997	48,962
Loss from operations	(48,741)	(25,853)	(90,945)	(48,322)
Other income (expense), net:				
Interest income, net	7,319	6,943	15,066	12,487
Other (expense) income, net	(4)	8	1	(1)
Total other income, net	7,315	6,951	15,067	12,486
Net loss and comprehensive loss	$ (41,426)	$ (18,902)	$ (75,878)	$ (35,836)
Net loss per share, basic and diluted	$ (0.54)	$ (0.28)	$ (1.00)	$ (0.63)
Weighted average shares of common stock outstanding, basic and diluted	76,226,829	66,649,443	76,207,333	56,857,104

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

CG ONCOLOGY, INC.

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

	Series A-1 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Series E Redeemable Convertible Preferred Stock		Series F Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance as of December 31, 2023	5,075,000	$ 3,570	11,973,000	$ 10,000	73,598,283	$ 22,000	53,271,754	$ 47,300	112,422,700	$ 120,000	81,587,937	$ 105,020	5,222,283	$ —	$ 6,842	$ (129,942)	$ (123,100)
Conversion of redeemable convertible preferred stock	(5,075,000)	(3,570)	(11,973,000)	(10,000)	(73,598,283)	(22,000)	(53,271,754)	(47,300)	(112,422,700)	(120,000)	(81,587,937)	(105,020)	38,413,909	4	307,886	—	307,890
Issuance of common stock in connection with an initial public offering, net of issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	23,000,000	3	399,562	—	399,565
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	60	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1,517	—	1,517
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(16,934)	(16,934)
Balance as of March 31, 2024	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	66,636,252	$ 7	$ 715,807	$ (146,876)	$ 568,938
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	23,600	—	77	—	77
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	2,246	—	2,246
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(18,902)	(18,902)
Balance as of June 30, 2024	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	66,659,852	$ 7	$ 718,130	$ (165,778)	$ 552,359
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
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	10,570	—	19	—	19
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	7,007	—	7,007
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(41,426)	(41,426)
Balance as of June 30, 2025	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	76,231,859	$ 8	$ 964,209	$ (293,859)	$ 670,358

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)

	Six Months Ended June 30,	
	2025	2024
Operating Activities		
Net loss	$ (75,878)	$ (35,836)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	180	11
Stock-based compensation expense	12,158	3,763
Accretion of discount on short-term investments	(2,166)	(4,665)
Non-cash interest income	(675)	—
Non-cash lease expense	13	(13)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	15	(4,444)
Accounts receivable - other	219	(90)
Other assets	(13)	(34)
Accounts payable	608	1,249
Accrued expenses and other current liabilities	8,303	(2,073)
Net cash used in operating activities	(57,236)	(42,132)
Investing Activities		
Proceeds from sales and maturities of short-term investments	370,520	315,991
Purchases of short-term investments	(529,852)	(659,639)
Issuance of note receivable	(26,000)	—
Purchases of property and equipment	(30)	(26)
Net cash used in investing activities	(185,362)	(343,674)
Financing Activities		
Proceeds from initial public offering, net of issuance costs	—	406,410
Payments of success fee or long-term debt	—	(365)
Proceeds from exercise of common stock options and issuance of common stock under the employee stock purchase plan	701	77
Deferred offering costs	(547)	(3,424)
Net cash provided by financing activities	154	402,698
Net (decrease) increase in cash and cash equivalents	(242,444)	16,892
Cash and cash equivalents at beginning of period	257,068	8,266
Cash and cash equivalents at end of period	$ 14,624	$ 25,158
Supplemental Disclosure of Cash Flow Information		
Cash paid for taxes	$ 11	$ —
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Reclassification of 38,413,909 redeemable convertible preferred stock to 38,413,909 shares of common stock	$ —	$ 307,890
Conversion of deferred offering costs	$ —	$ 6,845
Operating lease right-of-use asset obtained in exchange for lease liabilities	$ 859	$ —

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

1. Description of Business and Basis of Presentation

Description of Business

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

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

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

In February 2025, the Company's wholly owned subsidiary, SafeGuard Healthcare, LLC, established a note receivable with a principal amount of $26.0 million through a convertible promissory note (Note) from SP Healthcare SPV I, LLC (the SPV). The SPV used the proceeds from the Note to make an investment in Biovire, Inc. for the purpose of Biovire acquiring substantially all of the assets of a contract manufacturing organization that provides clinical supply of cretostimogene to the Company. See footnote 4 for more information on the accounting for the Note.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements as of June 30, 2025 and for the three and six months ended June 30, 2025 and 2024 have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) for interim financial information and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2024 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 (2024 Annual Report). In the opinion of management, the unaudited condensed consolidated financial statements reflect all adjustments, which include only normal and recurring adjustments, considered necessary for a fair statement of the interim periods.

