

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2024

OR

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

Commission File Number: 001-39856

CULLINAN THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

One Main Street

Suite 1350

Cambridge, MA

(Address of principal executive offices)

81-3879991

(I.R.S. Employer
Identification No.)

02142

(Zip Code)

(617) 410-4650

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	CGEM	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, a 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 ☒

The number of shares of the Registrant's common stock outstanding as of October 31, 2024 was 58,227,593.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks, uncertainties, and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, and expected market growth are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would”, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties, and other 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 these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed in our Annual Report on Form 10-K for the year ended December 31, 2023 (the “2023 10-K”) and other filings with the Securities Exchange Commission (the “SEC”), including the following:

- the commercial success, cost of development, and timing of the approval of our clinical-stage product candidates;
- the initiation, timing, progress, results, and cost of our research and development programs, and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or clinical trials and related preparatory work, and the period during which the results of the trials will become available;
- our ability to submit, and obtain clearance of, any global regulatory filings, including investigational new drug applications, on our expected timelines, or at all;
- our ability to initiate, recruit, and enroll patients in and conduct our clinical trials at the pace that we project;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations, or warnings in the label of any of our product candidates, if approved;
- our ability to compete with companies currently marketing therapies or developing product candidates with targets or indications similar to our product candidates’ targets or indications;
- our reliance on third parties to conduct our clinical trials and to manufacture drug substance and drug product for use in our clinical trials;
- the size and growth potential of the markets for any of our current and future product candidates, and our ability to serve those markets;
- our ability to identify and advance through clinical development any additional product candidates;
- the commercialization of our current and future product candidates, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current and future product candidates;
- our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop current and future product candidates;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain adequate intellectual property rights;
- our expectations regarding government and third-party payor coverage, pricing, and reimbursement;
- our estimates of our expenses, ongoing losses, capital requirements, the sufficiency of our current resources, and our needs for or ability to obtain additional financing;
- the milestone payments that we may receive from Taiho Pharmaceutical Co., Ltd.;
- potential investments in our pipeline and the potential for such product candidates;
- the potential benefits of strategic collaboration agreements, our ability to enter into additional strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory, and commercialization expertise; and
- developments and projections relating to our competitors or our industry.

These factors are discussed more fully in our 2023 10-K and elsewhere in this Quarterly Report on Form 10-Q and other reports we file with the SEC. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and investors should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, and expectations disclosed in the forward-looking statements we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make or collaborations or strategic partnerships we may enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This Quarterly Report on Form 10-Q also contains estimates, projections, and other information concerning our industry, our business, and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research, as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Quarterly Report on Form 10-Q, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section titled “Risk Factors” in our 2023 10-K and elsewhere in this Quarterly Report on Form 10-Q.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

**CULLINAN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except share amounts)**

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 102,085	\$ 98,434
Short-term investments	475,993	368,633
Prepaid expenses and other current assets	13,961	13,124
Total current assets	592,039	480,191
Property and equipment, net	760	989
Operating lease right-of-use assets	2,019	2,543
Other assets	460	459
Long-term investments	57,976	—
Total assets	\$ 653,254	\$ 484,182
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,115	\$ 2,493
Accrued expenses and other current liabilities	20,831	24,204
Operating lease liabilities, current	1,258	1,440
Total current liabilities	24,204	28,137
Long-term liabilities:		
Operating lease liabilities, net of current portion	1,188	2,150
Total liabilities	25,392	30,287
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 647,500 shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, \$0.0001 par value, 150,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 58,141,130 and 42,900,083 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	6	4
Additional paid-in capital	947,479	654,685
Accumulated other comprehensive income (loss)	970	(129)
Accumulated deficit	(320,593)	(200,857)
Total Cullinan stockholders' equity	627,862	453,703
Noncontrolling interests	—	192
Total stockholders' equity	627,862	453,895
Total liabilities and stockholders' equity	\$ 653,254	\$ 484,182

See accompanying notes to the unaudited consolidated financial statements.

CULLINAN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 35,506	\$ 33,821	\$ 102,411	\$ 113,308
General and administrative	13,349	10,982	39,460	31,856
Total operating expenses	48,855	44,803	141,871	145,164
Impairment of long-lived assets	—	(440)	—	(440)
Loss from operations	(48,855)	(45,243)	(141,871)	(145,604)
Other income (expense):				
Interest income	8,384	5,880	22,148	15,710
Other income (expense), net	(89)	180	(205)	356
Net loss	(40,560)	(39,183)	(119,928)	(129,538)
Net loss attributable to noncontrolling interests	—	—	(192)	(179)
Net loss attributable to common stockholders of Cullinan	<u>\$ (40,560)</u>	<u>\$ (39,183)</u>	<u>\$ (119,736)</u>	<u>\$ (129,359)</u>
Comprehensive income (loss):				
Net loss	\$ (40,560)	\$ (39,183)	\$ (119,928)	\$ (129,538)
Unrealized gain on investments	1,446	574	1,099	1,550
Comprehensive loss	(39,114)	(38,609)	(118,829)	(127,988)
Comprehensive loss attributable to noncontrolling interests	—	—	(192)	(179)
Comprehensive loss attributable to Cullinan	<u>\$ (39,114)</u>	<u>\$ (38,609)</u>	<u>\$ (118,637)</u>	<u>\$ (127,809)</u>
Net loss per share attributable to common stockholders of Cullinan:				
Basic and diluted	\$ (0.69)	\$ (0.91)	\$ (2.30)	\$ (3.15)
Weighted-average shares used in computing net loss per share attributable to common stockholders of Cullinan:				
Basic and diluted	58,337	42,734	52,157	41,130

See accompanying notes to the unaudited consolidated financial statements.

CULLINAN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands, except share amounts)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensi ve Income (Loss)	Accumulated Deficit	Noncontrolli ng Interests	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital				Equity
Balances at December 31, 2023	647,500	\$ —	42,900,083	\$ 4	\$ 654,685	\$ (129)	\$ (200,857)	\$ 192	\$ 453,895
Net issuance of common stock under equity-based compensation plans	—	—	165,562	—	1,085	—	—	—	1,085
Equity-based compensation	—	—	—	—	8,227	—	—	—	8,227
Unrealized loss on investments	—	—	—	—	—	(202)	—	—	(202)
Net loss	—	—	—	—	—	—	(37,148)	(192)	(37,340)
Balances at March 31, 2024	647,500	—	43,065,645	4	663,997	(331)	(238,005)	—	425,665
Issuance of common stock and pre-funded warrants, net of issuance costs	—	—	14,421,070	1	262,651	—	—	—	262,652
Net issuance of common stock under equity-based compensation plans	—	—	384,923	1	3,335	—	—	—	3,336
Equity-based compensation	—	—	—	—	10,533	—	—	—	10,533
Acquisition of noncontrolling interests	—	—	—	—	(3,792)	—	—	—	(3,792)
Unrealized loss on investments	—	—	—	—	—	(145)	—	—	(145)
Net loss	—	—	—	—	—	—	(42,028)	—	(42,028)
Balances at June 30, 2024	647,500	—	57,871,638	6	936,724	(476)	(280,033)	—	656,221
Net issuance of common stock under equity-based compensation plans	—	—	269,492	—	1,981	—	—	—	1,981
Equity-based compensation	—	—	—	—	9,430	—	—	—	9,430
Acquisition of noncontrolling interests	—	—	—	—	(656)	—	—	—	(656)
Unrealized loss on investments	—	—	—	—	—	1,446	—	—	1,446
Net loss	—	—	—	—	—	—	(40,560)	—	(40,560)
Balances at September 30, 2024	647,500	\$ —	58,141,130	\$ 6	\$ 947,479	\$ 970	\$ (320,593)	\$ —	\$ 627,862

See accompanying notes to the unaudited consolidated financial statements.

