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 September 30, 2025

OR

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

For the transition period from _____ to _____

Commission File Number: 001-41925

CG Oncology, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

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

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

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

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

As of November 12, 2025, the registrant had 80,666,179 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

CG ONCOLOGY, INC.

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

	September 30, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 45,145	$ 257,068
Marketable securities	635,118	484,930
Inventory	1,501	—
Accounts receivable, net	515	—
Prepaid expenses and other current assets	13,511	12,212
Total current assets	695,790	754,210
Property and equipment, net	15,329	272
Operating lease right-of-use assets	4,203	221
Intangible assets, net	1,672	—
Goodwill	12,805	—
Other assets	114	94
Total assets	$ 729,913	$ 754,797
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,193	$ 6,517
Operating lease liabilities, current portion	912	186
Accrued expenses and other current liabilities	20,423	14,665
Total current liabilities	30,528	21,368
Long-term debt	3,000	—
Operating lease liabilities, net of current portion	3,329	52
Deferred tax liability	1,609	—
Other liabilities	3,804	—
Total liabilities	42,270	21,420
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, $0.0001 par value per share; 700,000,000 and 700,000,000 shares authorized as of September 30, 2025 and December 31, 2024, respectively; 78,277,452 and 76,154,783 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	8	8
Additional paid-in capital	1,025,302	951,350
Accumulated deficit	(337,667)	(217,981)
Total stockholders' equity	687,643	733,377
Total liabilities and stockholders' equity	$ 729,913	$ 754,797

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

CG ONCOLOGY, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues				
Commercial and development revenue	$ 1,508	$ —	$ 1,508	$ —
License and collaboration revenue	158	43	210	683
Total revenues	1,666	43	1,718	683
Operating costs and expenses				
Cost of sales	1,577	—	1,577	—
Research and development	27,884	19,622	86,683	55,302
General and administrative	23,334	8,716	55,532	21,998
Total operating costs and expenses	52,795	28,338	143,792	77,300
Loss from operations	(51,129)	(28,295)	(142,074)	(76,617)
Other income (expense), net:				
Interest income, net	7,421	7,892	22,487	20,379
Other (expense) income, net	(100)	(2)	(99)	(3)
Total other income, net	7,321	7,890	22,388	20,376
Net loss and comprehensive loss	$ (43,808)	$ (20,405)	$ (119,686)	$ (56,241)
Net loss per share, basic and diluted	$ (0.57)	$ (0.30)	$ (1.57)	$ (0.93)
Weighted average shares of common stock outstanding, basic and diluted	76,729,726	67,143,744	76,383,376	60,311,003

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

CG ONCOLOGY, INC.

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

	Series A-1 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Series E Redeemable Convertible Preferred Stock		Series F Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance as of December 31, 2023	5,075,000	$ 3,570	11,973,000	$ 10,000	73,598,283	$ 22,000	53,271,754	$ 47,300	112,422,700	$ 120,000	81,587,937	$ 105,020	5,222,283	$ —	$ 6,842	$ (129,942)	$ (123,100)
Conversion of redeemable convertible preferred stock	(5,075,000)	(3,570)	(11,973,000)	(10,000)	(73,598,283)	(22,000)	(53,271,754)	(47,300)	(112,422,700)	(120,000)	(81,587,937)	(105,020)	38,413,909	4	307,886	—	307,890
Issuance of common stock in connection with an initial public offering, net of issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	23,000,000	3	399,562	—	399,565
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	60	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1,517	—	1,517
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(16,934)	(16,934)
Balance as of March 31, 2024	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	66,636,252	$ 7	$ 715,807	$ (146,876)	$ 568,938
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	23,600	—	77	—	77
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	2,246	—	2,246
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(18,902)	(18,902)
Balance as of June 30, 2024	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	66,659,852	$ 7	$ 718,130	$ (165,778)	$ 552,359
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	878,006	—	2,167	—	2,167
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	2,649	—	2,649
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(20,405)	(20,405)
Balance as of September 30, 2024	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	67,537,858	$ 7	$ 722,946	$ (186,183)	$ 536,770
Balance as of December 31, 2024	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	76,154,783	$ 8	$ 951,350	$ (217,981)	$ 733,377
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	66,506	—	682	—	682
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	5,151	—	5,151
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(34,452)	(34,452)
Balance as of March 31, 2025	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	76,221,289	$ 8	$ 957,183	$ (252,433)	$ 704,758
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	10,570	—	19	—	19
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	7,007	—	7,007
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(41,426)	(41,426)
Balance as of June 30, 2025	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	76,231,859	$ 8	$ 964,209	$ (293,859)	$ 670,358
Issuance of common stock in connection with a public offering, net of issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	1,515,151	—	48,663	$ —	48,663
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	530,442	—	5,099	—	5,099
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	7,331	—	7,331
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(43,808)	(43,808)
Balance as of September 30, 2025	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	78,277,452	$ 8	$ 1,025,302	$ (337,667)	$ 687,643

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

CG ONCOLOGY, INC.

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

	Nine Months Ended September 30,	
	2025	2024
Operating Activities		
Net loss	$ (119,686)	$ (56,241)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	596	32
Stock-based compensation expense	19,489	6,412
Accretion of discount on short-term investments	(1,965)	(6,247)
Non-cash interest income	(844)	—
Non-cash lease expense	21	(17)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(90)	(4,920)
Accounts receivable, net	(19)	—
Other assets	(20)	(34)
Accounts payable	1,835	834
Accrued expenses and other current liabilities	4,924	2,130
Inventory	(380)	—
Other liabilities	9	—
Net cash used in operating activities	(96,130)	(58,051)
Investing Activities		
Proceeds from sales and maturities of investments	621,899	517,230
Purchases of investments	(770,122)	(828,874)
Acquisition, net of cash acquired	(21,967)	—
Purchases of property and equipment	(127)	(25)
Net cash used in investing activities	(170,317)	(311,669)
Financing Activities		
Proceeds from initial public offering, net of issuance costs	—	406,410
Proceeds from at-the-market offering, net of issuance costs	49,001	—
Payments of success fee or long-term debt	—	(365)
Proceeds from exercise of common stock options and issuance of common stock under the employee stock purchase plan	5,800	2,244
Deferred offering costs	(277)	(3,424)
Net cash provided by financing activities	54,524	404,865
Net (decrease) increase in cash and cash equivalents	(211,923)	35,145
Cash and cash equivalents at beginning of period	257,068	8,266
Cash and cash equivalents at end of period	$ 45,145	$ 43,411
Supplemental Disclosure of Cash Flow Information		
Cash paid for taxes	$ 16	$ —
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Reclassification of 38,413,909 redeemable convertible preferred stock to 38,413,909 shares of common stock	$ —	$ 307,890
Conversion of deferred offering costs	$ —	$ 6,845
Deferred offering costs, unpaid and accrued	$ 61	$ —
Operating lease right-of-use asset obtained in exchange for lease liabilities	$ 859	$ —

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

1. Description of Business and Basis of Presentation

Description of Business

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

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

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

In February 2025, the Company's wholly owned subsidiary, SafeGuard Healthcare, LLC, established a convertible note receivable with a principal amount of $26.8 million, including accrued interest, through a convertible promissory note (Note) from SP Healthcare SPV I, LLC (the SPV). The SPV used the proceeds from the Note to make an investment in Biovire, Inc. (Biovire) for the purpose of Biovire acquiring substantially all of the assets of a contract manufacturing organization that provides clinical supply of cretostimogene to the Company. On July 20, 2025, following the cessation of services by SkyPath to the SPV and Biovire (Conversion Event), the Company converted the Note and obtained control of the SPV and Biovire. See footnote 15 for more information on the Conversion Event.

Basis of Presentation

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

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

Liquidity and Management's Plans

As of September 30, 2025, the Company had approximately $680.3 million of cash, cash equivalents and marketable securities and working capital of approximately $665.3 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 September 30, 2025, the Company had an accumulated deficit of $337.7 million. During the three and nine months ended September 30, 2025, the Company incurred net losses of $43.8 million and $119.7 million, respectively, and had negative cash flows from operations of $96.1 million during the nine months ended September 30, 2025. The Company will continue to incur significant costs and expenses related to its ongoing operations until it successfully develops, obtains regulatory approval, and gains market acceptance of a product candidate and achieves a level of revenues adequate to support the Company's operations.

At-the-Market Offering

On March 28, 2025, the Company entered into an Open Market Sale Agreement℠ (Jefferies Sales Agreement) with Jefferies LLC, as agent, pursuant to which the Company may offer and sell, from time to time through Jefferies, up to $250.0 million in shares of the Company's common stock. During the three months ended September 30, 2025, 1,515,151 shares were sold under the Jefferies Sales Agreement, at a price of $33.00 per share. The Company received net proceeds of $48.7 million, after deducting discounts and commissions and other offering expenses.

2. Summary of Significant Accounting Policies

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

Business Combinations

The Company uses the acquisition method of accounting for business combinations which requires assets acquired and liabilities assumed to be recognized at their fair values on the acquisition date. Goodwill represents the excess of the purchase price over the fair value of the net assets acquired. The fair values of the assets acquired and liabilities assumed are determined based upon the valuation of the acquired business and involves making significant estimates and assumptions based on facts and circumstances that existed as of the acquisition date. The Company uses a measurement period following the acquisition date to gather information that existed as of the acquisition date that is needed to determine the fair value of the assets acquired and liabilities assumed. The measurement period ends once all information is obtained, but no later than one year from the acquisition date.

Intangible Assets, Net

Intangible assets acquired in a business combination or an asset acquisition are initially recognized at their fair value on the acquisition date. Acquired definite-lived intangible assets are amortized using the straight-line method over their respective estimated useful lives. The amortization of these intangible assets is included in general and administrative expense on the consolidated statement of operations. Intangible assets are tested for impairment at least annually or more frequently if indicators of potential impairment exist. To date, no such impairments have been recognized.