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

Liquidity and Management's Plans

As of June 30, 2025, the Company had approximately $661.1 million of cash, cash equivalents and marketable securities and working capital of approximately $642.6 million. The Company has a relatively limited operating history, and the revenue and income potential of the Company's business and market are unproven. The Company has experienced net losses and negative cash flows from operations since its inception and, as of June 30, 2025, the Company had an accumulated deficit of $293.9 million. During the three and six months ended June 30, 2025, the Company incurred net losses of $41.4 million and $75.9 million, respectively, and had negative cash flows from operations of $57.2 million during the six months ended June 30, 2025. The Company will continue to incur significant costs and expenses related to its ongoing operations until it successfully develops, obtains regulatory approval, and gains market acceptance of a product candidate and achieves a level of revenues adequate to support the Company's operations.

At-the-Market Offering

On March 28, 2025, the Company entered into an Open Market Sale Agreement℠ (Jefferies Sales Agreement) with Jefferies LLC, as agent, pursuant to which the Company may offer and sell, from time to time through Jefferies, up to $250.0 million in shares of the Company's common stock. As of June 30, 2025, no sales have been made under the Jefferies Sales Agreement.

2. Summary of Significant Accounting Policies

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

Deferred Offering Costs

The Company capitalizes as deferred offering costs all direct and incremental legal, professional, accounting and other third-party fees incurred in connection with equity offerings. As of June 30, 2025 and December 31, 2024, the Company had $0.4 million and zero, respectively, in deferred offering costs. Deferred offering costs are included in Other assets in the Company's condensed consolidated balance sheets. The deferred offering costs as of June 30, 2025 were incurred in connection with the filing of a registration statement on Form S-3 in March 2025.

Recently Issued Accounting Standards

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

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

3. Fair Value Measurements

The following tables present the financial instruments carried at fair value on a recurring basis as of June 30, 2025 and December 31, 2024, respectively, in accordance with the ASC 820, *Fair Value Measurement* (ASC 820) hierarchy (in thousands):

	Fair Value Measurements at June 30, 2025			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 14,291	$ —	$ —	$ 14,291
Marketable securities	$ —	$ 646,428	$ —	$ 646,428

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

The Company’s cash equivalents represent deposits in a short-term U.S. Treasury money market fund quoted in an active market and were classified as a Level 1 fair value measurement. Marketable securities represent fixed income securities (U.S. treasury bills) with original maturities greater than 90 days and were classified as a Level 2 fair value measurement. As of June 30, 2025 and December 31, 2024, the amortized cost of the Company's available for sale marketable securities approximated their fair value. There was no material realized or unrealized gains or losses, either individually or in the aggregate.

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the three and six months ended June 30, 2025 and the year ended December 31, 2024.

4. Note Receivable

The Company's wholly owned subsidiary, SafeGuard Healthcare, LLC, has a note receivable from SPV totaling $26.0 million, which was established in February 2025. The note carries an interest rate of 8% and is due on February 3, 2029. As of June 30, 2025, no payments have been made, and the outstanding principal balance is $26.0 million. The note is recognized on an amortized cost basis, which is equal to the principal amount, adjusted for accrued interest.

5. Accrued Expenses and Other Current Liabilities

The components of accrued expenses and other current liabilities as of June 30, 2025 and as of December 31, 2024 were as follows (in thousands):

	June 30, 2025	December 31, 2024
External research and development expenses	$ 16,000	$ 7,181
Personnel-related expenses	4,561	5,793
Professional fees	2,166	1,255
Other	241	436
Total accrued expenses and other current liabilities	$ 22,968	$ 14,665

6. Commitments and Contingencies

Operating Leases

As of June 30, 2025 and December 31, 2024, the Company had three and two operating leases, respectively, in which the Company was the lessee for office space. As of June 30, 2025, the leases have varying terms expiring between 2026 and 2030. The Company had no finance leases as of June 30, 2025 and December 31, 2024.

The components of lease expense as of June 30, 2025 and 2024 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Lease cost				
Operating lease cost	$ 86	$ 35	$ 152	$ 96
Total lease cost	$ 86	$ 35	$ 152	$ 96
Other information				
Operating lease right-of-use asset obtained in exchange for new operating lease liabilities	$ —	$ —	$ 859	$ —
Cash paid for amounts included in the measurement of lease liabilities, included in operating cash flows	$ 86	$ 45	$ 161	$ 103
Weighted-average remaining lease term	3.71	1.63	3.71	1.63
Weighted-average discount rate	6.85%	1.63%	6.85%	1.63%

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

2025	$ 172
2026	324
2027	274
2028	227
2029	124
Thereafter	10
Total lease payment	1,131
Less: amount representing imputed interest	(137)
Total future minimum lease obligations	$ 994

Legal Proceedings

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

On March 4, 2024, 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, 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. The Company will continue to vigorously defend any post-trial motions and 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 June 30, 2025, the Company had not experienced any losses related to these indemnification obligations, and no claims with respect thereto were outstanding.

7. License and Collaboration Agreements

Lepu Biotech Co., Ltd.