CULLINAN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands, except share amounts)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensi ve Income (Loss)	Accumulated Deficit	Noncontrolli ng Interests	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital				Equity
Balances at December 31, 2022	—	\$ —	45,796,449	\$ 5	\$ 585,320	\$ (2,601)	\$ (47,695)	\$ —	\$ 535,029
Contributions from noncontrolling interests	—	—	—	—	—	—	—	179	179
Issuance of preferred stock in exchange for common stock	647,500	—	(6,475,000)	(1)	1	—	—	—	—
Net issuance of common stock under equity-based compensation plans	—	—	22,152	—	(36)	—	—	—	(36)
Equity-based compensation	—	—	—	—	7,259	—	—	—	7,259
Unrealized gain on investments	—	—	—	—	—	1,359	—	—	1,359
Net loss	—	—	—	—	—	—	(57,962)	(179)	(58,141)
Balances at March 31, 2023	647,500	—	39,343,601	4	592,544	(1,242)	(105,657)	—	485,649
Issuance of common stock	—	—	3,310,000	—	38,388	—	—	—	38,388
Net issuance of common stock under equity-based compensation plans	—	—	81,703	—	214	—	—	—	214
Equity-based compensation	—	—	—	—	7,920	—	—	—	7,920
Unrealized loss on investments	—	—	—	—	—	(383)	—	—	(383)
Net loss	—	—	—	—	—	—	(32,214)	—	(32,214)
Balances at June 30, 2023	647,500	—	42,735,304	4	639,066	(1,625)	(137,871)	—	499,574
Net issuance of common stock under equity-based compensation plans	—	—	25,340	—	112	—	—	—	112
Equity-based compensation	—	—	—	—	7,740	—	—	—	7,740
Unrealized loss on investments	—	—	—	—	—	574	—	—	574
Net loss	—	—	—	—	—	—	(39,183)	—	(39,183)
Balances at September 30, 2023	647,500	\$ —	42,760,644	\$ 4	\$ 646,918	\$ (1,051)	\$ (177,054)	\$ —	\$ 468,817

See accompanying notes to the unaudited consolidated financial statements.

CULLINAN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2024	2023
Operating activities:		
Net loss	\$ (119,928)	\$ (129,538)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation expense	28,190	22,919
Accretion on marketable securities	(11,958)	(6,533)
Depreciation and amortization	229	233
Impairment of long-lived assets	—	440
Realized gain on marketable securities	—	(20)
Non-cash contributions from noncontrolling interests	—	4
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(837)	(2,650)
Accounts payable	(378)	(1,709)
Accrued expenses and other current liabilities	(3,995)	4,992
Income tax payable	—	(4,282)
Net cash used in operating activities	<u>(108,677)</u>	<u>(116,144)</u>
Investing activities:		
Purchase of marketable securities	(553,095)	(307,371)
Maturities of marketable securities	400,817	291,915
Purchase of property and equipment	—	(208)
Net cash used in investing activities	<u>(152,278)</u>	<u>(15,664)</u>
Financing activities:		
Issuance of common stock and pre-funded warrants, net of issuance costs	262,652	38,388
Net issuance of common stock under equity-based compensation plans	6,402	290
Acquisition of noncontrolling interests	(4,448)	—
Issuance of convertible notes	—	1,825
Net cash provided by financing activities	<u>264,606</u>	<u>40,503</u>
Net increase (decrease) in cash and cash equivalents	<u>3,651</u>	<u>(91,305)</u>
Cash and cash equivalents at beginning of period	98,434	156,152
Cash and cash equivalents at end of period	<u>\$ 102,085</u>	<u>\$ 64,847</u>
SUPPLEMENTAL NONCASH DISCLOSURE		
Non-cash investing and financing activities and supplemental cash flow information		
Cash paid (refunded) for income taxes	\$ (2,274)	\$ 4,708
Conversion of convertible note into noncontrolling interest	\$ —	\$ 175

See accompanying notes to the unaudited consolidated financial statements.

CULLINAN THERAPEUTICS, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

(1) Nature of Business and Basis of Presentation

Organization

Cullinan Therapeutics, Inc., together with its consolidated subsidiaries ("Cullinan" or the "Company"), is a clinical-stage biopharmaceutical company dedicated to creating new standards of care for patients that was incorporated in September 2016 and has a principal place of business in Cambridge, Massachusetts. In April 2024, the Company changed its name from Cullinan Oncology, Inc. to Cullinan Therapeutics, Inc.

Liquidity

The Company has a history of significant operating losses and has had negative cash flows from operations since its inception and expects to continue to generate operating losses for the foreseeable future. Cullinan's ultimate success depends on the outcome of its research and development activities as well as its ability to commercialize the Company's product candidates. Cullinan is subject to a number of risks including, but not limited to, the need to obtain adequate additional funding for the ongoing and planned clinical development of its product candidates. Due to the numerous risks and uncertainties associated with pharmaceutical products and development, the Company is unable to accurately predict the timing or amount of funds required to complete development of its product candidates, and costs could exceed Cullinan's expectations for a number of reasons, including reasons beyond the Company's control.

Since inception, Cullinan has funded its operations primarily through the sale of equity securities and from licensing or selling the rights to its product candidates. The Company expects that its cash, cash equivalents, and short-term investments of \$578.1 million, and long-term investments and interest receivable of \$60.9 million as of September 30, 2024, will be sufficient to fund its operating expenses and capital expenditure requirements through the next twelve months from the date of issuance of these consolidated financial statements. In April 2024, Cullinan sold shares of its common stock and pre-funded warrants for shares of its common stock in a private placement (the "2024 Private Placement") for net proceeds of \$262.7 million, after deducting offering costs of \$17.3 million. Refer to Note 6 for additional detail regarding the 2024 Private Placement.

(2) Summary of Significant Accounting Policies

Cullinan's significant accounting policies have not changed materially from those disclosed in its annual audited consolidated financial statements and accompanying notes in its Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "2023 10-K").

Basis of Presentation

The accompanying unaudited consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") and in accordance with applicable rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial reporting and include the accounts of the Company and its consolidated subsidiaries. Intercompany balances and transactions have been eliminated in consolidation. The Company operates as one segment, which is developing early-stage therapeutics.

In the opinion of Cullinan's management, the unaudited consolidated financial statements reflect all adjustments, which are normal and recurring in nature, and necessary for fair financial statement presentation. The preparation of these unaudited consolidated financial statements and accompanying notes in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported. Actual results could differ materially from those estimates. These unaudited consolidated financial statements and accompanying notes should be read in conjunction with the Company's annual audited consolidated financial statements and accompanying notes included in the 2023 10-K.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (the "FASB") issued an accounting standards update to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The main provisions of this update require companies to disclose, on an annual and interim basis, significant segment expenses, segment profit and loss, and other segments items that are regularly provided to the Company's Chief Operating Decision Maker (the "CODM"). This update also requires companies to disclose the title and position of the CODM and to explain how the CODM uses the reported segment measures in assessing segment performance and deciding how to allocate resources. The update also requires companies with a single reportable segment to provide all required segment reporting disclosures. This new standard will be effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. Cullinan adopted this standard on January 1, 2024 for 2024 annual reporting and interim periods beginning in 2025.

