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, 2024

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 5, 2024, the registrant had 67,077,020 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 Balance Sheets
(In thousands, except share and per share amounts)
(unaudited)

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 25,158	$ 8,266
Marketable securities	527,722	179,408
Prepaid expenses and other current assets	10,802	6,358
Accounts receivable - other	182	92
Total current assets	563,864	194,124
Property and equipment, net	84	69
Operating lease right-of-use assets	329	422
Other assets	53	19
Deferred offering costs	—	4,667
Total assets	$ 564,330	$ 199,301
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,491	$ 3,242
Success fee liability, current portion	—	352
Operating lease liabilities, current portion	237	217
Accrued expenses and other current liabilities	7,125	10,443
Total current liabilities	11,853	14,254
Success fee liability, non-current	—	13
Operating lease liabilities, net of current portion	118	244
Total liabilities	11,971	14,511
Commitments and contingencies (Note 5)		
Redeemable convertible preferred stock:		
Series A-1 redeemable convertible preferred stock, $0.0001 par value per share; zero and 5,075,000 shares authorized, issued and outstanding as of June 30, 2024 and December 31, 2023, respectively; liquidation value of $0 and $3,570 as of June 30, 2024 and December 31, 2023, respectively	—	3,570
Series B redeemable convertible preferred stock, $0.0001 par value per share; zero and 11,973,000 shares authorized, issued and outstanding as of June 30, 2024 and December 31, 2023; liquidation value of $0 and $10,000 as of June 30, 2024 and December 31, 2023, respectively	—	10,000
Series C redeemable convertible preferred stock, $0.0001 par value per share; zero and 73,598,283 shares authorized, issued and outstanding as of June 30, 2024 and December 31, 2023, respectively; liquidation value of $0 and $22,000 as of June 30, 2024 and December 31, 2023, respectively	—	22,000
Series D redeemable convertible preferred stock, $0.0001 par value per share; zero and 53,271,754 shares authorized, issued and outstanding as of June 30, 2024 and December 31, 2023, respectively; liquidation value of $0 and $47,300 as of June 30, 2024 and December 31, 2023, respectively	—	47,300
Series E redeemable convertible preferred stock, $0.0001 par value per share; zero and 112,422,700 shares authorized, issued and outstanding as of June 30, 2024 and December 31, 2023, respectively; liquidation value of $0 and $120,000 as of June 30, 2024 and December 31, 2023, respectively	—	120,000
Series F redeemable convertible preferred stock, $0.0001 par value per share; zero and 81,587,937 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively; liquidation value of zero and $105,020 as of June 30, 2024 and December 31, 2023, respectively	—	105,020
Stockholders' equity (deficit):		
Common stock, $0.0001 par value per share; 700,000,000 and 493,530,000 shares authorized as of June 30, 2024 and December 31, 2023, respectively; 66,659,852 and 5,222,283 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	7	—
Additional paid-in capital	718,130	6,842
Accumulated deficit	(165,778)	(129,942)
Total stockholders' equity (deficit)	552,359	(123,100)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 564,330	$ 199,301

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

CG ONCOLOGY, INC.

Condensed 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,	
	2024	2023	2024	2023
Revenues				
Research and collaboration revenue	$ 111	$ —	$ 640	$ 194
Operating expenses				
Research and development	18,470	9,832	35,680	17,677
General and administrative	7,494	2,494	13,282	4,568
Total operating expenses	25,964	12,326	48,962	22,245
Loss from operations	(25,853)	(12,326)	(48,322)	(22,051)
Other income (expense), net:				
Interest income, net	6,943	771	12,487	1,817
Other (expense) income, net	8	(58)	(1)	(50)
Total other income (expense), net	6,951	713	12,486	1,767
Net loss and comprehensive loss	$ (18,902)	$ (11,613)	$ (35,836)	$ (20,284)
Cumulative redeemable convertible preferred stock dividends	—	(3,776)	—	(7,510)
Net loss attributable to common stockholders	$ (18,902)	$ (15,389)	$ (35,836)	$ (27,794)
Net loss per share, basic and diluted	$ (0.28)	$ (3.93)	$ (0.63)	$ (7.15)
Weighted average shares of common stock outstanding, basic and diluted	66,649,443	3,918,509	56,857,104	3,885,713

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

CG ONCOLOGY, INC.