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

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

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

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

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

During the six months ended June 30, 2025 and 2024, the Company recognized zero and $0.5 million, respectively, in license and collaboration revenue. The Company recognized no license and collaboration revenue during the three months ended June 30, 2025 and 2024.

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 Agreement, the Company and Kissei agree to use commercially reasonable efforts to collaborate on clinical development activities in the Kissei Territory and each party is responsible for conducting the applicable activities pursuant to an agreed development plan. Kissei is responsible for the costs of developing the Licensed Product in the Kissei Territory, and the Company is responsible for the costs of developing the Licensed Product outside the Kissei Territory (Global Development), provided that Kissei is responsible for a low-double digit percentage and the Company is responsible for a high-double digit percentage of the cost of development activities that cannot be attributed solely to the Kissei Territory or outside the Kissei Territory. The Company is obligated to supply and Kissei will exclusively purchase its clinical and commercial requirements of Licensed Product from the Company. Kissei is responsible for commercializing the Licensed Product in the Kissei Territory and is obligated to use commercially reasonable efforts to seek regulatory approval for and commercialize at least one Licensed Product in a specified indication. Until a certain period of time has passed after the first regulatory approval of the Licensed Product, the Company is prohibited from commercializing certain competing products worldwide and Kissei is prohibited from researching, developing or commercializing certain competing products worldwide.

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

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

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

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

The Company evaluated the Kissei Territory specific license and related activities under ASC 606, as these transactions are considered transactions with a customer, and identified two material promises at the outset of the Kissei License Agreement, which consists of the following: (1) the exclusive license and (2) the manufacturing activities related to development and commercial supply of the Licensed Product in the Kissei Territory. The Company further evaluated the material promise associated with manufacturing activities related to development and commercial supply of the Licensed Products in the Kissei Territory. Given Kissei is not obligated to purchase any minimum amount or quantities of the development and commercial supply from the Company, the Company concluded, for the purpose of ASC 606, the provision of manufacturing activities related to development and commercial supply of the Licensed Product in the Kissei Territory was an option but not a performance obligation of the Company at the inception of the Kissei Agreement and will be accounted for if and when exercised. The Company also concluded there is no separate material right in connection with the development and commercial supply of the licensed product, as the expected pricing was not issued at a significant and incremental discount. Therefore, the manufacturing activities were excluded as 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 recorded zero and $0.1 million in license and collaboration revenue for the three months ended June 30, 2025 and 2024, respectively, and less than $0.1 million and $0.1 million in license and collaboration revenue for the six months ended June 30, 2025 and 2024, respectively.

8. Segment Disclosures

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

The following table presents selected financial information with respect to the Company's single operating segment for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue	$ —	$ 111	$ 52	$ 640
Less:				
Research and development				
Clinical and manufacturing	26,371	14,932	49,436	29,158
Other research and development[(1)]	4,960	3,538	9,363	6,522
Total research and development	31,331	18,470	58,799	35,680
General and administrative	17,410	7,494	32,198	13,282
Total operating expenses	48,741	25,964	90,997	48,962
Loss from operations	(48,741)	(25,853)	(90,945)	(48,322)
Other income, net	7,315	6,951	15,067	12,486
Net loss	$ (41,426)	$ (18,902)	$ (75,878)	$ (35,836)

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

9. Common Stock

The Company is authorized to issue up to 700,000,000 shares of common stock at June 30, 2025 and December 31, 2024, of which 76,231,859 and 76,154,783 shares were issued and outstanding at June 30, 2025 and December 31, 2024, respectively.

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

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 June 30, 2025, the Company reserved the following shares of common stock for issuance:

	June 30, 2025
Stock options outstanding	8,963,925
Reserved for future stock option issuances	3,788,588
Reserved for future ESPP issuances	751,077
Total	13,503,590

10. Stock-Based Compensation

In 2015, the Company established the 2015 Plan, under which the Company may grant options and restricted stock to its employees and certain non-employees. As of June 30, 2025, there were 901,931 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 June 30, 2025, there were 3,306,669 shares of common stock subject to outstanding awards under the 2022 Plan.

On January 11, 2024, the Company's board of directors and stockholders approved the 2024 Equity Incentive Plan (the 2024 Plan), which became effective on the date immediately preceding the date on which the Company's registration statement was declared effective by the SEC. The 2024 Plan replaced the 2022 Plan, as the Company's board of directors has determined to not make additional grants under the 2022 Plan following the closing of the offering. However, the 2015 and 2022 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 June 30, 2025, there were 4,755,325 shares of common stock subject to outstanding awards and 3,788,583 shares of common stock remaining and available for issuance under the 2024 Plan.