Recently Issued Accounting Pronouncements

Cullinan currently qualifies as an emerging growth company (“EGC”) under the Jumpstart Our Business Startups Act, which allows the Company to delay adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has elected to use the extended transition period for new or revised accounting standards during the period in which it remains an EGC; however, Cullinan may adopt certain new or revised accounting standards early. Based on the market value of the Company's common stock held by non-affiliates as of June 30, 2024, the Company will cease to be an EGC as of December 31, 2024. As a result, beginning with the Company’s Annual Report on Form 10-K for the year ending December 31, 2024, the Company will not be able to rely on the extended transition period noted above and will be required to adopt all new accounting pronouncements within the same time periods as other public companies that are not EGCs.

In December 2023, the FASB issued an accounting standards update to enhance transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The main provisions in this update will require companies to disclose, on an annual basis, specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. This update will also require companies to disclose, on an annual basis, the amount of income taxes paid, income (or loss) from continuing operations before income tax expense (or benefit), and income tax expense (or benefit) from continuing operations, disaggregated by federal, state, and foreign jurisdictions. This new standard will be effective for fiscal years beginning after December 15, 2024, and early adoption is permitted. The Company expects that it will adopt this new standard on January 1, 2025. The Company is evaluating the impact this new standard will have on its consolidated financial statements and associated disclosures.

(3) Financial Instruments

Investments

Cullinan recognized its investments by security type at September 30, 2024 as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments				
U.S. government notes	\$ 227,900	\$ 244	\$ (1)	\$ 228,143
Corporate notes	222,233	640	(10)	222,863
Asset-backed securities	24,932	55	—	24,987
Total short-term investments	475,065	939	(11)	475,993
Long-term investments				
Corporate notes	57,934	98	(56)	57,976
Total long-term investments	57,934	98	(56)	57,976
Total investments	\$ 532,999	\$ 1,037	\$ (67)	\$ 533,969

Cullinan recognized its investments by security type at December 31, 2023 as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments				
U.S. government notes	\$ 208,289	\$ 221	\$ (16)	\$ 208,494
Corporate notes	99,359	27	(275)	99,111
Asset-backed securities	61,114	3	(89)	61,028
Total short-term investments	368,762	251	(380)	368,633
Total investments	\$ 368,762	\$ 251	\$ (380)	\$ 368,633

Fair Value of Financial Instruments

The following table sets forth the fair value of Cullinan's financial assets that were measured at fair value on a recurring basis as of September 30, 2024 (in thousands):

	Level 1	Level 2	Level 3	Total
Short-term investments				
U.S. government notes	\$ —	\$ 228,143	\$ —	\$ 228,143
Corporate notes	—	222,863	—	222,863
Asset-backed securities	—	24,987	—	24,987
Total short-term investments	—	475,993	—	475,993
Long-term investments				
Corporate notes	—	57,976	—	57,976
Total long-term investments	—	57,976	—	57,976
Total investments	\$ —	\$ 533,969	\$ —	\$ 533,969

The following table sets forth the fair value of the Company's financial assets that were measured at fair value on a recurring basis as of December 31, 2023 (in thousands):

	Level 1	Level 2	Level 3	Total
Short-term investments				
U.S. government notes	\$ —	\$ 208,494	\$ —	\$ 208,494
Corporate notes	—	99,111	—	99,111
Asset-backed securities	—	61,028	—	61,028
Total short-term investments	—	368,633	—	368,633
Total investments	\$ —	\$ 368,633	\$ —	\$ 368,633

As of September 30, 2024 and December 31, 2023, the fair values of Cullinan's cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximated their carrying values due to the short-term nature of these instruments.

(4) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024	December 31, 2023
Contracted research and development expenses	\$ 8,226	\$ 8,434
Due to Taiho under collaboration agreement, net	5,026	7,869
Employee compensation	5,870	6,987
Other current liabilities	1,709	914
Total accrued expenses and other current liabilities	\$ 20,831	\$ 24,204

(5) License and Collaboration Agreements

Harbour License Agreement

In February 2023, the Company and Harbour BioMed US Inc. ("Harbour") entered into a license and collaboration agreement (the "Harbour License Agreement"), pursuant to which Harbour granted to Cullinan an exclusive license for the development, manufacturing and commercialization of HBM7008 (CLN-418) in the U.S.

Under the terms of the Harbour License Agreement, Cullinan paid Harbour an upfront license fee of \$25.0 million at signing. In addition, under the Harbour License Agreement, Harbour granted Cullinan certain intellectual property rights to enable the Company to perform its obligations and exercise its rights under the Harbour License Agreement. Cullinan evaluated the Harbour License Agreement and determined that the exclusive license for the development, manufacturing and commercialization of HBM7008 (CLN-418) in the U.S. represented an asset acquisition of in-process research and development. The Company also determined that the asset had no alternative future use at the time of acquisition, and therefore, the upfront license fee of \$25.0 million was recorded within research and development expenses for the nine months ended September 30, 2023.

In August 2024, following a review of the data from the Phase 1 clinical trial of CLN-418, the Company notified Harbour of its decision to terminate the Harbour License Agreement, effective November 2024. In connection with the termination, the Company discontinued development of CLN-418 and returned development and commercial rights for CLN-418 to Harbour.

Taiho Agreements

Cullinan has a co-development agreement with an affiliate of Taiho Pharmaceutical Co., Ltd ("Taiho"), pursuant to which the Company is collaborating to develop zipalertinib and has the option to co-commercialize zipalertinib in the U.S. Development costs for zipalertinib are shared equally between Taiho and the Company with each party receiving 50% of any future pre-tax profits from potential U.S. sales of zipalertinib.

The Company concluded that the co-development agreement with Taiho is a collaborative arrangement because Cullinan is an active participant in the development of zipalertinib. Payments made to or received from Taiho for zipalertinib development activities after the execution of the co-development agreement are recorded within research and development expenses and general and administrative expenses. For the three and nine months ended September 30, 2024, the Company recorded \$6.5 million and \$17.6 million, respectively, related to its share of research and development costs incurred by Taiho. For the three and nine months ended September 30, 2024, the Company recorded \$0.7 million related to its share of general and administrative costs incurred by Taiho. Cullinan incurred \$2.2 million and \$6.9 million of costs that were reimbursable by Taiho during the three and nine months ended September 30, 2024, respectively, which were recorded as a reduction to research and development expenses. For the three and nine months ended September 30, 2023, the Company recorded \$5.4 million and \$15.6 million, respectively, related to its share of research and development costs incurred by Taiho. Cullinan incurred \$2.0 million and \$5.1 million of research and development costs that were reimbursable by Taiho during the three and nine months ended September 30, 2023, respectively, which were recorded as a reduction to research and development expenses. The net amounts of \$5.0 million and \$7.9 million due to Taiho as of September 30, 2024 and December 31, 2023, respectively, were recorded within accrued expenses and other current liabilities.

Cullinan is also eligible to receive up to \$130.0 million from Taiho tied to epidermal growth factor receptor exon 20 non-small-cell lung cancer regulatory milestones.

Other License and Collaboration Agreements

During the three and nine months ended September 30, 2024, no milestones were achieved under the Company's other license and collaboration agreements.

During each of the three and nine months ended September 30, 2023, Cullinan recorded \$0.5 million in research and development expenses for milestones achieved under its collaboration agreement with Adimab, LLC for CLN-978. During the nine months ended September 30, 2023, Cullinan recorded \$0.2 million in research and development expenses for milestones achieved under its license agreement with the Massachusetts Institute of Technology for CLN-617.