Condensed 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		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance as of December 31, 2022	5,075,000	$ 70	11,973,000	$ 10,000	73,598,283	$ 22,000	53,271,754	$ 47,300	112,422,700	$ 120,000	3,842,694	$ —	$ 3,642	$ (81,335)	$ (77,693)
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	13,656	—	68	—	68
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	179	—	179
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(8,671)	(8,671)
Balance as of March 31, 2023	5,075,000	$ 70	11,973,000	$ 10,000	73,598,283	$ 22,000	53,271,754	$ 47,300	112,422,700	$ 120,000	3,856,350	$ —	$ 3,889	$ (90,006)	$ (86,117)
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	183,790	—	165	—	165
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	177	—	177
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(11,613)	(11,613)
Balance as of June 30, 2023	5,075,000	$ 70	11,973,000	$ 10,000	73,598,283	$ 22,000	53,271,754	$ 47,300	112,422,700	$ 120,000	4,040,140	$ —	$ 4,231	$ (101,619)	$ (97,388)

	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'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance as of December 31, 2023	5,075,000	$ 70	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

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

CG ONCOLOGY, INC.

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

	Six Months Ended June 30,	
	2024	2023
Operating Activities		
Net loss	$ (35,836)	$ (20,284)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	11	8
Amortization of loan fees	—	7
Final payment amortization	—	709
Success fee amortization	—	13
Stock-based compensation expense	3,763	356
Accretion of discount on short-term investments	(4,665)	(257)
Non-cash lease expense	(13)	17
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,444)	(307)
Accounts receivable - other	(90)	—
Other assets	(34)	—
Accounts payable	1,249	40
Accrued expenses and other current liabilities	(2,073)	926
Net cash used in operating activities	(42,132)	(18,772)
Investing Activities		
Proceeds from sales and maturities of short-term investments	315,991	135,711
Purchases of short-term investments	(659,639)	(111,047)
Purchases of property and equipment	(26)	(6)
Net cash (used in) provided by investing activities	(343,674)	24,658
Financing Activities		
Proceeds from initial public offering, net of issuance costs	406,410	—
Payments of success fee or long-term debt	(365)	(16,223)
Proceeds from exercise of common stock options	77	233
Deferred offering costs	(3,424)	—
Net cash provided by (used in) financing activities	402,698	(15,990)
Net increase (decrease) in cash, cash equivalents and restricted cash	16,892	(10,104)
Cash, cash equivalents and restricted cash at beginning of period	8,266	88,143
Cash, cash equivalents and restricted cash at end of period	$ 25,158	$ 78,039
Supplemental Disclosure of Cash Flow Information		
Cash paid for interest	$ —	$ 376
Cash paid for taxes	$ —	$ —
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	$ —
Reclassification of deferred offering costs	$ 6,845	$ —

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

The shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. In addition, the conversion ratios for each series of the Company's redeemable convertible preferred stock, which automatically converted into shares of common stock upon the closing of the offering, were proportionally adjusted. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares.

On January 29, 2024, the Company completed the closing of its initial public offering (IPO) of 20,000,000 common shares at a price of $19.00 per share. Additionally, the underwriters exercised their option to purchase an additional 3,000,000 at a price of $19.00 per share. The common shares 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.

Basis of Presentation

The accompanying unaudited condensed financial statements as of June 30, 2024 and for the three and six months ended June 30, 2024 and 2023 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 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, 2023 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 (2023 Annual Report). In the opinion of management, the interim financial statements reflect all adjustments, which include only normal and recurring adjustments, considered necessary for a fair statement of the interim periods.

Liquidity and Management's Plans

As of June 30, 2024, the Company had approximately $552.9 million of cash, cash equivalents and marketable securities and working capital of approximately $552.0 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, 2024, the Company had an accumulated deficit of $165.8 million. During the three and six months ended June 30, 2024, the Company incurred net losses of $18.9 million and $35.8 million, respectively, and negative cash flows from operations of $42.1 million during the six months ended June 30, 2024. The Company will continue to incur significant costs and expenses related to its ongoing operations until it successfully develops, obtains regulatory approval, and gains market acceptance of a product candidate and achieves a level of revenues adequate to support the Company's operations.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements appearing in its 2023 Annual Report.

Deferred Offering Costs

The Company capitalizes as deferred offering costs all direct and incremental legal, professional, accounting and other third-party fees incurred in connection with the Company's IPO. Upon the completion of the IPO in January 2024, the total deferred offering costs were reclassified to additional paid-in capital on the condensed balance sheets.