Recently Issued Accounting Standards

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

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

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

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

3. Fair Value Measurements

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

	Fair Value Measurements at September 30, 2025			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 41,109	$ —	$ —	$ 41,109
Marketable securities	$ —	$ 635,118	$ —	$ 635,118

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

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

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

4. Property and Equipment, Net

The components of property and equipment, net as of September 30, 2025 and December 31, 2024 were as follows (in thousands):

	September 30, 2025	December 31, 2024
Leasehold Improvements	$ 9,387	$ —
Manufacturing and lab equipment	5,982	—
Machinery and Equipment	583	359
Total property and equipment, cost	15,952	359
Less: Accumulated depreciation	(623)	(87)
Property and equipment, net	$ 15,329	$ 272

Depreciation expense for the three and nine months ended September 30, 2025 was $0.5 million and $0.6 million, respectively, and less than $0.1 million for the three and nine months ended September 30, 2024.

5. Goodwill and Intangibles, Net

Goodwill

In connection with the Conversion Event in July 2025, the Company recognized goodwill of $12.8 million. See Note 15 for additional information on this transaction.

The Company annually assesses goodwill for impairment in the fourth quarter of each calendar year and at an interim date if indications of impairment exist. During the three and nine months ended September 30, 2025, no goodwill impairment was recognized.

Intangible Assets

As part of the Conversion Event, the Company acquired customer relationships of $1.4 million and trade names and trademarks of $0.3 million. The components of intangible assets as of September 30, 2025 were as follows (in thousands):

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Useful Lives (in years)
Customer relationships	$ 1,400	$ 23	$ 1,377	10
Trade names and trade marks	300	5	295	10
Total intangible assets, net	$ 1,700	$ 28	$ 1,672	

The Company's intangible assets are amortized on a straight-line basis over their useful lives. Intangible assets amortization expense was less than $0.1 million for the three and nine months ended September 30, 2025. The following table presents the estimated future amortization expense related to intangible assets as of September 30, 2025 (in thousands):

	Accumulated Amortization
2025	$ 43
2026	170
2027	170
2028	170
2029	170
Thereafter	949
Total future amortization expense	$ 1,672

6. Accrued Expenses and Other Current Liabilities

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

	September 30, 2025	December 31, 2024
External research and development expenses	$ 12,574	$ 7,181
Personnel-related expenses	6,085	5,793
Professional fees	961	1,255
Deferred revenue	259	—
Other	544	436
Total accrued expenses and other current liabilities	$ 20,423	$ 14,665

7. Commitments and Contingencies

Operating Leases

As of September 30, 2025 and December 31, 2024, the Company had four and two operating leases, respectively. Of the four operating leases as of September 30, 2025, three are leases in which the Company was the lessee for office space. The remaining operating lease was acquired in connection with the Conversion Event and includes office, manufacturing, and warehouse space. As of September 30, 2025, the leases have varying terms expiring between 2026 and 2030. The Company had no finance leases as of September 30, 2025 and December 31, 2024.

The components of lease expense for the periods ended September 30, 2025 and 2024 were as follows (in thousands):

	Three Months Ended September 30, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Lease cost				
Operating lease cost	$ 377	$ 77	$ 384	$ 173
Total lease cost	$ 377	$ 77	$ 384	$ 173
Other information				
Operating lease right-of-use asset obtained in exchange for new operating lease liabilities	$ —	$ —	$ 859	$ —
Cash paid for amounts included in the measurement of lease liabilities, included in operating cash flows	$ 222	$ 60	$ 383	$ 163
Weighted-average remaining lease term	4.22	1.41	4.22	1.41
Weighted-average discount rate	6.87%	1.63%	6.87%	1.63%

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

2025	$	291
2026		1,162
2027		1,137
2028		1,116
2029		1,039
Thereafter		164
Total lease payment		4,909
Less: amount representing imputed interest		(668)
Total future minimum lease obligations	$	4,241

Legal Proceedings

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

On March 4, 2024, ANI Pharmaceuticals, Inc. (ANI) filed a complaint against the Company in the Superior Court of the State of Delaware seeking (i) a declaratory judgment that a provision in an assignment and technology transfer agreement between the Company and ANI, dated November 15, 2010 (the ANI Agreement), obligates the Company to pay ANI a royalty on certain "net sales" of cretostimogene, and (ii) compensatory damages alleging the Company was unjustly enriched by obtaining the benefit of certain non-patent assets under the ANI Agreement without paying adequate consideration to ANI. On July 16, 2025, the Superior Court granted the Company's motion for summary judgment with respect to ANI's request for a declaratory judgment to receive royalty payments from the potential sale of cretostimogene but denied the Company's motion for summary judgment with respect to ANI's unjust enrichment claim. On July 29, 2025, a jury entered a verdict in favor of the Company, unanimously rejecting all of ANI's claims for unjust enrichment damages. As a result, the Company will not owe ANI a future royalty of 5% on commercial sales of cretostimogene, no damages have been awarded to ANI, and there are no further payments due to ANI under the ANI Agreement. The Company will continue to vigorously defend any post-trial motions and appeals brought by ANI.

Indemnification

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with officers and members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. As of September 30, 2025, the Company had not experienced any losses related to these indemnification obligations, and no claims with respect thereto were outstanding.

8. License and Collaboration Agreements

Lepu Biotech Co., Ltd.

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

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

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

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

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

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

Kissei Pharmaceutical Co., Ltd.

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

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

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

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

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

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

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

The Company recorded $0.2 million and less than $0.1 million in license and collaboration revenue for the three months ended September 30, 2025 and 2024, respectively, and $0.2 million in license and collaboration revenue for the nine months ended September 30, 2025 and 2024.

9. Segment Disclosures

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues				
Commercial and development revenue	$ 1,508	$ —	$ 1,508	$ —
License and collaboration revenue	158	43	210	683
Total revenues	1,666	43	1,718	683
Less:				
Cost of sales	1,577	—	1,577	—
Research and development				
Clinical and manufacturing	23,381	15,403	72,818	44,561
Other research and development[(1)]	4,503	4,219	13,865	10,741
Total research and development	27,884	19,622	86,683	55,302
General and administrative	23,334	8,716	55,532	21,998
Total costs and operating expenses	52,795	28,338	143,792	77,300
Loss from operations	(51,129)	(28,295)	(142,074)	(76,617)
Other income, net	7,321	7,890	22,388	20,376
Net loss	$ (43,808)	$ (20,405)	$ (119,686)	$ (56,241)

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

10. Common Stock

The Company is authorized to issue up to 700,000,000 shares of common stock at September 30, 2025 and December 31, 2024, of which 78,277,452 and 76,154,783 shares were issued and outstanding at September 30, 2025 and December 31, 2024, respectively.

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

Dividends

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

Liquidation Rights

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

Reserved Shares

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

	September 30, 2025
Stock options and awards outstanding	8,029,081
Reserved for future stock award issuances	4,230,364
Reserved for future ESPP issuances	713,703
Total	12,973,148

11. Stock-Based Compensation

In 2015, the Company established the 2015 Plan, under which the Company may grant options and restricted stock to its employees and certain non-employees. As of September 30, 2025, there were 669,684 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 September 30, 2025, there were 3,202,963 shares of common stock subject to outstanding awards under the 2022 Plan.

On January 11, 2024, the Company's board of directors and stockholders approved the 2024 Equity Incentive Plan (the 2024 Plan), which became effective on the date immediately preceding the date on which the Company's registration statement was declared effective by the SEC. The 2024 Plan replaced the 2022 Plan, as the Company's board of directors has determined to not make additional grants under the 2022 Plan following the closing of the offering. However, the 2015 and 2022 Plans will continue to govern outstanding equity awards granted under the 2015 and 2022 Plans. The 2024 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors and consultants. The number of shares initially available for issuance under awards granted pursuant to the 2024 Plan is (1) 8,246,565 shares, plus (2) any shares subject to outstanding awards under the 2015 and 2022 Plans as of the effective date of the 2024 Plan that become available for issuance under the 2024 Plan thereafter in accordance with its terms. As of September 30, 2025, there were 4,156,434 shares of common stock subject to outstanding awards and 4,230,359 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 nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Expected volatility	76.35% - 77.58%	77.34% - 77.74%	73.39% - 77.58%	77.34% - 84.50%
Risk-free interest rate	3.7% - 4.16%	3.46% - 4.15%	3.7% - 4.5%	3.46% - 4.62%
Expected dividend yield	0%	0%	0%	0%
Expected term (in years)	6.1	6.1	5.25 - 6.1	6.05 - 6.1

The weighted average grant-date fair value of the options granted was $14.49 and $17.14 per share for the nine months ended September 30, 2025 and 2024, respectively. The weighted average fair value of shares vested during the nine months ended September 30, 2025 and 2024 was $12.55 and $4.27 per share, respectively. The weighted average fair value of shares exercised during the nine months ended September 30, 2025 and 2024 was $6.25 and $2.07 per share, respectively.

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

	Number of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2024	6,574,580	$ 14.19	8.20	$ 108,155
Granted	2,566,341	$ 21.03		
Exercised	(538,125)	$ 8.79		
Forfeited/Expired	(668,339)	$ 20.42		
Balance at September 30, 2025	7,934,457	$ 16.24	8.21	$ 190,726
Vested and expected to vest at September 30, 2025	7,934,457	$ 16.24	8.21	$ 190,726
Exercisable at September 30, 2025	3,019,428	$ 10.56	7.24	$ 89,725

The Company recorded stock-based compensation expense related to stock options of $6.7 million and $2.0 million for the three months ended September 30, 2025 and 2024, respectively, and $17.5 million and $5.1 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, the Company had an aggregate $65.8 million of gross unrecognized stock-based compensation expense related to unvested options to be recognized over a weighted average period of 3.0 years.

Performance-Based Restricted Stock Units

A Performance Stock Unit (“PSU”) represents one equivalent share of the Company's common stock to be issued after achievement of the performance metrics specified in the grant. The Company estimates the fair value of a PSU based upon the expected achievement of the performance metrics specified in the grant and the closing market price of the Company's common stock on the date of grant.

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2024	—	$ —
Granted	94,624	$ 36.48
Nonvested at September 30, 2025	94,624	$ 36.48
Expected to vest at September 30, 2025	94,624	$ 36.48

Stock-based compensation expense associated with these PSUs is recognized if achievement of the underlying performance condition is considered probable of achievement based on the Company’s best estimates. As of September 30, 2025, the Company had an aggregate $3.4 million of gross unrecognized stock-based compensation expense related to unvested PSUs to be recognized over a weighted average period of 2.5 years.