(6) Stockholders' Equity

Common Stock

Each share of common stock entitles the holder to one vote and to receive dividends when and if declared by the board of directors of the Company. No dividends have been declared through September 30, 2024.

2024 Private Placement

In April 2024, Cullinan completed the 2024 Private Placement in which Cullinan issued approximately 14.4 million shares of its common stock and pre-funded warrants to purchase approximately 0.3 million additional shares of its common stock. Cullinan received net proceeds of \$262.7 million from the 2024 Private Placement, after deducting offering costs of \$17.3 million. Refer to the discussion under the heading "Warrants" below for further detail regarding the pre-funded warrants.

At-the-Market Equity Offering Program

In May 2023, Cullinan entered into an agreement with Cowen and Company, LLC ("Cowen") to establish an at-the-market equity offering program (the "ATM") pursuant to which the Company may offer and sell up to \$125.0 million of its common stock from time to time through Cowen, acting as its sales agent. The Company made no sales under the ATM in the nine months ended September 30, 2024. Through September 30, 2024, the Company has sold approximately 3.3 million shares under the ATM and received net proceeds of \$38.4 million after deducting commissions. As of September 30, 2024, Cullinan had \$85.6 million in shares of its common stock remaining under the ATM.

Preferred Stock

In January 2023, the Company entered into an exchange agreement with Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS LP, and MSI BVF SPV, LLC (the "Stockholders"), pursuant to which the Stockholders exchanged 6.5 million shares of Cullinan's common stock for 0.6 million shares of newly designated Series A convertible preferred stock, a "toothless" preferred stock, par value \$0.0001 per share.

Each share of the preferred stock will be convertible into ten shares of common stock at the option of the holder at any time, subject to certain limitations, including that the holder will be prohibited from converting preferred stock into common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock more than 9.99% of the total common stock then issued and outstanding immediately following the conversion of such shares of preferred stock. Holders of the preferred stock are permitted to increase this percentage to an amount not to exceed 19.99% upon 60 days notice.

Shares of preferred stock will generally have no voting rights, except as required by law and except that the consent of a majority of the holders of the outstanding preferred stock will be required to amend the terms of the preferred stock. In the event of the Company's liquidation, dissolution or winding up, holders of preferred stock will participate pari passu with any distribution of proceeds to holders of common stock. Holders of preferred stock are entitled to receive when, as, and if dividends are declared and paid on the common stock, an equivalent dividend, calculated on an as-converted basis. Shares of preferred stock are otherwise not entitled to dividends.

The preferred stock ranks (i) senior to any class or series of capital stock of Cullinan hereafter created specifically ranking by its terms junior to the preferred stock; (ii) on parity with the common stock and any class or series of capital stock of the Company created specifically ranking by its terms on parity with the preferred stock; and (iii) junior to any class or series of capital stock of Cullinan created specifically ranking by its terms senior to any preferred stock, in each case, as to distributions of assets upon liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily.

The Company determined that the preferred stock should be classified as permanent equity.

Noncontrolling Interests

Certain of the Company's clinical-stage product candidates are held through development subsidiaries in which the Company has controlling interests. These development subsidiaries have issued common stock and preferred stock to the Company and to third parties. The holders of subsidiary common stock and preferred stock are generally entitled to one vote per share. The holders of subsidiary common stock are entitled to receive dividends when and if declared by the subsidiaries' board of directors and distributions in either case only after the payment of all preferential amounts required to be paid to the holders of shares of preferred stock of the respective subsidiary. The following table shows the Company's ownership interest as of September 30, 2024 and December 31, 2023, respectively, in product candidates in which the Company has a controlling interest:

Product Candidate	Ownership Interest as of	
	September 30, 2024	December 31, 2023
CLN-619	99%	95%
CLN-049	97%	96%
CLN-617	94%	94%

During the nine months ended September 30, 2024, Cullinan paid \$4.4 million to acquire shares and options to purchase shares of its CLN-619 development subsidiary that were held by noncontrolling interests.

Warrants

As of September 30, 2024, the Company had potentially issuable shares of common stock related to unexercised pre-funded warrants to purchase 0.3 million shares of the Company's common stock at an exercise price of \$0.001 per share. The pre-funded warrants may be exercised at the option of the holder at any time, subject to certain limitations. The exercise price and the number of shares are subject to adjustment for certain dividend payments and upon reclassification, exchange, combination or substitution of the shares of common stock. The pre-funded warrants expire in April 2054 if they have not been exercised by that time.

Cullinan determined that the pre-funded warrants should be equity-classified. The Company also determined that the pre-funded warrants should be included in the weighted-average shares used in computing basic net loss per share attributable to common stockholders of Cullinan.

(7) Equity-Based Compensation

Cullinan recorded equity-based compensation in the following expense categories in the consolidated statements of operations and comprehensive income (loss) for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
General and administrative	\$ 5,503	\$ 4,536	\$ 17,274	\$ 13,412
Research and development	3,927	3,204	10,916	9,507
Total equity-based compensation	\$ 9,430	\$ 7,740	\$ 28,190	\$ 22,919

(8) Royalty Transfer Agreements

The Company's CLN-619, CLN-049, and CLN-617 development subsidiaries are each party to royalty transfer agreements with two charitable foundations. Under these royalty transfer agreements, the charitable foundations are collectively entitled to receive a low single digit royalty percentage of all global net sales of any products developed by the applicable subsidiary, subject to limitations after patent expirations and on intellectual property developed after a change of control. Cullinan has deemed these royalty transfer agreements to be freestanding financial instruments that should be accounted for at fair value. The Company concluded that these instruments had no value at the inception of the agreements.

Cullinan has not had any applicable net sales from its products and as a result, has not paid or incurred any royalties under these agreements as of September 30, 2024. Given the early-stage nature of the underlying technologies and inherent technical, regulatory and competitive risks associated with achieving approval and commercialization, the Company ascribed no value to the royalty transfer agreements as of September 30, 2024 and December 31, 2023.

(9) Commitments and Contingencies

The Company enters into contracts in the normal course of business with contract research organizations, contract manufacturing organizations, and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. These agreements generally include cancellation clauses.

Indemnification Agreements

In the ordinary course of business, Cullinan 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 members of its board of directors and executive officers that will require Cullinan, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in certain cases, unlimited. To date, Cullinan has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of September 30, 2024 and December 31, 2023.

Legal Proceedings

Cullinan is not currently party to or aware of any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. Cullinan expenses as incurred the costs related to such legal proceedings.

(10) Leases

Cullinan has an operating lease for approximately 14,000 square feet of office space in a multi-tenant building in Cambridge, Massachusetts, which commenced in August 2022 and goes through July 2026. The Company also had an operating lease for approximately 8,000 square feet of office space in a multi-tenant building in Cambridge, Massachusetts, which commenced in February 2018 and expired in June 2024 (the "Suite 520 Lease"). Lease expense consisted of operating lease costs of \$0.3 million and \$0.9 million for the three and nine months ended September 30, 2024, respectively. Lease expense consisted of operating lease costs of \$0.4 million and \$1.3 million for the three and nine months ended September 30, 2023, respectively.