Classification of Redeemable Convertible Preferred Stock

Classification of the Company's Series A-1, B, C, D, E and F redeemable convertible preferred stock as of December 31, 2023 was being treated as mezzanine equity and not as part of stockholders' equity (deficit) because the holders of such shares had liquidation rights in the event of a deemed liquidation that, in certain situations, were not solely within the control of the Company and would have required the redemption of the then-outstanding redeemable convertible preferred stock. In addition, all of the Company's redeemable convertible preferred stock was redeemable with the passage of time on or after July 28, 2028, by class and if requested by a requisite majority of each class. As a result of the Company's IPO, the Company's redeemable convertible preferred stock converted into common stock concurrently with the IPO.

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 financial statements.

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The guidance includes the requirements that a public entity disclose, on an annual and interim basis, significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, the title and position of the chief operating decision maker, and an explanation of how the chief operating decision maker uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. The guidance also requires that a public entity that has a single reportable segment provide all the disclosures required by the guidance and all existing segment disclosures in Accounting Standards Codification (ASC) 280, *Segment Reporting*. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. A public entity should apply the amendments in the guidance retrospectively to all prior periods presented in the financial statements. Upon transition, the segment expense categories and amounts disclosed in the prior periods should be based on the significant segment expense categories identified and disclosed in the period of adoption. The Company is currently evaluating the impact that this guidance may have on its financial statements.

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

3. Fair Value Measurements

The following tables present the financial instruments carried at fair value on a recurring basis as of June 30, 2024 and December 31, 2023, respectively, in accordance with the ASC 820, *Fair Value Measurement* (ASC 820) hierarchy (in thousands):

	Fair Value Measurements at June 30, 2024			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 25	$ —	$ —	$ 25
Marketable securities	$ —	$ 527,722	$ —	$ 527,722

	Fair Value Measurements at December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 8,240	$ —	$ —	$ 8,240
Marketable securities	$ —	$ 179,408	$ —	$ 179,408
Liabilities				
Success fee liability	$ —	$ —	$ 365	$ 365

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, 2024 and December 31, 2023, 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.

The success fee liability associated with the Loan and Security Agreement (the Loan Agreement) the Company entered into in January 2021 was classified as a Level 3 fair value measurement, due to the use of unobservable inputs. On March 5, 2024, the Company paid $0.4 million for the success fee. See Note 10 for additional information on the success fee.

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the three and six months ended June 30, 2024 and the year ended December 31, 2023.

4. Accrued Expenses and Other Current Liabilities

The components of accrued expenses and other current liabilities as of June 30, 2024 and as of December 31, 2023 were as follows (in thousands):

	June 30, 2024	December 31, 2023
External research and development expenses	$ 3,893	$ 6,164
Personnel-related expenses	2,520	2,822
Professional fees	581	341
Deferred offering costs	—	1,017
Other	131	99
Total accrued expenses and other current liabilities	$ 7,125	$ 10,443

5. Commitments and Contingencies

Operating Leases

As of June 30, 2024 and December 31, 2023, the Company had two operating leases, in which the Company was the lessee for office space. As of June 30, 2024 and December 31, 2023, the lease terms were through 2025 and 2026. The Company had no finance leases as of June 30, 2024 and December 31, 2023.

The components of lease expense as of June 30, 2024 and 2023 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Lease cost				
Operating lease cost	$ 35	$ 60	$ 96	$ 121
Total lease cost	$ 35	$ 60	$ 96	$ 121
Other information				
Cash paid for amounts included in the measurement of lease liabilities, included in operating cash flows	$ 45	$ 45	$ 103	$ 102
Weighted-average remaining lease term	1.63	2.59	1.63	2.59
Weighted-average discount rate	1.63%	1.63%	1.63%	1.63%

Maturities of lease liabilities as of June 30, 2024 were as follows (in thousands):

2024	$ 120
2025	187
2026	52
Total lease payment	359
Less: amount representing imputed interest	(4)
Total future minimum lease obligations	$ 355

Legal Proceedings

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

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

Indemnification

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with officers and members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. As of June 30, 2024, the Company had not experienced any losses related to these indemnification obligations, and no claims with respect thereto were outstanding.

6. License and Collaboration Agreements

Lepu Biotech Co., Ltd.