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

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

Stock Options

The following table provides the assumptions used in determining the fair value of option awards for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Expected volatility	73.62% - 77.58%	77.46% - 77.53%	73.39% - 77.58%	77.46% - 84.50%
Risk-free interest rate	3.99% - 4.16%	4.21% - 4.62%	3.99% - 4.5%	3.93% - 4.62%
Expected dividend yield	0%	0%	0%	0%
Expected term (in years)	5.25 - 6.1	6.1	5.25 - 6.1	6.05 - 6.1

The weighted average grant-date fair value of the options granted was $20.79 and $16.49 per share for the six months ended June 30, 2025 and 2024, respectively. The weighted average fair value of shares vested during the six months ended June 30, 2025 and 2024 was $17.50 and $3.73 per share, respectively. The weighted average fair value of shares exercised during the six months ended June 30, 2025 and 2024 was $3.03 and $2.07 per share, respectively.

The following table summarizes stock option activity for the six months ended June 30, 2025 (in thousands, except share and per share amounts):

	Number of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2024	6,574,580	$ 14.19	8.20	$ 108,155
Granted	2,470,041	$ 20.79		
Exercised	(45,057)	$ 3.03		
Forfeited/Expired	(35,639)	$ 12.82		
Balance at June 30, 2025	8,963,925	$ 16.07	8.29	$ 106,753
Vested and expected to vest at June 30, 2025	8,963,925	$ 16.07	8.29	$ 106,753
Exercisable at June 30, 2025	2,991,092	$ 8.90	6.89	$ 54,535

The Company recorded stock-based compensation expense related to stock options of $6.4 million and $1.5 million for the three months ended June 30, 2025 and 2024, respectively, and $10.8 million and $3.0 million for the six months ended June 30, 2025 and 2024, respectively. As of June 30, 2025, the Company had an aggregate $79.8 million of gross unrecognized stock-based compensation expense related to unvested options to be recognized over a weighted average period of 3.2 years.

Stock-based compensation expense related to stock options and the 2024 Employee Stock Purchase Plan (see Note 11) recorded in the accompanying statements of operations for the three and six months ended June 30, 2025 and 2024 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	$ 2,303	$ 779	$ 3,955	$ 1,322
General and administrative	4,704	1,467	8,203	2,441
Total stock-based compensation expense	$ 7,007	$ 2,246	$ 12,158	$ 3,763

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

11. Employee Stock Purchase Plan

On January 11, 2024, the Company's board of directors and stockholders approved the 2024 Employee Stock Purchase Plan (the ESPP), which became effective on the date on which the Company's registration statement was declared effective by the SEC. The number of shares initially available for issuance pursuant to the ESPP is 812,242 shares. The ESPP provides for the sale of the Company's common stock to eligible employees at 85% of the fair market value of the Company's common stock at the commencement date of each offering period or the relevant date of purchase, whichever is lower. Payroll deductions are limited to 15% of the employee's eligible compensation, subject to IRS limits. In addition, employees may not buy more than 100,000 shares during any purchase period or offering period. There were 32,019 shares purchased under the ESPP during the three and six months ended June 30, 2025. On June 30, 2025, there were 751,077 shares available for issuance under the ESPP.

The Company recorded stock-based compensation expense under the ESPP of approximately $0.6 million and $0.7 million for the three months ended June 30, 2025 and 2024, respectively, and $1.4 million and $0.7 million for the six months ended June 30, 2025 and 2024, respectively. As of June 30, 2025, the Company had $1.9 million of gross unrecognized stock-based compensation expense under the ESPP to be recognized over a weighted average period of 0.85 years.

12. Debt

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

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

On March 5, 2024, the Company paid $0.4 million for the Success Fee under the Success Fee Agreement. As of June 30, 2025, the Company has no further obligations in connection with the Loan Agreement.

13. Net Loss Per Share Attributable to Common Stockholders

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Numerator:				
Net loss and comprehensive loss	$ (41,426)	$ (18,902)	$ (75,878)	$ (35,836)
Denominator:				
Weighted-average common stock outstanding, basic and diluted	76,226,829	66,649,443	76,207,333	56,857,104
Net loss per share attributable to common stockholders, basic and diluted	$ (0.54)	$ (0.28)	$ (1.00)	$ (0.63)

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

The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders at June 30, 2025 and 2024 because including them would have had an anti-dilutive effect:

	June 30,	
	2025	2024
Stock options outstanding	8,963,925	6,040,339
Total	8,963,925	6,040,339

14. Subsequent Events

Subsequent to the balance sheet date, on July 20, 2025, the Company obtained control of the SPV following the conversion of a convertible note (Note) held by the Company, triggered by the cessation of services by SkyPath to the SPV and Biovire (Conversion Event). Prior to this event, the SPV was accounted for as a variable interest entity (VIE) under ASC 810, Consolidation, for which the Company was not the primary beneficiary. Accordingly, the Company did not consolidate the SPV as of June 30, 2025. The Note was accounted for as a note receivable and recognized on an amortized cost basis. See footnote 4 for more information on the accounting for the Note as of June 30, 2025.

Upon the occurrence of the Conversion Event, the Company reassessed the nature of the SPV and its relationship with the entity. As a result of this evaluation, the Company concluded that the SPV no longer meets the definition of a VIE. The Company now holds a controlling financial interest in the SPV through its 100% ownership of voting and participating Preferred Units. As such, effective July 20, 2025, the Company will consolidate the SPV in accordance with the requirements of ASC 810.