The following table summarizes supplemental cash flow information for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 1,381	\$ 1,378

The following table summarizes the Company's future minimum lease payments as of September 30, 2024 (in thousands):

	September 30, 2024
Remainder of 2024	\$ 357
2025	1,461
2026	871
Total future minimum lease payments	2,689
Less: imputed interest	(243)
Total lease liabilities at present value	\$ 2,446

The following table summarizes the weighted-average remaining lease term and discount rate as of September 30, 2024 and December 31, 2023:

	September 30, 2024	December 31, 2023
Weighted-average remaining lease term (in years)	1.8	2.4
Weighted-average discount rate	11.0%	10.9%

Sublease Agreement

Cullinan had a sublease agreement, which commenced in September 2022 and was scheduled to continue through May 2024 for the office space that the Company leased under the Suite 520 Lease. In September 2023, Cullinan and its subtenant cancelled the sublease agreement for the office space that the Company leased under the Suite 520 Lease, and Cullinan determined that the remaining right-of-use asset for the Suite 520 Lease and the related leasehold improvements (“Suite 520 Asset Group”) was not recoverable. Upon determining that the remaining Suite 520 Asset Group was not recoverable, the Company recorded an impairment of long-lived assets of \$0.4 million for the carrying value in excess of the fair value of the Suite 520 Asset Group within income from operations in its consolidated statements of operations and other comprehensive income (loss) for the three and nine months ended September 30, 2023.

(11) Net Loss per Share Attributable to Common Stockholders of Cullinan

The following table sets forth the calculation of basic and diluted net loss per share attributable to common stockholders of Cullinan for the three and nine months ended September 30, 2024 and 2023 (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss attributable to common stockholders of Cullinan	\$ (40,560)	\$ (39,183)	\$ (119,736)	\$ (129,359)
Denominator:				
Weighted-average common stock outstanding — basic and diluted	58,337	42,734	52,157	41,130
Net loss per share attributable to common stockholders of Cullinan:				
Basic and diluted	\$ (0.69)	\$ (0.91)	\$ (2.30)	\$ (3.15)

Cullinan used the treasury stock method for equity awards and the if-converted method for preferred stock to determine the number of dilutive shares. The following table sets forth potential common shares that were excluded from the computation of diluted net loss per share attributable to common stockholders of Cullinan for the nine months ended September 30, 2024 and 2023 because their effect would have been anti-dilutive (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Stock options	8,411	9,355
Preferred stock	6,475	6,024
Restricted stock awards and units	328	158
Employee stock purchase plan	9	1
Total	15,223	15,538

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023 (the "2023 10-K"), filed with the Securities and Exchange Commission (the "SEC") on March 14, 2024. This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Please also refer to those factors described in "Part I, Item 1A. Risk Factors" of our 2023 10-K and "Part II, Item 1A. Risk Factors" in this Quarterly Report on Form 10-Q for important factors that we believe could cause actual results to differ materially from those in our forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company dedicated to creating new standards of care for patients. Our strategy is to identify high-impact targets, which we define as those that inhibit key drivers of disease or harness the immune system to eliminate diseased cells in both autoimmune diseases and cancer, and then select what we believe is the optimal therapeutic modality for those targets. We source innovation both internally and externally, focusing on product candidates with novel technology or differentiated mechanisms. Before we advance a product candidate into clinical development, we evaluate its potential for activity as a single agent as well as its ability to generate an immune response or to inhibit disease processes. Using this strategy, we have built a broad and deep pipeline of targeted immunology and oncology programs that includes multiple distinct clinical-stage product candidates.

Immunology

- CLN-978 is a CD19xCD3 T cell engager ("TCE") that we are developing for autoimmune diseases. Academic investigators have published data demonstrating the potential for a CD19xCD3 TCE to achieve sustained improvements in disease manifestations, including durable remission from symptoms in some cases, in multiple autoimmune disease indications, including rheumatoid arthritis ("RA"). We believe that CLN-978 has several potential advantages relative to other CD19-directed therapies currently in development, including CAR T therapies as well as other TCEs. Specifically, we believe CLN-978 demonstrates:
 - o Deeper B cell depletion due to CLN-978's very high affinity binding to CD19;
 - o A wider therapeutic index due to CLN-978's 10 times higher potency for B cell depletion relative to cytokine induction;
 - o Potential for more efficient deep tissue penetration due to the relatively small size of the CLN-978 molecule;
 - o Potential for deeper tissue-level B cell depletion than attainable with monoclonal antibodies that work primarily through antibody-dependent cellular cytotoxicity ("ADCC");
 - o Unlike most current generation autologous CAR T therapies, no need for lymphodepleting chemotherapy which is associated with significant toxicities and recognized risk of secondary malignancies; and,
 - o Off-the-shelf convenience without extended manufacturing lead times or limitation to certified treatment centers.

Based on the emerging clinical data supporting the efficacy of CD19-directed therapy in multiple autoimmune diseases and our belief that CLN-978 has several potential advantages compared to other CD19-directed therapies in development, we are exploring the development of CLN-978 in a variety of autoimmune diseases and are committed to assessing its broad potential. In September 2024, we received Human Research Ethics Committee approval in Australia to initiate a global Phase 1 clinical trial to evaluate CLN-978 in patients with systemic lupus erythematosus ("SLE"). In October 2024, we received clearance from the FDA for an investigational new drug ("IND") application to evaluate CLN-978 in a Phase 1 clinical trial in patients with moderate to severe SLE. We plan to share initial clinical data for CLN-978 in the fourth quarter of 2025. In the second quarter of 2025, we also plan to initiate a sponsored clinical trial to evaluate CLN-978 in patients with RA designed and executed in collaboration with the Friedrich-Alexander University of Erlangen-Nuremberg and Università Cattolica del Sacro Cuore, Rome.

Clinical observations from three patients treated in a Phase 1 dose escalation trial in patients with relapsed/refractory B cell non-Hodgkin lymphoma showed that CLN-978 was clinically active at the initial starting dose of 30 micrograms administered subcutaneously once weekly. Two of the three patients experienced objective clinical benefit, including one patient who experienced a complete response. Grade 1 cytokine release syndrome (fever) occurred in two patients following the first dose of CLN-978 only, and no patients experienced immune effector cell-associated neurotoxicity syndrome. Other adverse events were mostly low-grade and/or mechanistically based (e.g., transient lymphopenia after the first dose only). Of the two patients with detectable B cells at baseline, both experienced rapid and deep B cell depletion after administration of CLN-978. These data support that CLN-978 can not only deplete peripheral blood B cells but also demonstrate clinical activity in a tissue resident disease at a dose with a favorable safety profile.

Oncology

- CLN-619, our lead unpartnered oncology program, is a monoclonal antibody that stabilizes expression of MICA/B on the tumor cell surface to promote tumor cell lysis mediated by both cytotoxic innate and adaptive immune cells. CLN-619 is being investigated as both monotherapy and in combination with checkpoint inhibitor ("CPI") therapy or chemotherapy in an ongoing Phase 1 clinical trial in patients with advanced solid tumors.

In June 2024, we presented the first clinical data from the CPI therapy combination dose escalation module of the clinical trial, as well as updated data from the monotherapy dose escalation module, at the American Society of Clinical Oncology Annual Meeting. The preliminary clinical data from CLN-619 in combination with the CPI pembrolizumab demonstrated objective tumor responses across multiple tumor types. Three partial responses were observed, including two in patients with non-small cell lung cancer ("NSCLC") with oncogenic mutations, which are tumor types typically unresponsive to CPI treatment. The expanded preliminary clinical observations for CLN-619 as a monotherapy demonstrated objective tumor responses and extended stable disease across multiple tumor types. We observed one complete response, two partial responses and nine stable disease for at least 18 weeks resulting in a clinical benefit rate of 41.4%. In general, this initial clinical data indicates CLN-619 has an acceptable safety profile across all doses assessed as both monotherapy and in combination with pembrolizumab. No dose-limiting toxicities were observed. Similar to other monoclonal antibodies, infusion-related reactions were limited to the first dose and were all Grade 1 or Grade 2 in patients receiving mandated pre-medication.