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

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

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

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

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

The Company recorded zero development income for the three months ended June 30, 2024 and 2023. The Company recorded $0.5 million and zero in development income for the six months ended June 30, 2024 and 2023, respectively.

Kissei Pharmaceutical Co., Ltd.

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

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

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

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

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

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

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

The Company recorded $0.1 million and zero in development income for the three months ended June 30, 2024 and 2023, respectively. The Company recorded $0.1 million and $0.2 million in development income for the six months ended June 30, 2024 and 2023, respectively.

7. Common Stock

The Company is authorized to issue up to 700,000,000 and 493,530,000 shares of common stock at June 30, 2024 and December 31, 2023, respectively, of which 66,659,852 and 5,222,283 shares were issued and outstanding at June 30, 2024 and December 31, 2023, respectively.

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

Voting

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

Dividends

The holders of common stock shall be entitled to receive dividends out of funds legally available therefor 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, 2024, the Company reserved the following shares of common stock for issuance:

	June 30, 2024
Stock options outstanding	6,040,339
Reserved for future stock option issuances	7,723,016
Reserved for future ESPP issuances	812,242
Total	14,575,597

8. 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, 2024, there were 1,725,019 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, 2024, there were 3,569,013 shares of common stock subject to outstanding awards under the 2022 Plan.

On January 11, 2024, the Company's board of directors and stockholders approved the 2024 Equity Incentive Plan (the 2024 Plan), which became effective on the date immediately preceding the date on which the Company's registration statement was declared effective by the SEC. The 2024 Plan replaced the 2022 Plan, as the Company's board of directors has determined to not make additional grants under the 2022 Plan following the closing of the offering. However, the 2015 and 2022 Plan will continue to govern outstanding equity awards granted under the 2015 and 2022 Plans. The 2024 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors and consultants. The number of shares initially available for issuance under awards granted pursuant to the 2024 Plan is (1) 8,246,565 shares, plus (2) any shares subject to outstanding awards under the 2015 Plan and 2022 Plan as of the effective date of the 2024 Plan that become available for issuance under the 2024 Plan thereafter in accordance with its terms. As of June 30, 2024, there were 746,307 shares of common stock subject to outstanding awards and 7,723,016 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, 2024 and 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Expected volatility	77.46% - 77.53%	81.4% - 81.7%	77.46% - 84.50%	81.4% - 83.7%
Risk-free interest rate	4.21% - 4.62%	4.00% - 4.05%	3.93% - 4.62%	3.58% - 4.0%
Expected dividend yield	0%	0%	0%	0%
Expected term (in years)	6.1	5.27 - 6.11	6.05 - 6.1	4.95 - 6.11

The weighted average grant-date fair value of the options granted was $16.49 and $2.62 per share for the six months ended June 30, 2024 and 2023, respectively. The fair value of shares vested during the six months ended June 30, 2024 and 2023 was $3.73 and $1.93 per share, respectively. The fair value of shares exercised during the six months ended June 30, 2024 and 2023 was $2.07 and $2.12 per share, respectively.

The following table summarizes stock option activity for the six months ended June 30, 2024 (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, 2023	5,532,871	$ 4.12	8.55	$ 40,290
Granted	746,307	$ 23.07		
Exercised	(23,660)	$ 2.07		
Forfeited/Expired	(215,179)	$ 4.63		
Balance at June 30, 2024	6,040,339	$ 6.45	7.59	$ 153,034
Vested and expected to vest at June 30, 2024	6,040,339	$ 6.45	7.59	$ 153,034
Exercisable at June 30, 2024	2,082,480	$ 2.26	5.11	$ 61,347

The Company recorded stock-based compensation expense related to stock options of $1.5 million and $0.2 million for the three months ended June 30, 2024 and 2023, respectively, and $3.0 million and $0.4 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, the Company had an aggregate $22.7 million of gross unrecognized stock-based compensation expense related to unvested options to be recognized over a weighted average period of 3.3 years.

Stock-based compensation expense related to stock options and the 2024 Employee Stock Purchase Plan (see Note 9) recorded in the accompanying statements of operations for the three and six months ended June 30, 2024 and 2023 was as follows (in thousands):

	Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 779	$ 91	$ 1,322	$ 193
General and administrative	1,467	86	2,441	163
Total stock-based compensation expense	$ 2,246	$ 177	$ 3,763	$ 356

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.

9. 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 no purchases of shares under the ESPP during the three and six months ended June 30, 2024. On June 30, 2024, there were approximately 0.8 million shares available for issuance under the ESPP.