Stock-based compensation expense related to stock awards and the 2024 Employee Stock Purchase Plan (see Note 12) recorded in the accompanying statements of operations for the three and nine months ended September 30, 2025 and 2024 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	$ 2,455	$ 901	$ 6,410	$ 2,223
General and administrative	4,876	1,748	13,079	4,189
Total stock-based compensation expense	$ 7,331	$ 2,649	$ 19,489	$ 6,412

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

12. Employee Stock Purchase Plan

On January 11, 2024, the Company's board of directors and stockholders approved the 2024 Employee Stock Purchase Plan (the ESPP), which became effective on 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 37,374 and 69,393 shares purchased under the ESPP during the three and nine months ended September 30, 2025, respectively, and 29,146 shares purchased under the ESPP during the three and nine months ended September 30, 2024. On September 30, 2025, there were 713,703 shares available for issuance under the ESPP.

The Company recorded stock-based compensation expense under the ESPP of approximately $0.6 million and $0.6 million for the three months ended September 30, 2025 and 2024, respectively, and $2.0 million and $1.4 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, the Company had $1.5 million of gross unrecognized stock-based compensation expense under the ESPP to be recognized over a weighted average period of 1.0 years.

13. Debt

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

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

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

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

14. Net Loss Per Share Attributable to Common Stockholders

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator:				
Net loss and comprehensive loss	$ (43,808)	$ (20,405)	$ (119,686)	$ (56,241)
Denominator:				
Weighted-average common stock outstanding, basic and diluted	76,729,726	67,143,744	76,383,376	60,311,003
Net loss per share attributable to common stockholders, basic and diluted	$ (0.57)	$ (0.30)	$ (1.57)	$ (0.93)

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 September 30, 2025 and 2024 because including them would have had an anti-dilutive effect:

	September 30,	
	2025	2024
Stock options outstanding	7,934,457	5,203,163
Total	7,934,457	5,203,163

15. Acquisition of Biovire

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

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

Consideration was determined to be the fair value of the note receivable that was exchanged for the majority of shares of the SPV and Biovire. The acquisition was accounted for as a business combination using the acquisition method of accounting, under which the acquired assets, including intangible assets, and assumed liabilities were recognized at their estimated fair values as of July 20, 2025, with the excess of the fair value of consideration transferred over the fair value of the net assets acquired recognized as goodwill. The Company's unaudited condensed consolidated financial statements include the operating results of the SPV and Biovire from the date of acquisition through September 30, 2025.

The purchase price allocation is set forth in the table below and represents the Company's provisional fair value estimates related to the acquisition as of July 20, 2025, and are subject to subsequent adjustments as additional information is obtained during the applicable measurement period.

		Estimated fair value
Identifiable assets acquired		
Cash	$	4,033
Current assets		2,826
Operating lease right-of-use assets		3,413
Property and equipment, net		15,498
Intangible assets		1,700
Total identifiable assets acquired		27,470
Liabilities assumed		
Current liabilities		2,227
Operating lease liabilities, non-current portion		2,800
Long-term debt		3,000
Deferred tax liability		1,609
Other long-term liabilities		3,795
Total liabilities assumed		13,431
Net identifiable assets acquired		14,039
Goodwill		12,805
Total fair value of consideration paid	$	26,844

The purchase price was allocated to the tangible assets and identifiable intangible assets acquired and liabilities assumed based on their acquisition date estimated fair values. The carrying amount of accounts receivable and inventory acquired represented their fair value. Property and equipment were assigned a fair value of $15.5 million and will be amortized over a weighted average of 5.6 years. The identifiable intangible assets consist of trade names and trademarks and customer relationships which were assigned fair values of approximately $0.3 million and $1.4 million, respectively, and will be amortized on a straight-line basis over their estimated useful lives of 10 years. The acquired property and equipment and intangible assets were valued utilizing either the relief from royalty method or the multi-period excess earnings method as deemed most applicable. These approaches require judgment, including those related to projected net cash flows, revenue growth rates, and the weighted average cost of capital used to discount the cash flows.

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

16. Subsequent Events

From October 1, 2025 through November 13, 2025, 2,343,967 shares were sold under the Jefferies Sales Agreement, at a weighted average price of $42.86 per share. The Company received net proceeds of $98.4 million, after deducting discounts and commissions and other offering expenses.

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

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

Forward-Looking Statements

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

In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "contemplate," "continue" "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target" or "will" or the negative of these terms or other similar expressions. These forward-looking statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial and other trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties, and assumptions, including, without limitation, the risk factors described in Part I, Item 1A, "Risk Factors" of the 2024 Annual Report, as supplemented in Part II, Item 1A, "Risk Factors" of the Quarterly Report on Form 10-Q for the quarter ended June 30, 2025. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Overview

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

In anticipation of potential U.S. Food and Drug Administration (FDA) approval, we are actively building our commercial operations, marketing, market access and patient access and field force capabilities. This includes pre-launch activities currently being executed, including scientific communication activities and engagements by our field medical organization. We are also implementing strategic initiatives to build seamless product distribution and patient support. Our efforts are focused on ensuring that we are fully prepared to launch and deliver cretostimogene to patients and healthcare providers, if approved. We are evaluating the safety and efficacy of cretostimogene as a monotherapy in BOND-003 Cohort C, our ongoing Phase 3 clinical trial in high-risk BCG-unresponsive NMIBC with carcinoma *in situ* (CIS) and with or without Ta/T1 disease. In September 2025, we reported topline data from Cohort C of the BOND-003 Phase 3 clinical trial. These updated data showed 12 additional patients with NMIBC were in complete response (CR) at 24 months. The 24-month complete response landmark rate of 41.8% (CR rate observed in 46 out of 110 patients) for cretostimogene monotherapy reaffirms the best-in-disease durability that we announced at the 2025 AUA Annual Meeting in April 2025. The study reported 75.5% CR at any time and 41.8% at 24 months with 46 confirmed CRs as of the cutoff date of June 23, 2025. The estimated 12- and 24-month duration of response (DOR) rates are 64.1% and 58.3%, respectively. Median DOR is 28 months and is ongoing.

Notably, 96.6% of patients were free from progression to muscle invasive disease at 24 months. Cretostimogene has been generally well-tolerated in the trial as of the cutoff date of June 23, 2025. There were no Grade 3 or greater treatment-related adverse events (TRAEs) or deaths reported to date. Patients who experienced TRAEs of any grade had a median resolution time of one day. No treatment-related discontinuation of cretostimogene was observed, and 97.3% of patients completed all expected treatments, demonstrating favorable patient adherence and compliance. The most common TRAEs (≥10%) were bladder spasm, pollakiuria, micturition urgency, dysuria, and hematuria. This trial served as the basis for our BLA submission for our initial indication to the U.S. FDA, which we initiated in the fourth quarter of 2025. Cretostimogene has received both Fast Track and Breakthrough Therapy designations from the FDA for the treatment of High-Risk BCG-unresponsive NMIBC with CIS with or without Ta or T1 tumors.

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

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

We have incurred significant operating losses and negative cash flows from operations since our inception. Our net losses were $119.7 million and $56.2 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $337.7 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and, to a lesser extent, from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses in the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for, and potentially commercialize cretostimogene and potentially seek to discover and develop additional product candidates, utilize third parties to manufacture cretostimogene, hire additional personnel, expand and protect our intellectual property, and incur additional costs associated with being a public company. If we obtain regulatory approval for cretostimogene, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we do not become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce or terminate our operations.

To date, we have primarily funded our operations with proceeds from the sale of shares of our common stock through public offerings and our redeemable convertible preferred stock, as well as through previously outstanding term debt. From inception through September 30, 2025, we have received aggregate gross proceeds of approximately $1,032.9 million from the sale of shares of our common stock from our IPO, our follow-on offering in December 2024, and our at-the-market facility, and sales of redeemable convertible preferred stock. In addition, from inception through September 30, 2025, we have recognized $26.3 million in license and collaboration revenue pursuant to our license and collaboration agreements. As of September 30, 2025, we had cash, cash equivalents and marketable securities of $680.3 million. Our ability to generate any product revenue and, in particular, our ability to generate product revenue sufficient to achieve profitability, will depend on the successful development and eventual commercialization of cretostimogene and any future product candidates.

In February 2025, the Company's wholly owned subsidiary, SafeGuard Healthcare, LLC (SafeGuard), established a note receivable with an initial principal amount of $25.0 million through a convertible promissory note (Note) from SP Healthcare SPV I, LLC (the SPV). The SPV used the proceeds from the Note to make an investment in Biovire, Inc. for the purpose of Biovire acquiring substantially all of the assets of a contract manufacturing organization that provides clinical supply of cretostimogene to the Company. On July 20, 2025, following the conversion of the Note triggered by the cessation of services by SkyPath to the SPV and Biovire (Conversion Event), we, through our subsidiary, SafeGuard, obtained control of the SPV and Biovire. As a result of this change in control, the operations of Biovire were consolidated as of the effective date of the conversion.

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

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

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

License and Collaboration Agreements

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

Lepu License Agreement

In March 2019, we entered into a development and license agreement (the Lepu License Agreement) with Lepu Biotech Co., Ltd. (Lepu), under which we granted an exclusive license to Lepu to develop, manufacture and commercialize cretostimogene and/or DDM to treat and/or prevent cancer in the Lepu Territory. Lepu paid to us a one-time upfront payment of $4.5 million and is obligated to make regulatory milestone payments of up to $2.5 million and commercial milestone payments of up to $57.5 million. We are entitled to receive a high single-digit royalty on net sales of cretostimogene and/or DDM sold in the Lepu Territory, subject to a specified reduction. During the three and nine months ended September 30, 2025, the Company did not recognize any license and collaboration revenue related to the Lepu License Agreement. During the three and nine months ended September 30, 2024, the Company recognized zero and $0.5 million, respectively, in license and collaboration revenue related to the Lepu License Agreement.