The Phase 1 clinical trial continues to enroll expansion cohorts in cervical cancer (monotherapy), endometrial cancers (monotherapy and combination), NSCLC (monotherapy and combination), and ovarian cancer (chemotherapy combination). Additional expansion cohorts may be initiated based on clinical activity observed in the current clinical trial. Initial data from the disease specific expansion cohorts for endometrial and cervical cancers are anticipated in the second quarter of 2025. In September 2024, we dosed the first patient in the Phase 1 clinical trial to evaluate CLN-619 in patients with relapsed/refractory multiple myeloma.

Separately, we were also issued a composition of matter patent by the United States Patent and Trademark Office, which is expected to extend CLN-619's patent protection to 2041, excluding possible patent term extension.

- Zipalertinib (CLN-081/TAS6417), which we are co-developing with an affiliate of Taiho Pharmaceutical Co., Ltd ("Taiho"), is an orally-available small-molecule, irreversible epidermal growth factor receptor ("EGFR") inhibitor that is designed to selectively target cells expressing EGFR exon 20 ("EGFRex20") insertion mutations with relative sparing of cells expressing wild-type EGFR. We are eligible to receive up to \$130.0 million from Taiho tied to EGFRex20 non-small-cell lung cancer regulatory milestones. We will also receive 50% of any future pre-tax profits from potential U.S. sales of zipalertinib. The FDA has granted Breakthrough Therapy designation to zipalertinib. We are evaluating zipalertinib in the pivotal Phase 2b portion of the REZILIENT1 clinical trial in patients with EGFRex20 NSCLC who progressed after prior systemic therapy. Taiho is evaluating zipalertinib in a global Phase 3 clinical trial ("REZILIENT3") in combination with chemotherapy as a potential first-line treatment for EGFRex20 NSCLC adult patients.

In September 2024, at the European Society for Medical Oncology Congress we announced updated clinical data from the pivotal Phase 2b portion of our REZILIENT1 clinical trial of zipalertinib in patients with NSCLC harboring EGFRex20 insertion mutations who received zipalertinib after prior treatment with amivantamab. As of a March 29, 2024 data cut-off, 45 patients had been enrolled. Patients had received a median of three prior systemic therapies including amivantamab. At the data cut-off, 30 patients were evaluable for response and showed a 40% objective response rate ("ORR"), which was similar to the ORR for patients receiving zipalertinib after prior chemotherapy in the previously reported Phase 1/2a part of the clinical trial. Zipalertinib demonstrated a manageable safety profile, similar to what has been previously reported. There were no grade 4 or grade 5 treatment-related adverse events.

In September 2024, we successfully completed enrollment of the pivotal Phase 2b portion of our REZILIENT1 clinical trial, which was originally planned for the end of 2024. We plan to share results of the pivotal Phase 2b portion of the REILIENT1 clinical trial at mid-year 2025.

- CLN-049 is a FLT3xCD3 T cell engaging bispecific antibody. CLN-049 is being investigated in an ongoing Phase 1 clinical trial in patients with relapsed/refractory acute myeloid leukemia ("AML") or myelodysplastic syndrome ("MDS"). We have also initiated a second Phase 1 clinical trial designed to evaluate the safety of CLN-049 in minimal residual disease ("MRD")-positive AML. Following a review of data from the Phase 1 clinical trial of CLN-049, we reported that in the ongoing Phase 1 clinical trial of CLN-049 in patients with relapsed/refractory AML and MDS, dose-limiting injection site reactions were observed during dose escalation with subcutaneous administration. Based on these findings, together with observations of preliminary clinical activity, we discontinued subcutaneous administration. Dose escalation continues in the Phase 1 clinical trial of CLN-049 with intravenous administration.

- CLN-617 is a fusion protein combining two potent antitumor cytokines, interleukin-2 ("IL-2") and interleukin-12 ("IL-12") with tumor retention domains for the treatment of solid tumors. Patient enrollment continues in the ongoing CLN-617 first-in human Phase 1 clinical trial in patients with advanced solid tumors.

Preclinical and Discontinued Programs

In addition to the product candidates described above, we are developing several preclinical programs, all in the discovery stage, including our collaboration with Icahn School of Medicine at Mount Sinai for the development of novel hematopoietic progenitor kinase 1 degraders.

In August 2024, following a review of the data from the Phase 1 clinical trial of CLN-418, we notified Harbour BioMed US Inc. ("Harbour") of our decision to terminate the license and collaboration agreement for CLN-418 (the "Harbour License Agreement"), effective November 2024. In connection with the termination of the Harbour License Agreement, we will discontinue development of CLN-418 and return development and commercial rights for CLN-418 to Harbour and focus our resources on our other product candidates. Refer to Note 5 of our notes to the consolidated financial statements in this Quarterly Report on Form 10-Q for additional detail regarding the Harbour License Agreement.

Intellectual Property

We have a controlling interest in the worldwide intellectual property rights for CLN-619, CLN-049, and CLN-617. We hold the worldwide intellectual property rights for CLN-978, and we hold the worldwide intellectual property rights or exclusive options for worldwide intellectual property for our earlier-stage programs. We are co-developing zipalertinib, for which Taiho holds the intellectual property rights, with an affiliate of Taiho. The following table shows our ownership interest as of September 30, 2024 in product candidates in which we have a controlling interest in the worldwide intellectual property rights:

Product Candidate	Ownership Interest as of September 30, 2024
CLN-619	99%
CLN-049	97%
CLN-617	94%

Financing and Business Operations

Since our inception in 2016, we have focused all of our efforts and financial resources on raising capital, organizing and staffing our company, identifying, acquiring or in-licensing and developing product and technology rights, establishing and protecting our intellectual property portfolio and developing and advancing our programs. We do not have any products approved for sale and have not generated any revenue from product sales.

We have funded our operations primarily through the sale of equity securities and from licensing or selling the rights to our product candidates. As of September 30, 2024, we have received net proceeds of \$842.2 million from equity financings. We have received \$18.9 million in revenue from a previous license agreement and cash proceeds of \$275.0 million from the sale of our equity interest in our zipalertinib development subsidiary to Taiho. In April 2024, we sold shares of our common stock and pre-funded warrants for shares of our common stock in a private placement (the "2024 Private Placement") for net proceeds of \$262.7 million, after deducting offering expenses of \$17.3 million. Refer to Note 6 of our notes to the consolidated financial statements in this Quarterly Report on Form 10-Q for additional detail regarding the 2024 Private Placement.

As of September 30, 2024, we had cash, cash equivalents, and short-term investments of \$578.1 million, and long-term investments and interest receivable of \$60.9 million. Interest receivable is included in prepaid expenses and other current assets on the consolidated balance sheets and represents accrued and unpaid interest on our marketable securities. We have a history of significant operating losses and have had negative cash flows from operations since our inception. As of September 30, 2024, we had an accumulated deficit of \$320.6 million. We expect to continue to generate operating losses for the foreseeable future. Our future viability is dependent on the success of our research and development and our ability to access additional capital to fund our operations. There can be no assurance that our current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the ability to obtain additional capital to fund operations. Our current and future product candidates will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require additional capital, adequate personnel and extensive compliance-reporting capabilities. There can be no assurance that our research and development will be successfully completed, that adequate protection for our intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable.