The Company is currently in the process of performing the preliminary purchase price allocation and related consolidation accounting.

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

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

Forward-Looking Statements

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

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

Overview

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

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

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

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

We have incurred significant operating losses and negative cash flows from operations since our inception. Our net losses were $75.9 million and $35.8 million for the six months ended June 30, 2025 and 2024, respectively. As of June 30, 2025, we had an accumulated deficit of $293.9 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and, to a lesser extent, from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses in the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for, and potentially commercialize cretostimogene and potentially seek to discover and develop additional product candidates, utilize third parties to manufacture cretostimogene, hire additional personnel, expand and protect our intellectual property, and incur additional costs associated with being a public company. If we obtain regulatory approval for cretostimogene, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we do not become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce or terminate our operations.

To date, we have primarily funded our operations with proceeds from the sale of shares of our common stock through public offerings and our redeemable convertible preferred stock, as well as through previously outstanding term debt. From inception through June 30, 2025, we have received aggregate gross proceeds of approximately $982.9 million from the sale of shares of our common stock from our IPO, a follow-on offering in December 2024, and sales of redeemable convertible preferred stock. In addition, from inception through June 30, 2025, we have recognized $26.2 million in license and collaboration revenue pursuant to our license and collaboration agreements. As of June 30, 2025, we had cash, cash equivalents and marketable securities of $661.1 million. Our ability to generate any product revenue and, in particular, our ability to generate product revenue sufficient to achieve profitability, will depend on the successful development and eventual commercialization of cretostimogene and any future product candidates.

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

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

We rely, and expect to continue to rely, on third parties for the manufacture of cretostimogene for clinical testing, as well as for commercial manufacture if we obtain marketing approval. In addition, we rely on third parties to package, label, store, and distribute cretostimogene, and we intend to rely on third parties for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the development of cretostimogene.

License and Collaboration Agreements

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

Lepu License Agreement

In March 2019, we entered into a development and license agreement (the Lepu License Agreement) with Lepu 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 and six months ended June 30, 2025, the Company did not recognize any license and collaboration revenue related to the Lepu License Agreement. During the three and six months ended June 30, 2024, the Company recognized zero and $0.5 million, respectively, in 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 the three and six months ended June 30, 2025, zero and less than $0.1 million in license and collaboration revenue was recorded related to the Kissei License Agreement, respectively. During the three and six months ended June 30, 2024, $0.1 million in license and collaboration revenue was recorded related to the Kissei License Agreement.

Components of Our Results of Operations

Revenue

From inception through June 30, 2025, we have recognized $26.2 million in license and collaboration revenue through our license and collaboration agreements. We have not generated any revenue from the sale of products, however, and do not expect to generate any revenue from the sale of products in the foreseeable future, if at all. If our or our collaborators' development efforts for cretostimogene and any future product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales, payments from existing or potential future collaboration or license agreements with third parties, or any combination thereof.

Operating Expenses

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

Research and Development Expenses

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

Our R&D expenses consist of:

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

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

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

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

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

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses such as salaries, stock-based compensation and benefits, for our personnel in executive, legal, finance and accounting, human resources and other administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters and professional fees paid for accounting, auditing, consulting and tax services, as well as 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

Interest Income, Net

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

Other Income (Expense)

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

Results of Operations

Comparison of the Three Months Ended June 30, 2025 and 2024

The following table summarizes our results of operations for the three months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		
	2025	2024	Change
Revenue:			
License and collaboration revenue	$ —	$ 111	$ (111)
Operating expenses:			
Research and development	31,331	18,470	12,861
General and administrative	17,410	7,494	9,916
Total operating expenses	48,741	25,964	22,777
Loss from operations	(48,741)	(25,853)	(22,888)
Other income (expense), net:			
Interest income, net	7,319	6,943	376
Other (expense) income, net	(4)	8	(12)
Total other income, net	7,315	6,951	364
Net loss and comprehensive loss	$ (41,426)	$ (18,902)	$ (22,524)

License and Collaboration Revenue

License and collaboration revenue was zero for the three months ended June 30, 2025 compared to $0.1 million for the three months ended June 30, 2024. All revenue recognized during the three months ended June 30, 2024 was related to the Kissei License Agreement.