Kissei License Agreement

In March 2020, and as amended September 2022, we entered into a license and collaboration agreement (the Kissei License Agreement) with Kissei Pharmaceutical Co., Ltd. (Kissei), under which we granted to Kissei an exclusive license to certain intellectual property rights in Bangladesh, Bhutan, Brunei, Cambodia, India, Indonesia, Japan, South Korea, Laos, Malaysia, Myanmar, Nepal, Pakistan, Palau, Philippines, Singapore, Sri Lanka, Taiwan, Thailand and Vietnam (the Kissei Territory), for Kissei to develop and commercialize, but not manufacture, cretostimogene in combination with DDM (the Licensed Product) for all uses in oncology. Kissei paid to us a one-time upfront payment of $10.0 million under the agreement. Kissei is obligated to pay development milestone payments of up to $33.0 million and commercial milestone payments of up to $67.0 million. We have also agreed to pay Kissei a royalty on net sales of Licensed Product outside the Kissei Territory and outside the Lepu Territory, including on any U.S. sales, in a low-single digit percentage, subject to certain capped reductions. We are entitled to receive a royalty on net sales of Licensed Product in the Kissei Territory in the mid-twenties percentage, subject to certain capped reductions and offset rights. We are obligated to supply and Kissei will exclusively purchase its clinical and commercial requirements of Licensed Product from us. During the three and nine months ended September 30, 2025, $0.2 million in license and collaboration revenue was recorded related to the Kissei License Agreement, respectively. During the three and nine months ended September 30, 2024, less than $0.1 million and $0.2 million in license and collaboration revenue was recorded related to the Kissei License Agreement, respectively.

Components of Our Results of Operations

Revenue

License and Collaboration Revenue

From inception through September 30, 2025, we have recognized $26.3 million in license and collaboration revenue through our license and collaboration agreements. We have not generated any revenue from the sale of our cretostimogene products, however, and do not expect to generate any revenue from the sale of our cretostimogene products in the foreseeable future, if at all. If our or our collaborators' development efforts for cretostimogene and any future product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales, payments from existing or potential future collaboration or license agreements with third parties, or any combination thereof.

Commercial and Development Revenue

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

Operating Costs and Expenses

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

Cost of Sales

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

Research and Development Expenses

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

Our R&D expenses consist of:

•external costs incurred under agreements with contract research organizations (CROs), contract manufacturers, consultants and other third parties to conduct and support our clinical trials and preclinical studies; and

•internal costs, including R&D personnel-related expenses such as salaries, stock-based compensation and benefits, as well as allocated facilities costs and dues and subscriptions.

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

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

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

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

General and Administrative Expenses

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

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

Other Income (Expense), Net

Other Income (Expense)

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

Interest Income, Net

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

Results of Operations

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

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

	Three Months Ended September 30,		
	2025	2024	Change
Revenues			
Commercial and development revenue	$ 1,508	$ —	$ 1,508
License and collaboration revenue	158	43	115
Total revenues	1,666	43	1,623
Operating costs and expenses			
Cost of sales	1,577	—	1,577
Research and development	27,884	19,622	8,262
General and administrative	23,334	8,716	14,618
Total operating costs and expenses	52,795	28,338	24,457
Loss from operations	(51,129)	(28,295)	(22,834)
Other income (expense), net:			
Interest income, net	7,421	7,892	(471)
Other income (expense), net	(100)	(2)	(98)
Total other income, net	7,321	7,890	(569)
Net loss and comprehensive loss	$ (43,808)	$ (20,405)	$ (23,403)

Commercial and Development Revenue

Commercial and development revenue was $1.5 million for the three months ended September 30, 2025 compared to zero for the three months ended September 30, 2024. As the Conversion Event occurred in July 2025, there was no corresponding commercial and development revenue in the prior period.

License and Collaboration Revenue

License and collaboration revenue was $0.2 million for the three months ended September 30, 2025 compared to less $0.1 million for the three months ended September 30, 2024. All revenue recognized during the three months ended September 30, 2025 and 2024 was related to the Kissei License Agreement.

Cost of Sales

Cost of sales was $1.6 million for the three months ended September 30, 2025 compared to zero for the three months ended September 30, 2024. As the Conversion Event occurred in July 2025, there was no corresponding costs in the prior period.

Research and Development Expenses

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

	Three Months Ended September 30,		
	2025	2024	Change
External clinical trial expenses	$ 17,486	$ 13,254	$ 4,232
Personnel-related expenses	8,645	5,790	2,855
Other research and development	1,753	578	1,175
Total research and development expenses	$ 27,884	$ 19,622	$ 8,262

R&D expenses were $27.9 million for the three months ended September 30, 2025 compared to $19.6 million for the three months ended September 30, 2024. The increase of $8.3 million in R&D expenses for the three months ended September 30, 2025 was primarily due to an increase of $4.2 million in external clinical trial expenses related to higher CRO fees as patient enrollment increased, as well as an increase of $2.9 million in compensation costs due to increased headcount, including a $1.6 million increase in stock-based compensation, and an increase in other research and development costs of $1.2 million.

General and Administrative Expenses

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

	Three Months Ended September 30,		
	2025	2024	Change
Personnel-related expenses	$ 10,576	$ 5,855	$ 4,721
Professional and consultant fees	9,273	1,790	7,483
Other general and administrative	3,485	1,071	2,414
Total general and administrative expenses	$ 23,334	$ 8,716	$ 14,618

General and administrative expenses were $23.3 million for the three months ended September 30, 2025 compared to $8.7 million for the three months ended September 30, 2024. The increase of $14.6 million in general and administrative expenses for the three months ended September 30, 2025 was primarily due to an increase in professional and consultant fees of $7.5 million, including a $4.1 million increase in legal fees, an increase in compensation costs of $4.7 million due to increased headcount, including a $3.1 million increase in stock-based compensation, an increase in marketing-related costs of $0.7 million, and an increase in insurance, fees, and other costs of $1.7 million.

Other Income (Expense), Net

Other income, net, for the three months ended September 30, 2025 was $7.3 million compared to $7.9 million for the three months ended September 30, 2024. The $0.6 million decrease was driven by a decrease in interest income earned related to cash equivalents and marketable securities balances and interest expense related to debt acquired through SPV and Biovire, with no corresponding interest expense in the prior period.

Comparison of the Nine Months Ended September 30, 2025 and 2024

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

	Nine Months Ended September 30, 2025	2024	Change
Revenue:			
Commercial and development revenue	$ 1,508	$ —	$ 1,508
License and collaboration revenue	210	683	(473)
Total revenues	1,718	683	1,035
Operating costs and expenses			
Cost of sales	1,577	—	1,577
Research and development	86,683	55,302	31,381
General and administrative	55,532	21,998	33,534
Total operating costs and expenses	143,792	77,300	66,492
Loss from operations	(142,074)	(76,617)	(65,457)
Other income (expense), net:			
Interest income, net	22,487	20,379	2,108
Other income (expense), net	(99)	(3)	(96)
Total other income, net	22,388	20,376	2,012
Net loss and comprehensive loss	$ (119,686)	$ (56,241)	$ (63,445)

Commercial and Development Revenue

Commercial and development revenue was $1.5 million for the nine months ended September 30, 2025 compared to zero for the nine months ended September 30, 2024. As the Conversion Event occurred in July 2025, there was no corresponding commercial and development revenue in the prior period.

License and Collaboration Revenue

License and collaboration revenue was $0.2 million for the nine months ended September 30, 2025 compared to $0.7 million for the nine months ended September 30, 2024. During the nine months ended September 30, 2025 we recognized $0.2 million in license and collaboration revenue related to the Kissei License Agreement. During the nine months ended September 30, 2024, we recognized $0.5 million in license and collaboration revenue related to the Lepu License Agreement and $0.2 million in license and collaboration revenue related to the Kissei License Agreement.

Cost of Sales

Cost of sales was $1.6 million for the nine months ended September 30, 2025 compared to zero for the nine months ended September 30, 2024. As the Conversion Event occurred in July 2025, there was no corresponding costs in the prior period.

Research and Development Expenses

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

	Nine Months Ended September 30, 2025	2024	Change
External clinical trial expenses	$ 57,060	$ 39,379	$ 17,681
Personnel-related expenses	24,730	14,458	10,272
Other research and development	4,893	1,465	3,428
Total research and development expenses	$ 86,683	$ 55,302	$ 31,381

R&D expenses were $86.7 million for the nine months ended September 30, 2025 compared to $55.3 million for the nine months ended September 30, 2024. The increase of $31.4 million in R&D expenses for the nine months ended September 30, 2025 was primarily due to an increase of $17.7 million in external clinical trial expenses related to higher CRO fees as patient enrollment increased, as well as an increase of $10.3 million in compensation costs due to increased headcount, including a $4.2 million increase in stock-based compensation, and an increase in other research and development costs of $3.4 million.

General and Administrative Expenses

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

	Nine Months Ended September 30, 2025	2024	Change
Personnel-related expenses	$ 28,750	$ 13,323	$ 15,427
Professional and consultant fees	17,651	5,393	12,258
Other general and administrative	9,131	3,282	5,849
Total general and administrative expenses	$ 55,532	$ 21,998	$ 33,534

General and administrative expenses were $55.5 million for the nine months ended September 30, 2025 compared to $22.0 million for the nine months ended September 30, 2024. The increase of $33.5 million in general and administrative expenses for the nine months ended September 30, 2025 was primarily due to an increase in compensation costs of $15.4 million due to increased headcount, including a $8.9 million increase in stock-based compensation, and increased professional and consultant fees of $12.3 million, which includes a $8.3 million increase in legal fees, as well as an increase in marketing-related costs of $2.2 million and an increase in insurance, fees, and other costs of $3.6 million.

Other Income (Expense), Net

Other income, net, for the nine months ended September 30, 2025 was $22.4 million compared to $20.4 million for the nine months ended September 30, 2024. The $2.0 million increase was driven by higher interest income earned related to cash equivalents and marketable securities balances, partially offset by $0.1 million of interest expense related to debt acquired through SPV and Biovire, with no corresponding interest expense in the prior period.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales of cretostimogene and have incurred significant operating losses and negative cash flows from operations. We expect to incur significant expenses and operating losses in the foreseeable future as we advance the clinical development of cretostimogene and any future product candidates. To date, we have primarily funded our operations with proceeds from the sale of shares of our common stock through public offerings and our redeemable convertible preferred stock, as well as through previously outstanding term debt. From inception through September 30, 2025, we have received aggregate gross proceeds of $1,032.9 million from the sale of shares of our common stock through our public offerings and our redeemable convertible preferred stock. In addition, through September 30, 2025, we have recognized $26.3 million in license and collaboration revenue through our license and collaboration agreements. As of September 30, 2025, we had cash, cash equivalents and marketable securities of $680.3 million.