Components of Our Results of Operations

Revenue

We have not generated any revenue from the sale of products since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of our product candidates and programs. These expenses include:

- compensation costs for employees engaged in research and development functions;
- expenses incurred under agreements with organizations that support our drug discovery and development activities;
- expenses incurred in connection with the preclinical and clinical development of our product candidates and programs, including under agreements with contract research organizations ("CROs");
- costs related to contract manufacturing organizations that are primarily engaged to provide drug substance, raw materials, and drug product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, nonclinical studies and other scientific development services;
- the costs of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches;
- costs related to compliance with quality and regulatory requirements;
- payments made under third-party licensing agreements; and
- direct and allocated costs related to facilities, information technology, personnel and other overhead.

Development costs and any future potential pre-tax profits from U.S. sales of zipalertinib are shared equally between us and Taiho.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation costs for personnel in executive management, finance, legal, corporate and business development, and other administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax, and administrative consulting services; insurance costs; administrative travel expenses; marketing expenses; and other operating costs.

Impairment of Long-Lived Assets

Impairment of long-lived assets represents the impairment charge for the carrying value in excess of the fair value of the assets. Refer to Note 10 of our notes to the consolidated financial statements in this Quarterly Report on Form 10-Q for additional details relating to the impairment.

Other Income

Other income consists primarily of interest income earned on our cash, cash equivalents, and investments.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2024 and 2023

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 35,506	\$ 33,821	\$ 102,411	\$ 113,308
General and administrative	13,349	10,982	39,460	31,856
Total operating expenses	48,855	44,803	141,871	145,164
Impairment of long-lived assets	—	(440)	—	(440)
Loss from operations	(48,855)	(45,243)	(141,871)	(145,604)
Other income (expense):				
Interest income	8,384	5,880	22,148	15,710
Other income (expense), net	(89)	180	(205)	356
Net loss	(40,560)	(39,183)	(119,928)	(129,538)
Net loss attributable to noncontrolling interests	—	—	(192)	(179)
Net loss attributable to common stockholders of Cullinan	<u>\$ (40,560)</u>	<u>\$ (39,183)</u>	<u>\$ (119,736)</u>	<u>\$ (129,359)</u>

Research and Development Expenses

The following table summarizes our research and development expenses for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
CLN-978	\$ 4,888	\$ 2,231	\$ 10,849	\$ 3,874
CLN-619	7,120	7,301	21,802	17,804
Zipalertinib	7,596	6,593	23,110	20,005
CLN-049	2,943	2,045	7,857	6,838
CLN-617	2,142	2,146	5,186	6,191
CLN-418	927	5,535	6,036	33,505
Clinical-stage product candidates	25,616	25,851	74,840	88,217
Early-stage research	1,266	1,288	4,035	3,839
Unallocated personnel and other	4,697	3,478	12,620	11,745
Equity-based compensation	3,927	3,204	10,916	9,507
Total research and development expenses	<u>\$ 35,506</u>	<u>\$ 33,821</u>	<u>\$ 102,411</u>	<u>\$ 113,308</u>

The \$1.7 million increase in research and development expenses in the three months ended September 30, 2024 compared to the same period in 2023 was primarily due to increases in personnel costs relating to additional headcount (\$1.8 million), other research and development costs (\$1.4 million), clinical costs (\$1.3 million), preclinical costs (\$1.3 million), and equity-based compensation costs (\$0.7 million), partially offset by a decrease in chemistry, manufacturing and controls ("CMC") costs (\$4.3 million).

The \$10.9 million decrease in research and development expenses in the nine months ended September 30, 2024 compared to the same period in 2023 was primarily due to the one-time upfront in-licensing fee for CLN-418 in 2023 (\$25.0 million) and lower CMC costs (\$3.9 million), partially offset by increases in clinical costs (\$8.7 million), personnel costs relating to additional headcount (\$4.1 million), preclinical costs (\$3.5 million), and equity-based compensation costs (\$1.4 million).

General and Administrative Expenses

The \$2.4 million increase in general and administrative expenses in the three months ended September 30, 2024 compared to the same period in 2023 was primarily due to increases in other professional fees (\$1.3 million) and equity-based compensation costs (\$1.0 million).

The \$7.6 million increase in general and administrative expenses in the nine months ended September 30, 2024 compared to the same period in 2023 was primarily due to increases in both equity-based compensation costs (\$3.9 million) and personnel costs (\$3.1 million) relating to additional headcount, and increases in other professional fees (\$2.0 million), partially offset by decreases in occupancy costs (\$0.9 million) and legal fees (\$0.5 million).

Impairment of Long-Lived Assets

Impairment of long-lived assets represents the impairment charge for the carrying value in excess of the fair value of the assets. Refer to Note 10 of our notes to the consolidated financial statements in this Quarterly Report on Form 10-Q for additional details relating to the impairment.

Other Income

The \$2.2 million and \$5.9 million increases in other income for the three and nine months ended September 30, 2024, respectively, compared to the same periods in 2023 were primarily related to higher investment income.

Net Loss Attributable to Noncontrolling Interests

Net loss attributable to noncontrolling interests is determined as the difference in the noncontrolling interests in the consolidated balance sheets between the start and end of each reporting period, after taking into account any capital transactions between our development subsidiaries and third parties.

Liquidity and Capital Resources

Overview

We have a history of significant operating losses and have had negative cash flows from operations since our inception and expect to continue to generate operating losses for the foreseeable future. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. To date, we have funded our operations primarily with proceeds from the sale of equity securities and from licensing or selling the rights to our product candidates. As of September 30, 2024, we had cash, cash equivalents, and short-term investments of \$578.1 million, and long-term investments and interest receivable of \$60.9 million.

Based on our current operational plans and assumptions, we expect that our current cash, cash equivalents, investments, and interest receivable, will be sufficient to fund operations through at least twelve months from the date of issuance of our consolidated financial statements. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We cannot guarantee that we will be able to raise additional capital on reasonable terms or at all.

In May 2023, we entered into an agreement with Cowen and Company, LLC ("Cowen") to establish an at-the-market equity offering program (the "ATM"), pursuant to which we may offer and sell up to \$125.0 million of our common stock from time to time through Cowen, acting as our sales agent. We made no sales under the ATM in the nine months ended September 30, 2024. Through September 30, 2024, we have sold approximately 3.3 million shares under the ATM and received net proceeds of \$38.4 million, after deducting commissions. As of September 30, 2024, we had \$85.6 million in shares of our common stock remaining under the ATM.

In April 2024, we completed the 2024 Private Placement in which we issued approximately 14.4 million shares of our common stock and pre-funded warrants to purchase approximately 0.3 million additional shares of our common stock. We received net proceeds of \$262.7 million from the 2024 Private Placement, after deducting offering costs of \$17.3 million. Refer to Note 6 of our notes to the consolidated financial statements in this Quarterly Report on Form 10-Q for additional detail regarding the 2024 Private Placement.

Comparison of Cash Flows for the Nine Months Ended September 30, 2024 and 2023

The following table summarizes our sources and uses of cash for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	\$ (108,677)	\$ (116,144)
Net cash used in investing activities	(152,278)	(15,664)
Net cash provided by financing activities	264,606	40,503
Net increase (decrease) in cash and cash equivalents	\$ 3,651	\$ (91,305)

Cash Flow from Operating Activities

For the nine months ended September 30, 2024, our operating activities used \$108.7 million of cash, which primarily consisted of our operating expenses, excluding non-cash items, of \$113.5 million and a \$7.5 million net change in our non-tax operating assets and liabilities, partially offset by interest income, excluding accretion on marketable securities, of \$10.2 million, and a net income tax refund of \$2.3 million. The non-cash operating expenses primarily consisted of equity-based compensation expense.