Research and Development Expenses

The following table summarizes our R&D expenses for the three months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		
	2025	2024	Change
External clinical trial expenses	$ 21,273	$ 13,394	$ 7,879
Personnel-related expenses	8,412	4,555	3,857
Other research and development	1,646	521	1,125
Total research and development expenses	$ 31,331	$ 18,470	$ 12,861

R&D expenses were $31.3 million for the three months ended June 30, 2025 compared to $18.5 million for the three months ended June 30, 2024. The increase of $12.9 million in R&D expenses for the three months ended June 30, 2025 was primarily due to an increase of $7.9 million in external clinical trial expenses related to higher CRO fees as patient enrollment increased, as well as an increase of $3.9 million in compensation costs due to increased headcount, including a $1.5 million increase in stock-based compensation, and an increase in other fees and costs of $1.1 million.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		
	2025	2024	Change
Personnel-related expenses	$ 9,733	$ 4,327	$ 5,406
Professional and consultant fees	5,156	1,821	3,335
Other general and administrative	2,521	1,346	1,175
Total general and administrative expenses	$ 17,410	$ 7,494	$ 9,916

General and administrative expenses were $17.4 million for the three months ended June 30, 2025 compared to $7.5 million for the three months ended June 30, 2024. The increase of $9.9 million in general and administrative expenses for the three months ended June 30, 2025 was primarily due to an increase in compensation costs of $5.4 million due to increased headcount, including a $3.2 million increase in stock-based compensation, as well as increased professional and consultant fees of $3.3 million, including a $3.0 million increase in legal fees, an increase in marketing-related costs of $0.4 million, and an increase in insurance, fees, and other costs of $0.8 million.

Other Income (Expense), Net

Other income (expense), net, for the three months ended June 30, 2025 was $7.3 million compared to $7.0 million for the three months ended June 30, 2024. The $0.4 million increase was driven by higher interest income earned related to cash equivalents and marketable securities balances.

Comparison of the Six Months Ended June 30, 2025 and 2024

The following table summarizes our results of operations for the six months ended June 30, 2025 and 2024 (in thousands):

	Six Months Ended June 30, 2025	2024	Change
Revenue:			
License and collaboration revenue	$ 52	$ 640	$ (588)
Operating expenses:			
Research and development	58,799	35,680	23,119
General and administrative	32,198	13,282	18,916
Total operating expenses	90,997	48,962	42,035
Loss from operations	(90,945)	(48,322)	(42,623)
Other income (expense), net:			
Interest income, net	15,066	12,487	2,579
Other income (expense), net	1	(1)	2
Total other income, net	15,067	12,486	2,581
Net loss and comprehensive loss	$ (75,878)	$ (35,836)	$ (40,042)

License and Collaboration Revenue

License and collaboration revenue was less than $0.1 million for the six months ended June 30, 2025 compared to $0.6 million for the six months ended June 30, 2024. During the six months ended June 30, 2025 we recognized less than $0.1 million in license and collaboration revenue related to the Kissei License Agreement. During the six months ended June 30, 2024, we recognized $0.5 million in license and collaboration revenue related to the Lepu License Agreement and $0.1 million in license and collaboration revenue related to the Kissei License Agreement.

Research and Development Expenses

The following table summarizes our R&D expenses for the six months ended June 30, 2025 and 2024 (in thousands):

	Six Months Ended June 30, 2025	2024	Change
External clinical trial expenses	$ 39,574	$ 26,125	$ 13,449
Personnel-related expenses	16,085	8,668	7,417
Other research and development	3,140	887	2,253
Total research and development expenses	$ 58,799	$ 35,680	$ 23,119

R&D expenses were $58.8 million for the six months ended June 30, 2025 compared to $35.7 million for the six months ended June 30, 2024. The increase of $23.1 million in R&D expenses for the six months ended June 30, 2025 was primarily due to an increase of $13.4 million in external clinical trial expenses related to higher CRO fees as patient enrollment increased, as well as an increase of $7.4 million in compensation costs due to increased headcount, including a $2.6 million increase in stock-based compensation, and an increase in other fees and costs of $2.3 million.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the six months ended June 30, 2025 and 2024 (in thousands):

	Six Months Ended June 30, 2025	2024	Change
Personnel-related expenses	$ 18,173	$ 7,468	$ 10,705
Professional and consultant fees	8,378	3,603	4,775
Other general and administrative	5,647	2,211	3,436
Total general and administrative expenses	$ 32,198	$ 13,282	$ 18,916

General and administrative expenses were $32.2 million for the six months ended June 30, 2025 compared to $13.3 million for the six months ended June 30, 2024. The increase of $18.9 million in general and administrative expenses for the six months ended June 30, 2025 was primarily due to an increase in compensation costs of $10.7 million due to increased headcount, including a $5.8 million increase in stock-based compensation, as well as increased professional and consultant fees of $4.8 million related to legal, accounting and consulting fees, an increase in marketing-related costs of $1.5 million, and an increase in insurance, fees, and other costs of $2.0 million.

Other Income (Expense), Net

Other income (expense), net, for the six months ended June 30, 2025 was $15.1 million compared to $12.5 million for the six months ended June 30, 2024. The $2.6 million increase was driven by higher interest income earned related to cash equivalents and marketable securities balances.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We expect to incur significant expenses and operating losses in the foreseeable future as we advance the clinical development of cretostimogene and any future product candidates. To date, we have primarily funded our operations with proceeds from the sale of shares of our common stock through public offerings and our redeemable convertible preferred stock, as well as through previously outstanding term debt. From inception through June 30, 2025, we have received aggregate gross proceeds of $982.9 million from the sale of shares of our common stock through our public offerings and our redeemable convertible preferred stock. In addition, through June 30, 2025, we have recognized $26.2 million in license and collaboration revenue through our license and collaboration agreements. As of June 30, 2025, we had cash, cash equivalents and marketable securities of $661.1 million.