At-the-Market Offering

On March 28, 2025, we entered into an Open Market Sale Agreement℠ (Jefferies Sales Agreement) with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time through Jefferies, up to $250 million of shares of our common stock. On the same day, we filed a shelf registration statement on Form S-3ASR with the SEC, which contains a base prospectus, covering an unlimited amount of our common stock, preferred stock, debt securities and warrants to purchase any of such securities, and a sales agreement prospectus, covering the offering, issuance and sale of up to a maximum aggregate offering price of $250 million of our common stock that may be issued and sold from time to time under the Jefferies Sales Agreement. During the three months ended September 30, 2025, 1,515,151 shares were sold under the Jefferies Sales Agreement, at a price of $33.00 per share. The Company received net proceeds of $48.7 million, after deducting discounts and commissions and other 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 operations into the first half of 2028. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, we could utilize our available capital resources sooner than we expect.

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

Material Cash Requirements for Known Contractual and Other Obligations

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

Cash Flows

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

	Nine Months Ended September 30,	
	2025	2024
Net cash used in operating activities	$ (96,130)	$ (58,051)
Net cash used in investing activities	(170,317)	(311,669)
Net cash provided by financing activities	54,524	404,865
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (211,923)	$ 35,145

Operating Activities

During the nine months ended September 30, 2025, operating activities used $96.1 million of cash, primarily resulting from our net loss of $119.7 million, as well as accretion of the discount on short-term investments of $2.0 million, partially offset by non-cash stock-based compensation charges of $19.5 million and net cash provided by changes in our operating assets and liabilities of $6.3 million.

During the nine months ended September 30, 2024, operating activities used $58.1 million of cash, primarily resulting from our net loss of $56.2 million, accretion of the discount on short-term investments of $6.2 million, and net cash used in changes in our operating assets and liabilities of $2.0 million, partially offset by $6.4 million of non-cash stock-based compensation charges.

Investing Activities

During the nine months ended September 30, 2025, net cash used in investing activities was $170.3 million, primarily due to $770.1 million of purchases of marketable securities and $22.0 million, net of cash acquired, for the acquisition of SPV and Biovire through the Conversion Event, partially offset by proceeds from sales and maturities of short-term investments.

During the nine months ended September 30, 2024, net cash used in investing activities was $311.7 million, primarily due to purchases of marketable securities offset by proceeds from sales and maturities of short-term investments.

Financing Activities

During the nine months ended September 30, 2025, net cash provided by financing activities was $54.5 million, consisting primarily of proceeds of $49.0 million from the sale of our common stock pursuant to the Jefferies Sales Agreement, net of issuance costs, and proceeds from exercise of options of $5.8 million, partially offset by deferred offering costs of $0.3 million.

During the nine months ended September 30, 2024, net cash provided by financing activities was $404.9 million, consisting primarily of net proceeds from the initial public offering, net of issuance costs and deferred offering costs of $403.0 million, partially offset by the long-term debt success fee payoff of $0.4 million.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

R&D Expenses and Related Prepaid and Accrued Expenses

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

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

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

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Standards

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

Our exposure to market risk is limited primarily to interest rate sensitivity. As of September 30, 2025, we had cash, cash equivalents and marketable securities of approximately $680.3 million, which consisted primarily of money market funds and marketable securities, comprised of fixed income securities (U.S. Treasury bills).

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

Effects of inflation

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

Item 4. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

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

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

Changes in Internal Control Over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

On March 4, 2024, ANI Pharmaceuticals, Inc. (ANI) filed a complaint against the Company in the Superior Court of the State of Delaware seeking (i) a declaratory judgment that a provision in an assignment and technology transfer agreement between the Company and ANI, dated November 15, 2010 (the ANI Agreement), obligates the Company to pay ANI a royalty on certain "net sales" of cretostimogene, and (ii) compensatory damages alleging the Company was unjustly enriched by obtaining the benefit of certain non-patent assets under the ANI Agreement without paying adequate consideration to ANI. On July 16, 2025, the Superior Court granted the Company's motion for summary judgment with respect to ANI's request for a declaratory judgment to receive royalty payments from the potential sale of cretostimogene but denied the Company's motion for summary judgment with respect to ANI's unjust enrichment claim. On July 29, 2025, a jury entered a verdict in favor of the Company unanimously rejecting all of ANI's claims for unjust enrichment damages. As a result, the Company will not owe ANI a future royalty of 5% on commercial sales of cretostimogene, no damages have been awarded to ANI, and there are no further payments due to ANI under the ANI Agreement. The Company will continue to vigorously defend any post-trial motions and appeals brought by ANI.

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

Item 1A. Risk Factors.

In Part II, Item 1A, Risk Factors of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, we provided, in supplemental form (Supplemental Risk Factors), updates to our risk factors from those previously disclosed in Part I, Item 1A, "Risk Factors" of our 2024 Annual Report. Our risk factors disclosed in Part I, Item 1A of our 2024 Annual Report provide additional discussion regarding these supplemental risks and we encourage you to read and carefully consider all of the risk factors disclosed in Part I, Item 1A of our 2024 Annual Report, together with the Supplemental Risk Factors, for a more complete understanding of the risks and uncertainties material to our business. Other than the Supplemental Risk Factors, there have been no material changes to the risk factors disclosed in Part I, Item 1A, "Risk Factors" of our 2024 Annual Report.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On January 24, 2024, our registration statement on Form S-1 (File No. 333-276350) was declared effective by the SEC for our initial public offering. At the closing of our initial public offering on January 29, 2024, we sold 23,000,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 3,000,000 additional shares, at an initial public offering price of $19.00 per share and received gross proceeds of $437.0 million, which resulted in net proceeds to us of approximately $399.6 million, after deducting underwriting discounts and commissions of approximately $30.6 million and offering-related transaction costs of approximately $6.8 million. As of September 30, 2025, we estimate that we have used approximately $279.6 million of the proceeds from our initial public offering for general corporate purposes, including to fund the research and development of cretostimogene, manufacturing and pre-commercial activities, and to fund a contract manufacturing organization that provides us with clinical supply of cretostimogene. There has been no material change in the planned use of proceeds from that described in the final prospectus for our initial public offering filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

From time to time, our Section 16 officers (as defined in Rule 16a–1(f)) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K) for the purchase or sale of our securities. During the three months ended September 30, 2025, except for Arthur Kuan's adoption of a 10b5-1 plan for the purchase of our securities, none of our officers or directors adopted, modified or terminated any such trading arrangements.

			Type of Trading Arrangement			
Name and Position	**Action**	**Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares to be Purchased**	**Expiration Date**
Arthur Kuan, Chairman and Chief Executive Officer	Adoption	September 15, 2025	X		690,420	The earliest to occur of (i) September 15, 2026, and (ii) the date the aggregate number of shares of stock purchased under the plan is 690,420 shares.

* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.
** “Non-Rule 10b5-1 trading arrangement” as defined in Item 408(c) of Regulation S-K under the Exchange Act.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	S-1/A	01/18/24	3.3	
3.2	Amended and Restated Bylaws	S-1	01/02/24	3.4	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1/A	01/18/24	4.1	
4.2	Amended and Restated Investors' Rights Agreement, dated July 28, 2023, as amended, by and among the Registrant and certain of its stockholders	S-1/A	01/18/24	4.2	
10.1	Form of Performance Based Restricted Stock Unit Agreement (2024 Incentive Award Plan)				X
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of Principal Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

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

SIGNATURES

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

CG Oncology, Inc.

Date: November 14, 2025 By: /s/ Arthur Kuan
Arthur Kuan
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2025 By: /s/ Robert Lapetina
Robert Lapetina
Vice President, Financial Planning & Analysis
(Principal Financial and Accounting Officer)

Exhibit 10.1

CG ONCOLOGY, INC.

2024 INCENTIVE AWARD PLAN

PERFORMANCE BASED RESTRICTED STOCK UNIT GRANT NOTICE

Capitalized terms not specifically defined in this Restricted Stock Unit Grant Notice (the "***Grant Notice***") have the meanings given to them in the 2024 Incentive Award Plan (as amended from time to time, the "***Plan***") of CG Oncology, Inc. (the "***Company***").

The Company hereby grants to the participant listed below ("***Participant***") the Performance Based Restricted Stock Units described in this Grant Notice (the "***PSUs***"), subject to the terms and conditions of the Plan and the Performance Based Restricted Stock Unit Agreement attached hereto as **Exhibit A** (the "***Agreement***"), both of which are incorporated into this Grant Notice by reference.

Participant:	[Insert full name here]
Grant Date:	Insert grant date]
Number of PSUs:	[Insert number of PSUs]
Performance Period:	[Insert performance period] (the "***Performance Period***")
Vesting Schedule:	The number of PSUs that will vest pursuant to this Award is an amount ranging from 0% to 100% of the PSUs based on Company's achievement of the performance goals as described in **Attachment A** attached hereto (the "***Performance Goal***"), subject to Participant remaining as a Service Provider through the vesting date of the PSUs. The Number of PSUs, if any, that become vested will be determined promptly by the Board (or a committee of the Board) following the Performance Period and will be determined in accordance with the Company's achievement of the Performance Goal. Vesting shall terminate upon Participant's Termination of Service. In addition, in the event a Participant experiences a Termination of Service as a result of (a) Participant's termination by the Company other than for Cause (and excluding a Termination of Service as a result of Participant's death or Disability), or (b) Participant's resignation for Good Reason, in each case within eighteen (18) months following a Change in Control, then any remaining unvested PSUs shall become fully vested on the date of such Termination of Service.

If the Company uses an electronic capitalization table system (such as E*Trade, Shareworks or Carta) and the fields in this Grant Notice are blank or the information is otherwise provided in a different format electronically, the blank fields and other information will be deemed to come from the electronic capitalization system and is considered part of this Grant Notice.