The Company recorded stock-based compensation expense under the ESPP of approximately $0.7 million for the three and six months ended June 30, 2024. As of June 30, 2024, the Company had $3.1 million of gross unrecognized stock-based compensation expense under the ESPP to be recognized over a weighted average period of 1.8 years.

10. Debt

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. On March 5, 2024, the Company paid $0.4 million for the success fee under the Success Fee Agreement entered into in connection with the Loan Agreement.

11. 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,	
	2024	2023	2024	2023
Numerator:				
Net loss and comprehensive loss	$ (18,902)	$ (11,613)	$ (35,836)	$ (20,284)
Cumulative redeemable convertible preferred stock dividends	—	(3,776)	—	(7,510)
Net loss attributable to common stockholders	$ (18,902)	$ (15,389)	$ (35,836)	$ (27,794)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	66,649,443	3,918,509	56,857,104	3,885,713
Net loss per share attributable to common stockholders, basic and diluted	$ (0.28)	$ (3.93)	$ (0.63)	$ (7.15)

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, 2024 and 2023 because including them would have had an anti-dilutive effect:

	June 30,	
	2024	2023
Stock options outstanding	6,040,339	4,484,097
Total	6,040,339	4,484,097

12. Related Parties

In 2023, the Company entered into an agreement with Danforth Advisors, LLC for the provision of interim Chief Financial Officer (CFO) services. Under the agreement, the Company paid Danforth Advisors, LLC for Stephen DiPalma's services as part-time CFO approximately $0.1 million or less for services rendered for each of the three and six months ended June 30, 2024 and 2023.

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

The following discussion and analysis and the unaudited interim 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, 2023 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, 2023 (the 2023 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 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 product candidate, cretostimogene, is initially in clinical development for the treatment of patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) who are unresponsive to Bacillus Calmette Guerin (BCG) therapy, the current standard-of-care for high-risk NMIBC. There is significant unmet need for treatments in these patients given the limitations of currently approved therapies and patient reluctance to undergo radical cystectomy, or the complete removal of the bladder. We are evaluating the safety and efficacy of cretostimogene as monotherapy in BOND-003, our ongoing Phase 3 clinical trial in high-risk BCG-unresponsive NMIBC patients. We have completed enrollment for this trial, reported interim data in May 2024 and expect to report primary data by the end of 2024. If successful, we believe that this trial could serve as the basis for a Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA). In addition, in our CORE-001 Phase 2 clinical trial, we evaluated the use of cretostimogene when administered to this same patient population in combination with FDA-approved pembrolizumab, and reported positive final results from the CORE-001 trial in May 2024. Moreover, we intend to assess the safety and efficacy of cretostimogene in treating a range of other bladder cancer indications as an alternative to BCG therapy and in patients who are not categorized as BCG-unresponsive, including our second Phase 3 clinical trial, PIVOT-006, evaluating adjuvant cretostimogene in up to 364 intermediate-risk NMIBC patients following transurethral resection of the bladder tumor (TURBT). In June 2024, we initiated an expanded access program (EAP) for cretostimogene in the U.S. for patients with NMIBC who are unresponsive to BCG and meet certain program eligibility criteria. The first patient has been dosed in the EAP and enrollment in the study is ongoing. We believe cretostimogene, if approved, has the potential to serve as first-line 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 $35.8 million and $20.3 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we had an accumulated deficit of $165.8 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 common shares from our IPO, our redeemable convertible preferred stock and previously outstanding term debt. From inception through June 30, 2024, we have received aggregate gross proceeds of approximately $747.5 million from the sale of common shares from our IPO and sales of redeemable convertible preferred stock. In addition, from inception through June 30, 2024, we have recognized $25.6 million in research and collaboration revenue pursuant to our license and collaboration agreements. As of June 30, 2024, we had cash, cash equivalents and marketable securities of $552.9 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 projected operating expenses and capital expenditure requirements through 2027. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, we could utilize our available capital resources sooner than we expect.

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

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

In January 2024, we completed our initial public offering of 23,000,000 common shares at a price of $19.00 per share, including the exercise in full by the underwriters of their option to purchase an additional 3,000,000 shares of common stock. We received net proceeds of $399.6 million, after deducting discounts and commissions and offering expenses. In addition, as a result of our initial public offering, our redeemable convertible preferred stock converted into common stock concurrently with the initial public offering.