At-the-Market Offering

On March 28, 2025, we entered into an Open Market Sale Agreement℠ (Jefferies Sales Agreement) with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time through Jefferies, up to $250 million of shares of our common stock. On the same day, we filed a shelf registration statement on Form S-3ASR with the SEC, which contains a base prospectus, covering an unlimited amount of our common stock, preferred stock, debt securities and warrants to purchase any of such securities, and a sales agreement prospectus, covering the offering, issuance and sale of up to a maximum aggregate offering price of $250 million of our common stock that may be issued and sold from time to time under the Jefferies Sales Agreement. As of June 30, 2025, no sales have been made under the shelf registration statement or the Jefferies Sales Agreement.

Future Funding Requirements

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

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

- the initiation, type, number, scope, progress, expansions, results, costs and timing of clinical trials and preclinical studies of cretostimogene and any future product candidates we may choose to pursue, including the costs of modification to clinical development plans based on feedback that we may receive from regulatory authorities and any third-party products used as combination agents in our clinical trials
- the costs, timing and outcome of regulatory meetings and reviews of cretostimogene or any future product candidates, including requirements of regulatory authorities in any additional jurisdictions in which we may seek approval for cretostimogene and any future product candidates;
- the costs of obtaining, maintaining, enforcing and protecting our patents and other intellectual property and proprietary rights;

•our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;

•the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, CMC quality and commercial personnel;

•the timing and payment of milestone, royalty or other payments we must make pursuant to our existing and potential future license or collaboration agreements with third parties;

•the costs and timing of establishing or securing sales and marketing capabilities if cretostimogene or any future product candidate is approved;

•our ability to achieve sufficient market acceptance, coverage, and adequate reimbursement from third- party payors and adequate market share and revenue for any approved products;

•our ability and strategic decision to develop future product candidates other than cretostimogene, and the timing of such development, if any;

•patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;

•the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and

•costs associated with any products or technologies that we may in-license or acquire.

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

We have no other committed sources of capital. Until such time, if ever, we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings, or other capital sources, including current or potential future collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments or declaring dividends. If we raise additional funds through collaborations or license agreements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or even cease operations.

Material Cash Requirements for Known Contractual and Other Obligations

During the three and six months ended June 30, 2025, there have been no material changes outside of the ordinary course of business in the composition to the material contractual obligations or commitments discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Material Cash Requirements for Known Contractual and Other Obligations" included in the 2024 Annual Report.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2025 and 2024 (in thousands):

	Six Months Ended June 30,	
	2025	2024
Net cash used in operating activities	$ (57,236)	$ (42,132)
Net cash used in investing activities	(185,362)	(343,674)
Net cash provided by financing activities	154	402,698
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (242,444)	$ 16,892

Operating Activities

During the six months ended June 30, 2025, operating activities used $57.2 million of cash, primarily resulting from our net loss of $75.9 million, as well as accretion of the discount on short-term investments of $2.2 million, partially offset by non-cash stock-based compensation charges of $12.2 million and net cash provided by changes in our operating assets and liabilities of $9.1 million.

During the six months ended June 30, 2024, operating activities used $42.1 million of cash, primarily resulting from our net loss of $35.8 million, accretion of the discount on short-term investments of $4.7 million, and net cash used in changes in our operating assets and liabilities of $5.4 million, partially offset by $3.8 million of non-cash stock-based compensation charges.

Investing Activities

During the six months ended June 30, 2025, net cash used in investing activities was $185.4 million, primarily due to purchases of marketable securities and the issuance of a note receivable through a convertible promissory note in the principal amount of $26.0 million, partially offset by proceeds from sales and maturities of short-term investments.

During the six months ended June 30, 2024, net cash used in investing activities was $343.7 million, primarily due to purchases of marketable securities offset by proceeds from sales and maturities of short-term investments.

Financing Activities

During the six months ended June 30, 2025, net cash provided by financing activities was $0.2 million, consisting primarily of proceeds from exercise of options of $0.7 million, partially offset by deferred offering costs of $0.5 million.

During the six months ended June 30, 2024, net cash provided by financing activities was $402.7 million, consisting primarily of net proceeds from the initial public offering, net of issuance costs and deferred offering costs of $403.0 million, partially offset by the long-term debt success fee payoff of $0.4 million.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

R&D Expenses and Related Prepaid and Accrued Expenses

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

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

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

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Standards

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

Our exposure to market risk is limited primarily to interest rate sensitivity. As of June 30, 2025, we had cash, cash equivalents and marketable securities of approximately $661.1 million, which consisted primarily of money market funds and marketable securities, comprised of fixed income securities (U.S. Treasury bills).