By accepting (whether in writing, electronically or otherwise, including an acceptance through an electronic capitalization table system used by the Company) the PSUs, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has received a copy of the prospectus for the Plan, has had an

opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

Internet Availability of Plan Materials. The Company will furnish Plan materials (including the Plan, prospectus, annual report on Form 10-K and proxy statement and other information provided to the Company's stockholders) relating to the Plan to Participant electronically, instead of mailing printed copies of these materials to each person eligible to participate in the plans. This process is designed to expedite Participant's receipt of the plan materials, reduce the costs of printing and distributing these materials, and help conserve natural resources. These materials are available through the Company's electronic capitalization table system (such as E*Trade, Shareworks or Carta) and the annual report on Form 10-K and proxy statement and other information provided to our stockholders is also available on the Company's website at https://cgoncology.com/. The Plan is available at https://www.sec.gov/Archives/edgar/data/1991792/000119312524016881/d746958dex103.htm. However, if Participant would prefer to receive printed copies of the Plan materials or information provided to the Company's stockholders without charge, please contact: CG Oncology, Inc., Attn: Secretary, 400 Spectrum Center Drive, Suite 2040, Irvine, CA 92618, Telephone: (949) 409-3700, Email: information@cgoncology.com.

CG ONCOLOGY, INC.		**PARTICIPANT**	
By:	_____	By:	_____
Print Name:	_____	Print Name:	_____
Title:	_____	Title:	_____
	_____		

ATTACHMENT A

PERFORMANCE GOAL

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EXHIBIT A
PERFORMANCE BASED RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Performance Based Restricted Stock Unit Grant Notice (the "***Grant Notice***") or, if not defined in the Grant Notice, in the Plan.

ARTICLE I.
GENERAL

1.1Award of PSUs. The Company has granted the PSUs to Participant effective as of the grant date set forth in the Grant Notice (the "***Grant Date***"). Each PSU represents the right to receive one Share, as set forth in this Agreement. Participant will have no right to the distribution of any Shares until the time (if ever) the PSUs have vested.

1.2Incorporation of Terms of Plan. The PSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3Unsecured Promise. The PSUs will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

ARTICLE II.
VESTING; FORFEITURE AND SETTLEMENT

2.

2.1 Vesting; Forfeiture. The PSUs will vest according to the vesting schedule in the Grant Notice (the "***Vesting Schedule***"), except that any fraction of a PSU that would otherwise be vested will be accumulated and will vest only when a whole PSU has accumulated, if applicable. Except as provided in the Grant Notice, in the event of Participant's Termination of Service for any reason, all unvested PSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company.

2.2Settlement.

(a) PSUs will be paid in Shares as soon as administratively practicable after the vesting of the applicable PSU, but in no event more than sixty (60) days after the applicable vesting date. Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Laws until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)), provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(b) All distributions shall be made by the Company in the form of whole shares of Common Stock.

(c) Neither the time nor form of distribution of Shares with respect to the PSUs may be changed, except as may be permitted by the Administrator in accordance with the Plan and Section 409A of the Code and the Treasury Regulations thereunder.

ARTICLE III.
TAXATION AND TAX WITHHOLDING

3.

3.1Tax Withholding.

(a) Regardless of any action the Company, any Subsidiary or Participant's employing company, if different (the "***Employer***," and, collectively, the "***Company Group***") takes with respect to any or all Tax Obligations (as defined below), Participant understands that Participant (and not the Company) shall be responsible for any Tax Obligations, which may exceed the amount actually withheld by the Company Group. Participant agrees to indemnify and keep indemnified the Company Group from and against any such Tax Obligations.

(b) The Company Group shall not be obligated to deliver any certificate representing Shares issuable with respect to the PSUs to Participant or his or her legal representative unless and until Participant or his or her legal representative will have paid or otherwise satisfied in full the amount of all Tax Obligations resulting from the grant, vesting, or settlement of the PSUs, the distribution of the Shares issuable with respect thereto, or any other taxable event related to the PSUs. The Company Group will have the authority and the right to deduct or withhold, or require Participant to remit to the Company, an amount sufficient to satisfy any Tax Obligation, including, without limitation, the authority to deduct such amounts from other compensation payable to Participant by the Company Group. Participant acknowledges that if Participant is subject to Tax Obligations in more than one jurisdiction, the Company Group may be required to withhold or account for Tax Obligations in more than one jurisdiction. Participant agrees to pay the Company Group any Tax Obligations that cannot be satisfied by the means described in this Section 3.1 or Section 9.5 of the Plan.

(c) Unless Participant elects to satisfy the Tax Obligation by some other means in accordance with Section 9.5 of the Plan, the Company Group will have the right, but not the obligation, with respect to the Tax Obligation arising as a result of the grant, vesting, or settlement of the PSUs, to treat Participant's failure to provide timely payment in accordance with Section 9.5 of the Plan as Participant's election to satisfy the Tax Obligation by requesting the Company Group to withhold a net number of vested Shares otherwise issuable pursuant to the PSUs having a then-current fair market value not exceeding the amount necessary to satisfy the Tax Obligation in accordance with Section 9.5 of the Plan (provided that if Participant is subject to Section 16 of the Exchange Act, any such action by the Company will require the approval of the Administrator).

(d) Subject to the limitations set forth in Section 9.5 of the Plan, the Company Group may withhold or account for Tax Obligations by considering applicable statutory withholding rates (or such other rate as may be determined by the Company after considering any accounting consequences or costs) (but in no event in excess of such rate as may be required to avoid the liability classification of the PSUs under generally accepted accounting principles in the United States of America). In the event of over-withholding, Participant may receive a refund of any over-withheld amount in cash and (with no entitlement to the equivalent in Shares) or if not refunded, Participant may seek a refund from the local tax authorities. In the event of under-withholding, Participant may be required to pay any additional Tax Obligations directly to the applicable tax authority or to the Company Group.

(c) Neither the Company nor any Subsidiary makes any representation or undertaking regarding the tax treatment to Participant in connection with the awarding, vesting or settlement of the PSUs or the subsequent sale of Shares. The Company and its Subsidiaries do not commit and are under no obligation to structure the PSUs to reduce or eliminate Participant's tax liability.

(d) Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this Award and the transactions contemplated by

the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company and/or any of its agents.

(e) For purposes of this Agreement, "***Tax Obligations***" shall mean (i) all federal, state, local and foreign withholding or other taxes applicable to Participant's taxable income, plus (ii) if permitted under the laws of the jurisdiction in which Participant resides, any liability of the Company Group for income tax, withholding tax, wage tax, solidarity surcharge, and any other employment related taxes or social security contributions in any jurisdiction, in each case resulting from the grant, vesting or settlement of the PSUs, the acquisition of Shares by Participant, the disposal of any Shares, or otherwise pursuant to this Agreement, or any other taxable event related to the PSUs.

ARTICLE IV.
OTHER PROVISIONS

4.

4.1Award Not Transferable; Other Restrictions. Without limiting the generality of any other provision hereof, the Award will be subject to the restrictions on transferability set forth in Section 9.1 of the Plan. Without limiting the generality of any other provision hereof, Participant hereby expressly acknowledges that Section 10.8 ("***Lock-Up Period***") of the Plan is expressly incorporated into this Agreement and is applicable to the Shares issued pursuant to this Agreement.

4.2Clawback Provisions. By executing this Agreement and accepting this Award, Participant agrees that all compensation received by Participant, including Awards under the Plan (including, without limitation, any proceeds, gains or other economic benefit actually or constructively received by Participant upon receipt of this Award or upon the receipt or resale of any Shares underlying this Award), shall be subject to reduction, cancellation, forfeiture and/or recoupment to the extent necessary to comply with the Recovery Arrangements and Section 10.13 of the Plan, notwithstanding any other agreement to the contrary. Participant agrees that Participant is not entitled to indemnification in connection with any enforcement of the Recovery Arrangements and expressly waives any rights to such indemnification under the Company's organizational documents or otherwise. By executing this Award Agreement, Participant agrees to take all required action in a reasonably prompt manner, as applicable, to enable the enforcement of the Recovery Arrangements and Section 10.13 of the Plan.

4.3Adjustments. Participant acknowledges that the PSUs and the Shares subject to the PSUs are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

4.4Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.5Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.6Conformity to Securities Laws. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the PSUs will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended to the extent necessary to conform to such Applicable Laws or any such exemptive rule described in the preceding sentence.

4.7Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.8Entire Agreement. The Plan, the Grant Notice and this Agreement constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof. This Agreement may be amended by the Company in accordance with Section 9.6 of the Plan.

4.9Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.10Limitation on Participant’s Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the PSUs, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to the PSUs, as and when settled pursuant to the terms of this Agreement.

4.11Rights as a Stockholder. Neither Participant nor any person claiming under or through Participant will have any of the rights or privileges of a stockholder of the Company in respect of any Shares deliverable hereunder unless and until certificates representing such Shares (which may be in book-entry form) will have been issued and recorded on the records of the Company or its transfer agents or registrars, and delivered to Participant (including through electronic delivery to a brokerage account). Except as otherwise provided herein, after such issuance, recordation and delivery, Participant will have all the rights of a stockholder of the Company with respect to such Shares, including, without limitation, the right to receipt of dividends and distributions on such Shares.

4.12Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.13Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

4.14Governing Law. The provisions of the Plan and all Awards made thereunder, including the PSUs, shall be governed by and interpreted in accordance with the laws of the State of Delaware, disregarding choice-of-law principles of the law of any state that would require the application of the laws of a jurisdiction other than such state.

4.15Section 409A.

(a) Notwithstanding any other provision of the Plan, this Agreement or the Grant Notice, the Plan, this Agreement and the Grant Notice shall be interpreted in accordance with, and incorporate the terms and conditions required by, Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Grant Date, "***Section 409A***"). The Administrator may, in its discretion, adopt such amendments to the Plan, this Agreement or the Grant Notice or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate to comply with the requirements of Section 409A.