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 2023 Annual Report.

Lepu License Agreement

In March 2019, we entered into a development and license agreement (the Lepu License Agreement) with Lepu, under which we granted an exclusive license to Lepu to develop, manufacture and commercialize cretostimogene and/or DDM to treat and/or prevent cancer in the Lepu Territory. Lepu paid to us a one-time upfront payment of $4.5 million and is obligated to make regulatory milestone payments of up to $2.5 million and commercial milestone payments of up to $57.5 million. We are entitled to receive a high single-digit royalty on net sales of cretostimogene and/or DDM sold in the Lepu Territory, subject to a specified reduction. During the years ended December 31, 2023 and 2022, less than $0.1 million and zero collaboration revenue, respectively, was recorded related to the Lepu License Agreement. During the three months ended June 30, 2024 and 2023, no collaboration revenue was recorded related to the Lepu License Agreement. During the six months ended June 30, 2024 and 2023, $0.5 million and zero in collaboration revenue was recorded related to the Lepu License Agreement, respectively.

Kissei License Agreement

In March 2020, and as amended September 2022, we entered into a license and collaboration agreement (the Kissei License Agreement) with Kissei, under which we granted to Kissei an exclusive license to certain intellectual property rights in Bangladesh, Bhutan, Brunei, Cambodia, India, Indonesia, Japan, South Korea, Laos, Malaysia, Myanmar, Nepal, Pakistan, Palau, Philippines, Singapore, Sri Lanka, Taiwan, Thailand and Vietnam (the Kissei Territory), for Kissei to develop and commercialize, but not manufacture, cretostimogene in combination with DDM (the Licensed Product) for all uses in oncology. Kissei paid to us a one-time upfront payment of $10.0 million under the agreement. Kissei is obligated to pay development milestone payments of up to $33.0 million and commercial milestone payments of up to $67.0 million. We have also agreed to pay Kissei a royalty on net sales of Licensed Product outside the Kissei Territory and outside the Lepu Territory, including on any U.S. sales, in a low-single digit percentage, subject to certain capped reductions. We are entitled to receive a royalty on net sales of Licensed Product in the Kissei Territory in the mid-twenties percentage, subject to certain capped reductions and offset rights. We are obligated to supply and Kissei will exclusively purchase its clinical and commercial requirements of Licensed Product from us. During the years ended December 31, 2023 and 2022, we recorded $0.2 million and $0.2 million, respectively in development income related to the Kissei License Agreement. During the three months ended June 30, 2024 and 2023, $0.1 million and zero in collaboration revenue was recorded related to the Kissei License Agreement, respectively. During the six months ended June 30, 2024 and 2023, $0.5 million and $0.2 million in collaboration revenue was recorded related to the Kissei License Agreement, respectively.

Components of Our Results of Operations

Revenue

From inception through June 30, 2024, we have recognized $25.6 million in research and collaboration revenue through our license and collaboration agreements. We have not generated any revenue from the sale of products, however, and do not expect to generate any revenue from the sale of products in the foreseeable future, if at all. If our or our collaborators' development efforts for cretostimogene and any future product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales, payments from existing or potential future collaboration or license agreements with third parties, or any combination thereof.

Operating Expenses

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

Research and Development Expenses

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

Our R&D expenses consist of:

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

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

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

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

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

General and Administrative Expenses

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

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

Other Income (Expense), Net

Interest Income, Net

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

Other (Expense) Income

Other (expense) income 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, 2024 and 2023

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		
	2024	2023	Change
Revenue:			
Research and collaboration revenue	$ 111	$ —	$ 111
Operating expenses:			
Research and development	18,470	9,832	8,638
General and administrative	7,494	2,494	5,000
Total operating expenses	25,964	12,326	(13,638)
Loss from operations	(25,853)	(12,326)	(13,527)
Other income (expense), net:			
Interest income (expense), net	6,943	771	6,172
Other (expense), net	8	(58)	66
Total other income (expense), net	6,951	713	6,238
Net loss and comprehensive loss	$ (18,902)	$ (11,613)	$ (7,289)

Research and Collaboration Revenue

Research and collaboration revenue was $0.1 million for the three months ended June 30, 2024 compared to zero for the three months ended June 30, 2023. We recorded $0.1 million in development revenue related to the Kissei License Agreement for the three months ended June 30, 2024, with zero development revenue during the prior year period.