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

Effects of inflation

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

Item 4. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

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

Our management, with the participation of our principal executive officer and our principal financial officer, has evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report. Based on such evaluation, our principal executive officer and our principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2025.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the three months ended June 30, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

On March 4, 2024, 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, 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. The Company will continue to vigorously defend any post-trial motions and appeals brought by ANI.

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

Item 1A. Risk Factors.

Below we are providing, in supplemental form, updates to our risk factors from those previously disclosed in Part I, Item 1A, "Risk Factors" of our 2024 Annual Report. Our risk factors disclosed in Part I, Item 1A of our 2024 Annual Report provide additional discussion regarding these supplemental risks and we encourage you to read and carefully consider all of the risk factors disclosed in Part I, Item 1A of our 2024 Annual Report, together with the below, for a more complete understanding of the risks and uncertainties material to our business.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. For example, on March 4, 2024, ANI Pharmaceuticals, Inc. (ANI) filed a complaint against us 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 us and ANI (formerly BioSante Pharmaceuticals, Inc.), dated November 15, 2010 (the ANI Agreement), obligates us to pay ANI 5% of worldwide net sales of cretostimogene, and (ii) compensatory damages alleging we were unjustly enriched by obtaining the benefit of certain non-patent assets without paying adequate consideration to ANI. On July 16, 2025, the Superior Court granted our 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 our motion for summary judgment with respect to ANI's unjust enrichment claim. On July 21, 2025, trial commenced regarding ANI's unjust enrichment claim. On July 29, 2025, a jury entered a verdict in our favor. We expect ANI will continue to pursue its claims, including through post-trial motions and appeals. We will continue to vigorously defend against ANI's claims, including any post-trial motions and appeals that ANI my file. While we intend to vigorously defend this matter, such litigation could result in substantial costs and divert our management's attention from other business concerns, cause us reputational damage, negatively affect our stock price and result in monetary damages. An adverse outcome resulting from any legal proceedings, investigations or enforcement actions could result in significant damages, awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could, in each case, have a material adverse effect on our business, financial condition, results of operations and prospects. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, several of our suppliers are located outside of the United States, and our principal suppliers of certain raw materials are located outside of the United States. The active pharmaceutical ingredients (APIs) for cretostimogene is manufactured in the United States, and cretostimogene is manufactured in the United States. We also rely on specialized laboratory equipment, supplies, materials, and precursor compounds, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report and in our 2024 Annual Report.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize cretostimogene or any future product candidates and may adversely affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell cretostimogene or any future product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act (ACA), as amended by the Health Care and Education Reconciliation Act of 2010, was enacted in the United States, which substantially changed healthcare financing, access and delivery by both governmental and private insurers.

Since its enactment, there have been executive, judicial and Congressional challenges and amendments to certain aspects of the ACA. For example, on July 4, 2025, the annual reconciliation bill, the "One Big Beautiful Bill Act" (OBBBA) was signed into law, which is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. OBBBA also narrows access to ACA marketplace exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance.

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA (i) directs the Department of Health and Human Services (HHS) to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare (the Medicare Drug Price Negotiation Program) and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services (CMS) and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, propose policy changes that create additional uncertainty for our business. These actions and proposals, for example, include (1) reducing agency workforce; (2) directing program cuts; (3) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation (CMMI) to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan; (4) directing HHS and other agencies to lower prescription drug costs for Medicare through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (5) imposing tariffs of imported pharmaceutical products; and (6) directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and by standardizing prices across hospitals and health plans. Additionally, in its June 2024 decision in Loper Bright, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for cretostimogene and any future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We expect that these existing laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize cretostimogene or any future product candidates, if approved.

Changes in tax law may materially adversely affect our financial condition, results of operations and cash flows, or adversely impact the value of an investment in our common stock.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. For example, the U.S. government recently enacted the OBBBA, that (along with other recent U.S. federal tax reform) has resulted in significant changes to the taxation of business entities including, among other changes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. The Trump administration and the U.S. Congress could also enact other tax law changes that could have an adverse effect on our operations, cash flows and results from operations and contribute to overall market volatility. In addition, it is uncertain if and to what extent various states will conform to federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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 June 30, 2025, we estimate that we have used approximately $204.7 million of the proceeds from our initial public offering for general corporate purposes, including to fund the research and development of cretostimogene, and manufacturing and pre-commercial activities. There has been no material change in the planned use of proceeds from that described in the final prospectus for our initial public offering filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

From time to time, our Section 16 officers (as defined in Rule 16a–1(f)) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K) for the purchase or sale of our securities. During the six months ended June 30, 2025, except for James J. Mulé, 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	June 6, 2025	X		99,032	June 30, 2026

* 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	
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)				

* 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: August 8, 2025 By: /s/ Arthur Kuan
Arthur Kuan
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2025 By: /s/ Robert Lapetina
Robert Lapetina
Vice President, Financial Planning & Analysis
(Principal Financial and Accounting Officer)