(b) This Agreement is not intended to provide for any deferral of compensation subject to Section 409A of the Code, and, accordingly, the Shares issuable pursuant to the PSUs hereunder shall be distributed to Participant no later than the later of: (A) the fifteenth (15th) day of the third month following Participant's first taxable year in which such PSUs are no longer subject to a substantial risk of forfeiture, and (B) the fifteenth (15th) day of the third month following first taxable year of the Company in which such PSUs are no longer subject to substantial risk of forfeiture, as determined in accordance with Section 409A and any Treasury Regulations and other guidance issued thereunder.

4.16 Electronic Delivery and Acceptance. The Company may, in its sole discretion, decide to deliver any documents related to the PSUs awarded under the Plan or future awards that may be awarded under the Plan by electronic means or request Participant's consent to participate in the Plan by electronic means. Participant hereby consents to receive such documents by electronic delivery and agrees to participate in the Plan through any on-line or electronic system established and maintained by the Company or a third party designated by the Company.

4.17 Appendix. Notwithstanding any provisions in this Agreement, the PSUs shall be subject to any additional terms and conditions for Participant's country set forth in the Appendix attached hereto. Moreover, if Participant relocates to one of the countries included in the Appendix, the additional terms and conditions for such country, if any, will apply to Participant, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Agreement.

* * * * *

APPENDIX TO THE CG ONCOLOGY, INC.
2024 INCENTIVE AWARD PLAN
PERFORMANCE BASED RESTRICTED STOCK UNIT AGREEMENT

FOR PARTICIPANTS OUTSIDE OF THE UNITED STATES

This Appendix includes additional terms and conditions applicable to Participants who provide services to the Company in the countries identified below. These terms and conditions are in addition to those set forth in the Grant Notice and Agreement and to the extent there are any inconsistencies between these terms and conditions and those set forth in the Grant Notice or the Agreement, these terms and conditions shall prevail. Any capitalized term used in this Appendix without definition shall have the meaning ascribed to such term in the Plan, the Grant Notice or the Agreement, as applicable. This Appendix forms part of the Agreement.

If Participant is a citizen or resident of a country other than the one in which Participant is currently residing and/or working, transfers employment and/or residency to another country after the Grant Date, or is considered a resident of another country for local law purposes, the Company shall, in its discretion, determine to what extent the terms and conditions contained herein shall be applicable to Participant.

For Participant's convenience and information, the Company has provided certain general information regarding some of the tax and/or exchange control requirements that may apply to Participant in certain of the countries identified below. The Company undertakes no obligation to update any such information and does not ensure that it is complete or correct. As a result, the Company strongly recommends that Participant not rely on the information in this Appendix as the only source of information relating to the consequences of Participant's participation in the Plan because the information may be out of date at the time the PSUs vest and are settled and Participant acquires Shares or sells Shares acquired under the Plan. The absence of any information on tax or foreign exchange requirements for any particular country should not be regarded as an indication that no such requirements apply in that country. The laws, rules and regulations of any country regarding the holding of securities may be subject to frequent change.

Participant is advised to seek appropriate professional advice as to how the relevant exchange control and tax laws in Participant's country may apply to Participant's individual situation.

GLOBAL PROVISIONS

1.Data Protection. As a condition for receiving this Award, Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this section by and among the Company Group exclusively for implementing, administering and managing Participant's participation in the Plan. The Company Group may hold certain personal information about a Participant, including Participant's name, address and telephone number; birthdate; social security, insurance number or other identification number; salary; nationality; job title(s); any Shares held in the Company Group; and Award details, to implement, manage and administer the Plan and Awards (the "***Data***"). The Company Group may transfer the Data amongst themselves as necessary to implement, administer and manage Participant's participation in the Plan, and the Company Group may transfer the Data to third parties assisting the Company with Plan implementation, administration and management. These recipients may be located in Participant's country, or elsewhere, and Participant's country may have different data privacy laws and protections than the recipients' country. By accepting an Award, Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, to implement, administer and manage Participant's participation in the Plan, including any required Data transfer to a broker or other third party with whom the Company or Participant may elect to deposit any Shares. The Data related to Participant will be held only as long as necessary to implement, administer,

and manage Participant's participation in the Plan. Participant may, at any time, view the Data that the Company holds regarding Participant, request additional information about the storage and processing of the Data regarding Participant, recommend any necessary corrections to the Data regarding Participant or refuse or withdraw the consents in this paragraph in writing, without cost, by contacting the local human resources representative. The Company may cancel Participant's ability to participate in the Plan and, in the Administrator's discretion, Participant may forfeit any outstanding Awards if Participant refuses or withdraws the consents in this paragraph. For more information on the consequences of refusing or withdrawing consent, Participant may contact his or her local human resources representative.

If Participant resides in the United Kingdom or the European Union, the Company Group will hold, collect and otherwise process certain Data as set out in the applicable Company's GDPR-compliant data privacy notice, which will be or has been provided to Participant separately. All personal data will be treated in accordance with applicable data protection laws and regulations.

2.Insider Trading Restrictions/Market Abuse Laws. Participant may be subject to insider trading restrictions and/or market abuse laws in applicable jurisdictions, including the United States and Participant's country, if different, which may affect Participant's ability to directly or indirectly, for himself or herself or for a third party, acquire or sell, or attempt to sell, Shares during such times as such Participant is considered to have "inside information" regarding the Company (as defined by Applicable Laws) or the trade in Shares. Any restrictions under these laws or regulations may be separate and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. It shall be each Participant's responsibility to comply with any applicable restrictions, and each Participant should speak with a personal advisor on this matter.

3.Foreign Asset/Account Reporting; Exchange Controls. Each country may have certain foreign asset and/or account reporting requirements and/or exchange controls which may affect Participant's ability to purchase or hold Shares or cash received in respect of the PSUs (including from any dividends received or sale proceeds arising from the sale of Shares) in a brokerage or bank account outside Participant's country. Participant may be required to report such accounts, assets or transactions to the tax or other authorities in Participant's country. Participant also may be required to repatriate sale proceeds or other funds received as a result of his or her participation in the Plan to Participant's country through a designated bank or broker and/or within a certain time after receipt. It shall be Participant's responsibility to be compliant with such regulations, and Participant should consult a personal legal advisor for any details.

4.Language. By participating in the Plan, Participant acknowledges that Participant is proficient in the English language, or has consulted with an advisor who is sufficiently proficient in English, so as to allow him or her to understand the terms and conditions of the Plan and the Award Agreement applicable to Participant's country of residence. If Participant has received the Award Agreement and the Plan applicably to his or her country of residence or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

5.Currency. Participant understands that, any amounts related to the PSUs will be denominated in U.S. dollars and will be converted to any local currency using a prevailing exchange rate in effect at the time such conversion is performed, as determined by the Company. Participant understands and agrees that neither the Company nor any affiliate shall be liable for any foreign exchange rate fluctuation between Participant's local currency and the U.S. dollar that may affect the value of the PSUs,

or of any amounts due to Participant or as a result of the subsequent sale of any Shares issuable upon settlement of the Award.

6.Additional Restrictions. The Company reserves the right to impose other requirements on the PSUs and the shares of Stock issuable upon settlement of the Award, to the extent the Company determines it is necessary or advisable in order to comply with local laws or facilitate the administration of the Plan, and to require Participant to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

7.Securities Law Notice. Unless otherwise noted, neither the Company nor the Shares are registered with any local stock exchange or under the control of any local securities regulator outside the United States. The Award Agreement (of which this Addendum is a part), the Plan, and any other communications or materials that Participant may receive regarding participation in the Plan do not constitute advertising or an offering of securities outside the United States, and the issuance of securities described in any Plan-related documents is not intended for public offering or circulation in Participant's jurisdiction.

8.No EU Prospectus. This document does not constitute a prospectus within the meaning of Regulation (EU) 2017/1129. In participating in the Plan, Participant acknowledges that no prospectus will be published for the purpose of the offering, issuance and sale of the underlying Shares and any offering of the Shares is conducted by the Company in reliance on an exemption from the obligation to publish a prospectus set forth in Article 1 of the Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC.

9.Acknowledgment of Nature of Plan and Rights. In participating in the Plan, Participant acknowledges that:

(a) For employment and labor law purposes, the PSUs and any Shares issuable upon settlement of the PSUs are an extraordinary item that do not constitute wages of any kind for services of any kind rendered to the Company Group, and the award of rights is outside the scope of Participant's employment or service contract, if any;

(b) For employment and labor law purposes, the PSUs and any Shares issuable upon settlement of the PSUs are not part of normal or expected wages or salary for any purposes, including, but not limited to, calculation of any severance, resignation, termination, redundancy, dismissal, end of service payments or entitlements, notice of termination or indemnity, compensation or damages in lieu of such notice, bonuses, holiday pay, long-service awards, pension or retirement benefits or similar payments and in no event should be considered as compensation for, or relating in any way to, past services for the Company Group;

(c) The PSUs and any Shares issuable upon settlement of the PSUs are not intended to be an integral component of compensation or to replace any pension rights or compensation;

(d) Neither the rights nor any provision of Plan or the policies adopted pursuant to the Plan confer upon any Participant any right with respect to service or employment or continuation of current service or employment and shall not be interpreted to form a service or employment contract or relationship with the Company Group;

(e) The future value of the underlying Shares is unknown and cannot be predicted with certainty;

(f) If the underlying Shares do not increase in value, the right may have no value;

(g) If the PSUs vest and settle and Participant acquires Shares, the value of the Shares acquired upon settlement may increase or decrease in value;

(h) In consideration of the grant of the PSUs hereunder, no claim or entitlement to compensation or damages arises from termination of the PSUs, and no claim or entitlement to compensation or damages shall arise from forfeiture of the PSUs resulting from termination of Participant's employment by the Company Group (for any reason whatsoever, whether with or without Cause, whether with or without prior notice, and whether or not in breach of local employment or labor laws) and Participant irrevocably releases the Company Group from any such claim that may arise; if, notwithstanding the foregoing, any such claim is found by a court of competent jurisdiction to have arisen, Participant shall be deemed irrevocably to have waived Participant's entitlement to pursue such claim; and

(i) For purposes of the PSUs, a Termination of Service will be deemed to have occurred as of the date Participant is no longer actively providing services to the Company (regardless of the reason for such Termination of Service and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where Participant is employed or otherwise rendering services, or the terms of Participant's employment or other service agreement, if any). Participant's employment or service relationship will not be extended by any notice period (e.g., Participant's period of service will not be extended by any contractual notice period or period of "garden leave" or similar period mandated under employment laws in the jurisdiction where Participant is employed or otherwise rendering services, or the terms of Participant's employment or other service agreement, if any). Unless otherwise expressly provided in the Plan or determined by the Company, Participant's right to vest in the PSUs, if any, will terminate as of the date of Termination of Service. Notwithstanding the forgoing, the Administrator shall have exclusive discretion to determine when a Termination of Service has occurred for purposes of the PSUs (including when Participant is no longer considered to be actively providing services while on a leave of absence). In the event of Participant's leave of absence, vesting of the PSUs shall be governed by the Company's leave of absence policies, as may be amended from time to time, and in accordance with Applicable Laws.