Research and Development Expenses

The following table summarizes our R&D expenses for the three months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		
	2024	2023	Change
External clinical trial expenses	$ 13,394	$ 6,958	$ 6,436
Personnel-related expenses	4,555	2,670	1,885
Other research and development	521	204	317
Total research and development expenses	$ 18,470	$ 9,832	$ 8,638

R&D expenses were $18.5 million for the three months ended June 30, 2024 compared to $9.8 million for the three months ended June 30, 2023. The increase of $8.6 million in R&D expenses for the three months ended June 30, 2024 was primarily due to an increase of $6.4 million in external clinical trial expenses, including an increase of $3.2 million of chemistry, manufacturing and control (CMC) costs, and an increase of $1.7 million in compensation costs due to increased headcount.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		
	2024	2023	Change
Personnel-related expenses	$ 4,327	$ 1,067	$ 3,260
Professional and consultant fees	1,821	1,154	667
Other general and administrative	1,346	273	1,073
Total general and administrative expenses	$ 7,494	$ 2,494	$ 5,000

General and administrative expenses were $7.5 million for the three months ended June 30, 2024 compared to $2.5 million for the three months ended June 30, 2023. The increase of $5.0 million in general and administrative expenses for the three months ended June 30, 2024 was primarily due to an increase in personnel-related expenses, including an increase in compensation costs of $3.0 million due to increased headcount, an increase in professional and consultant fees of $0.7 million related to legal, accounting and consulting fees, and an increase of marketing-related costs of $0.6 million.

Other Income (Expense), Net

Other income (expense), net, for the three months ended June 30, 2024 was an other income, net of $7.0 million compared to an other income, net of $0.7 million for the three months ended June 30, 2023. For the three months ended June 30, 2024, other income (expense), net primarily consisted of $6.9 million in interest income related to marketable securities balances, and for the three months ended June 30, 2023, other income (expense), net primarily consisted of interest income of $0.8 million related to marketable securities balances.

Comparison of the Six Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30,		
	2024	2023	Change
Revenue:			
Research and collaboration revenue	$ 640	$ 194	$ 446
Operating expenses:			
Research and development	35,680	17,677	18,003
General and administrative	13,282	4,568	8,714
Total operating expenses	48,962	22,245	(26,717)
Loss from operations	(48,322)	(22,051)	(26,271)
Other income (expense), net:			
Interest income (expense), net	12,487	1,817	10,670
Other (expense), net	(1)	(50)	49
Total other income (expense), net	12,486	1,767	10,719
Net loss and comprehensive loss	$ (35,836)	$ (20,284)	$ (15,552)

Research and Collaboration Revenue

Research and collaboration revenue was $0.6 million for the six months ended June 30, 2024 compared to $0.2 million for the three months ended June 30, 2023. For development revenue, we recorded $0.5 million and zero for the six months ended June 30, 2024 and 2023, respectively, related to the Lepu License Agreement, and we recorded $0.1 million and $0.2 million related to the Kissei License Agreement for the six months ended June 30, 2024 and 2023, respectively.

Research and Development Expenses

The following table summarizes our R&D expenses for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30,		
	2024	2023	Change
External clinical trial expenses	$ 26,125	$ 11,898	$ 14,227
Personnel-related expenses	8,668	5,383	3,285
Other research and development	887	396	491
Total research and development expenses	$ 35,680	$ 17,677	$ 18,003

R&D expenses were $35.7 million for the six months ended June 30, 2024 compared to $17.7 million for the six months ended June 30, 2023. The increase of $18.0 million in R&D expenses for the six months ended June 30, 2024 was primarily due to an increase of $14.2 million in external clinical trial expenses related to higher CRO fees as patient enrollment increased, including an $8.0 million increase in CMC costs, as well as an increase of $2.8 million in compensation costs due to increased headcount, including a $1.1 million increase in stock-based compensation.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30,		
	2024	2023	Change
Personnel-related expenses	$ 7,468	$ 2,082	$ 5,386
Professional and consultant fees	3,603	2,065	1,538
Other general and administrative	2,211	421	1,790
Total general and administrative expenses	$ 13,282	$ 4,568	$ 8,714

General and administrative expenses were $13.3 million for the six months ended June 30, 2024 compared to $4.6 million for the six months ended June 30, 2023. The increase of $8.7 million in general and administrative expenses for the six months ended June 30, 2024 was primarily due to an increase in compensation costs of $5.0 million due to increased headcount, including a $2.3 million increase in stock-based compensation, as well as increased professional and consultant fees of $1.5 million related to legal, accounting and consulting fees, and an increase in marketing-related costs of $1.0 million.

Other Income (Expense), Net

Other income (expense), net, for the six months ended June 30, 2024 was an other income, net of $12.5 million compared to an other income, net of $1.8 million for the six months ended June 30, 2023. For the six months ended June 30, 2024, other income (expense), net primarily consisted of $12.5 million in interest income related to marketable securities balances, and for the six months ended June 30, 2023, other income (expense), net primarily consisted of interest income of $1.8 million related to marketable securities balances.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We expect to incur significant expenses and operating losses in the foreseeable future as we advance the clinical development of cretostimogene and any future product candidates. To date, we have primarily funded our operations with proceeds from the sale of shares of our common stock in our initial public offering, the sale of shares of our redeemable convertible preferred stock and previously outstanding term debt. Through June 30, 2024, we have received aggregate gross proceeds of $747.5 million from the sale of common stock in our IPO and sale of redeemable convertible preferred stock. In addition, through June 30, 2024, we have recognized $25.6 million in research and collaboration revenue through our license and collaboration agreements. As of June 30, 2024, we had cash, cash equivalents and marketable securities of $552.9 million. On January 29, 2024, we closed our initial public offering of common stock for aggregate net proceeds of $399.6 million, after deducting discounts and commissions and offering expenses.

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 projected operating expenses and capital expenditure requirements through 2027. 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, 2024, 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 2023 Annual Report.

Cash Flows

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

	Six Months Ended June 30,	
	2024	2023
Net cash used in operating activities	$ (42,132)	$ (18,772)
Net cash used in investing activities	(343,674)	24,658
Net cash provided by (used in) financing activities	402,698	(15,990)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 16,892	$ (10,104)

Operating Activities

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, as well as 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 non-cash stock-based compensation charges of $3.8 million.

During the six months ended June 30, 2023, operating activities used $18.8 million of cash, primarily resulting from our net loss of $20.3 million, partially offset by $1.1 million of non-cash charges, which includes stock-based compensation expense and amortization associated with the term loan final payoff and success fees, and net cash used in changes in our operating assets and liabilities of $0.7 million.

Investing Activities

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.

During the six months ended June 30, 2023, net cash used in investing activities was $24.7 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, 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.

During the six months ended June 30, 2023, net cash used in financing activities was $16.0 million, consisting of payments of long-term debt of $16.2 million partially offset by the exercise of common stock options of $0.2 million.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our condensed 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 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 2023 Annual Report.

R&D Expenses and Related Prepaid and Accrued Expenses

As part of the process of preparing our condensed 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 financial statements included elsewhere in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of June 30, 2024, there have been no material changes surrounding our market risk, including interest rate risk, foreign currency exchange risk, and inflation risk, from the discussion provided in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Quantitative and Qualitative Disclosures about Market Risk" in the 2023 Annual Report.

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, have 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.

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, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

From time to time, we may be subject to other legal proceedings. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors. There have been no material developments to the legal proceedings disclosed in Part II, Item 1, "Legal Proceedings" in our 2023 Annual Report.

Item 1A. Risk Factors.

There have been no material changes to the risk factors disclosed in Part I, Item 1A, “Risk Factors” of our 2023 Annual Report.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On January 24, 2024, our registration statement on Form S-1 (File No. 333-276350) was declared effective by the SEC for our initial public offering. At the closing of our initial public offering on January 29, 2024, we sold 23,000,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 3,000,000 additional shares, at an initial public offering price of $19.00 per share and received gross proceeds of $437.0 million, which resulted in net proceeds to us of approximately $399.6 million, after deducting underwriting discounts and commissions of approximately $30.6 million and offering-related transaction costs of approximately $6.8 million. As of June 30, 2024, we estimate that we have used approximately $46.9 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 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). During the three months ended June 30, 2024, none of our officers or directors adopted, modified or terminated any such trading arrangements.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	S-1/A	01/18/24	3.3	
3.2	Amended and Restated Bylaws	S-1	01/02/24	3.4	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1/A	01/18/24	4.1	
4.2	Amended and Restated Investors' Rights Agreement, dated July 28, 2023, as amended, by and among the Registrant and certain of its stockholders	S-1/A	01/18/24	4.2	
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

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

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, 2024

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

Date: August 8, 2024

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