CANADA

1.Termination of Service. The following provision replaces Section 9(i) of this Appendix:

For purposes of the Award and any related rights or entitlements, Participant's Termination of Service is deemed to occur (regardless of the reason for the termination, whether with or without Cause, whether with or without prior notice, and whether or not later found to be invalid or in breach of Applicable Laws in the jurisdiction where Participant is employed or otherwise rendering services or the terms of Participant's employment or service agreement, if any) on the date that is the earliest of (a) the effective termination date of Participant's employment or service agreement, or (b) the date Participant is no longer actively employed by or actively providing services to the Company or any of its Subsidiaries following Participant's receipt of a notice of termination of employment or service agreement, or Participant's delivery of a notice of resignation or termination of service agreement to the Company or any of its Subsidiaries, in any such case regardless of (and without including) any notice of termination or resignation period or any period of pay, indemnity, compensation or damages in lieu of such notice mandated under Applicable Laws (including, but not limited to, statutory law, regulatory law, civil law and/or common law) in the jurisdiction where Participant is employed or otherwise rendering services or the terms of Participant's employment or other service agreement, if any. For greater certainty, for purposes of this

Award and any related rights or entitlements, Participant will not be considered to be employed by or providing services to the Company or any of its Subsidiaries, whether actively or otherwise, and shall not be entitled to further vesting of the Award, or any indemnity, compensation or damages in lieu thereof, in respect of any notice of termination period required or any retroactive period during which Participant is deemed to be in the employ or service of the Company or any of its Subsidiaries, whether pursuant to Applicable Laws in the jurisdiction where Participant is employed or rendering services or pursuant to a decision of a court or tribunal of competent jurisdiction.

Notwithstanding the foregoing, if applicable employment standards legislation explicitly requires continued participation in the Plan during a minimum statutory notice period, Participant acknowledges that his or her right to participate in the Plan, if any, will terminate effective as of the last day of Participant's minimum statutory notice period, but Participant will not earn or be entitled to pro-rata vesting if the vesting date falls after the end of Participant's statutory notice period, nor will Participant be entitled to any compensation for lost vesting.

2.Payment After Vesting. The grant of PSUs does not provide any right for Participant to receive a cash payment, and settlement of the PSUs is payable only in Shares.

3.Language. The following provisions will apply if Participant is a resident of Quebec. The parties acknowledge that it is their express wish that the Agreement, as well as all documents, notices and written communications relating directly or indirectly hereto be drawn up in English.

Langue: Les parties reconnaissent avoir exigé la rédaction en anglais de cette convention, ainsi que de tous documents, avis et communications écrites s'y rattachant, directement ou indirectement.

4.Securities Law Information. Canadian residents are permitted to sell shares of Common Stock acquired under the Plan through the designated broker appointed under the Plan, if any, provided the sale of such shares acquired under the Plan takes place outside Canada through the Nasdaq stock exchange on which the shares of Common Stock are listed.

5.Notwithstanding any other provisions, the Company designates that any stock issued under the PSUs granted herein is a "non-qualifying security" pursuant to subsection 110(1.4) of the Income Tax Act (Canada).

6.Foreign Asset/Account Reporting Information. Canadian taxpayers are required to report any foreign specified property, including Shares acquired under the Plan and rights to receive Shares (e.g., PSUs) on Form T1135 (Foreign Income Verification Statement) if the total cost of the foreign specified property exceeds C$100,000 at any time during the year. PSUs must be reported (generally, at nil cost) if the C$100,000 cost threshold is exceeded because of other foreign specified property held by Participant. For Shares acquired under the Plan, cost generally is the adjusted cost basis ("***ACB***"), which would ordinarily be equal the fair market value of such shares at the time of acquisition. If, however, Participant owns other Shares in the Company, the ACB of the Shares acquired under the Plan will need to be averaged with the ACB of the other Shares. The statement is due at the same time as Participant's annual tax return. Participant should consult their personal tax advisor to ensure compliance with applicable reporting obligations.

TAIWAN

1.Securities Law Information. The offer of participation in the Plan is available only for Consultants, Directors and Employees of the Company and its Subsidiaries. The offer of participation in the Plan is not a public offer of securities by a Taiwanese company. Neither the Plan nor the PSUs are registered in Taiwan with the Securities and Futures Bureau or subject to the securities laws of Taiwan.

UNITED KINGDOM

1.Incorporation of Terms of the Plan. Notwithstanding anything in the Plan to the contrary, in the United Kingdom only Employees are eligible to be granted Awards. Other persons who are not Employees are not eligible to receive Awards in the United Kingdom. This Agreement forms the rules of the employee share scheme applicable to United Kingdom-based Employees. All Awards granted to Employees who are based in the United Kingdom will be granted on similar terms. This Agreement incorporates the terms of the Plan with the exception that reference to "Service Provider" when used in the Plan (as incorporated into the Agreement) and in the Agreement itself shall mean Employee only and shall not include other persons providing services to the Company or any Subsidiary. Accordingly, all references in the Agreement to Participant's service, service agreement or termination of service shall be interpreted as references to Participant's employment, contract of employment or termination of employment.

2.Tax Withholding and Indemnity. This provision supplements Section 3.1 of the Agreement:

(a) If Participant is a resident of the United Kingdom, then the "***Tax Obligations***" shall also include Participant's primary (employee) national insurance contributions and, at the Company's discretion, any secondary (employer) national insurance contributions of the Company Group (or other similar obligations wherever in the world arising). Participant agrees that Participant is liable for all Tax Obligations and hereby covenants to pay all such Tax Obligations as and when requested by the Company Group or by His Majesty's Revenue and Customs ("***HMRC***") (or any other tax authority or any other relevant authority). Participant also agrees to indemnify and keep indemnified the Company Group against any Tax Obligations that they are required to pay or withhold or have paid or will pay to HMRC (or any other tax authority or any other relevant authority) on Participant's behalf that is attributable to: (1) the grant or settlement of, or any benefit derived by Participant from, the PSUs or the Shares which are the subject of the PSUs; (2) the transfer or issuance of Shares on the settlement of the PSUs; (3) any restrictions applicable to any Shares held by Participant ceasing to apply thereto; or (4) the disposal of any Shares (each, a "***Taxable Event***").

(b) The PSUs cannot be settled until Participant has made such arrangements as the Company may require for the satisfaction of any Tax Obligations that may arise in connection with the vesting and settlement of the PSUs and/or the acquisition of Shares by Participant. The Company shall not be required to issue, allot or transfer Shares until Participant has satisfied this obligation. Participant undertakes that, upon request by the Company, Participant will join with his or her Employer in electing, pursuant to Section 431(1) of the Income Tax (Earnings and Pensions) Act 2003 ("***ITEPA***") that, for relevant tax purposes, the market value of the Shares issued upon vesting of the PSUs on any occasion will be calculated as if the Shares were not restricted and Sections 425 to 430 (inclusive) of ITEPA are not to apply to such Shares.

(c) Participant agrees that if Participant does not pay or the Company Group does not withhold from Participant the full amount of all Tax Obligations that Participant owes due to any Taxable Event within ninety (90) days after the end of the tax year in which the Taxable Event occurred, or such

other period specified in Section 222(1)(c) of ITEPA, then the amount that should have been withheld shall constitute a loan owed by Participant to the Employer, effective ninety (90) days after the end of the tax year in which the Taxable Event occurred. Participant agrees that the loan will bear interest at the HMRC's official rate and will be immediately due and repayable by Participant, and the Company and/or the Employer may recover it at any time thereafter by withholding the funds from salary, bonus or any other funds due to Participant by the Employer, by withholding in Shares issued upon vesting and settlement of the PSUs or from the cash proceeds from the sale of Shares or by demanding cash or a cheque from Participant. Participant also authorizes the Company to delay the issuance of any Shares to Participant unless and until the loan is repaid in full.

(d) Notwithstanding the foregoing, if Participant is a director or executive officer of the Company (within the meaning of Section 13(k) of the Exchange Act), Participant understands that the foregoing provision will not apply. Instead, any Tax Obligations not collected within ninety (90) days of the end of the UK tax year in which an event giving rise to the Tax Obligation occurs may constitute a benefit to Participant on which additional income tax and national insurance contributions may be payable. Participant understands that he or she will be responsible for reporting and paying any income tax due on this additional benefit directly to HMRC under the self-assessment regime and for paying to the Company and/or the Employer (as appropriate) the amount of any national insurance contributions due on this additional benefit, which can be recovered by any means set out in the Agreement.

Exhibit 31.1

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

I, Arthur Kuan, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of CG Oncology, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a.Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b.(Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

c.Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d.Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and.

5.The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a.All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b.Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2025

By: /s/ Arthur Kuan
Name: Arthur Kuan
Title: Chairman and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

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

I, Robert Lapetina, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of CG Oncology, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a.Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b.(Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

c.Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d.Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a.All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b.Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2025

By: /s/ Robert Lapetina
Name: Robert Lapetina
Title: Vice President, Financial Planning & Analysis
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of CG Oncology, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: November 14, 2025

By: /s/ Arthur Kuan
Name: Arthur Kuan
Title: Chairman and Chief Executive Officer
(principal executive officer)

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

Exhibit 32.2

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

In connection with the Quarterly Report of CG Oncology, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: November 14, 2025

By: /s/ Robert Lapetina
Name: Robert Lapetina
Title: Vice President, Financial Planning & Analysis
(Principal Financial and Accounting Officer)

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