For the nine months ended September 30, 2023, our operating activities used \$116.1 million of cash, which primarily consisted of our operating expenses, excluding non-cash items, of \$122.0 million and income taxes paid of \$4.7 million, partially offset by interest income, excluding accretion on marketable securities, of \$9.2 million and a \$1.1 million benefit from the net change in our non-tax operating assets and liabilities. The non-cash operating expenses primarily consisted of equity-based compensation expense.

Cash Flow from Investing Activities

For the nine months ended September 30, 2024, net cash used in investing activities was \$152.3 million, which consisted of \$553.1 million of purchases of marketable securities, partially offset by \$400.8 million of proceeds from the maturities of marketable securities.

For the nine months ended September 30, 2023, net cash used in investing activities was \$15.7 million, which primarily consisted of \$307.4 million of purchases of marketable securities, partially offset by \$291.9 million of proceeds from the maturities of marketable securities.

Cash Flow from Financing Activities

For the nine months ended September 30, 2024, net cash provided by financing activities was \$264.6 million, which consisted of \$262.7 million of net proceeds from the issuance of common stock under our 2024 Private Placement and \$6.4 million in net proceeds from the issuance of common stock under equity-based compensation plans, partially offset by \$4.4 million paid to acquire shares and options to purchase shares of our CLN-619 development subsidiary that were held by noncontrolling interests.

For the nine months ended September 30, 2023, net cash provided by financing activities was \$40.5 million, which primarily consisted of \$38.4 million of net proceeds from the issuance of common stock under our ATM, and \$1.8 million from the issuance of a convertible note by our CLN-619 development subsidiary to a noncontrolling interest.

Future Funding Requirements

We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we:

- continue our research and development of our current and future product candidates and programs;
- conduct preclinical studies and clinical trials for our current and future product candidates;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, or trials, complex results, safety issues, or other regulatory challenges;
- develop the necessary processes, controls, and manufacturing capabilities to obtain marketing approval for our current and future product candidates and to support manufacturing on a commercial scale;
- develop and implement plans to establish and operate in-house manufacturing operations and facilities, if deemed appropriate;
- seek regulatory approvals for our current and future product candidates that successfully complete clinical trials;
- hire and retain additional personnel, such as nonclinical, clinical, pharmacovigilance, quality assurance, regulatory affairs, manufacturing, distribution, legal, compliance, medical affairs, finance, general and administrative, commercial, and scientific personnel; and
- develop, maintain, expand, and protect our intellectual property portfolio.

Based on our current operational plans and assumptions, we expect that our current cash, cash equivalents, investments, and interest receivable will be sufficient to fund operations through at least twelve months from the date of issuance of our consolidated financial statements. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. As we progress with our development programs and the regulatory review process, we expect to incur significant expenses related to product manufacturing, pre-commercial activities and commercialization. We may also require additional capital to pursue in-licenses or acquisitions of other programs to further expand our pipeline.

Because of the numerous risks and uncertainties associated with research, development and commercialization of our product candidates and programs, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results, and costs of drug discovery, laboratory testing, and preclinical and clinical development for our current and future product candidates;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- the prevalence, duration, and severity of potential side effects or other safety issues experienced by patients receiving our current and future product candidates;
- our ability to establish and maintain collaborations and license agreements on favorable terms, if at all, and the extent to which we acquire or in-license technologies or programs, if at all;
- our ability to enroll clinical trials in a timely manner and to quickly resolve any delays or clinical holds that may be imposed on our development programs;

- the costs of expanding our facilities to accommodate our expected growth in personnel;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our current and future product candidates, remain in good standing with regulatory authorities and develop, validate, and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- the extent to which we acquire or in-license technologies or programs;
- the sales price and availability of adequate third-party coverage and reimbursement for our product candidates, if and when approved; and
- the ongoing costs of operating as a public company.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements, and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity, current ownership interests will be diluted. If we raise additional funds through government or third-party funding, collaboration agreements, strategic alliances, licensing arrangements, or marketing and distribution arrangements, 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. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we are unable to raise additional funds 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 products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Other Commitments

We have certain payment obligations under various license and collaboration agreements. Under these agreements, we are required to make milestone payments upon successful completion and achievement of certain intellectual property, clinical, regulatory, and sales milestones. The payment obligations under the license and collaboration agreements are contingent upon future events, such as our achievement of specified development, clinical, regulatory, and commercial milestones, and we will be required to make milestone and royalty payments in connection with the sale of products developed under these agreements. As the achievement and timing of these future milestone payments are not probable or estimable, such amounts have not been included in our consolidated balance sheets as of September 30, 2024 and December 31, 2023.

As of September 30, 2024, total future minimum lease payments were \$2.7 million with \$1.5 million payable within twelve months. See Note 10 to our consolidated financial statements included in this Quarterly Report on Form 10-Q for further detail on our lease obligations and the timing of expected future payments.

In addition, we enter into agreements in the normal course of business with CROs for clinical trials and with other vendors for preclinical studies, manufacturing services, and other services and products for operating purposes, which are generally cancelable upon written notice.

Critical Accounting Policies and Estimates

Our critical accounting policies have not materially changed from those described in the 2023 10-K.

Emerging Growth Company Status

We currently qualify as an "emerging growth company" ("EGC") under the Jumpstart Our Business Startups Act which allows us to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an EGC; however, we may adopt certain new or revised accounting standards early.

Because (i) the market value of our common stock held by non-affiliates exceeded \$700 million as of June 30, 2024, (ii) we have been a public company for more than one year, and (iii) we have filed at least one annual report, we will cease to be an EGC as of December 31, 2024. As a result, beginning with our Annual Report on Form 10-K for the year ended December 31, 2024, we will not be able to rely on the extended transition period noted above and will be required to adopt all new accounting pronouncements within the same time periods as other public companies that are not EGCs. We will also be subject to certain other requirements that apply to other public companies but did not previously apply to us due to our status as an EGC, including the provisions of Section 404 of the Sarbanes-Oxley Act, which require that our independent registered public accounting firm provides an attestation report on the effectiveness of our internal control over financial reporting.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 of our consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Information required by this Item is not applicable as we are electing scaled disclosure requirements available to smaller reporting companies with respect to this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (as amended, the "Exchange Act"), designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of September 30, 2024, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies our judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective at the reasonable assurance level as of September 30, 2024.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting, identified in connection with the evaluation carried out pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act, that occurred during the fiscal quarter ended September 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023 (the “2023 10-K”), which could materially affect our business, financial condition or future results. The risk factors disclosure in our 2023 10-K is qualified by the information that is described in this Quarterly Report on Form 10-Q. The risks described in our 2023 10-K are not our only risks. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may materially adversely affect our business, financial condition or future results. There have been no material changes to our risk factors as previously disclosed in the 2023 10-K except as follows:

We will no longer qualify as an “emerging growth company” nor a “smaller reporting company” after December 31, 2024, and, as a result, we will have to comply with increased disclosure and compliance requirements.

We are currently an “emerging growth company” (“EGC”) as defined in the Jumpstart Our Business Startups Act and a “smaller reporting company” (“SRC”) under the Securities and Exchange Commission (“SEC”) rules. However, because (i) the market value of our common stock held by non-affiliates exceeded \$700 million as of June 30, 2024, (ii) we have been a public company for more than one year, and (iii) we have filed at least one annual report, we will no longer qualify as an EGC or a SRC as of December 31, 2024 and will be a large accelerated filer beginning January 1, 2025 for future filings.

As a large accelerated filer, we will be subject to certain disclosure and compliance requirements that apply to other public companies but that did not previously apply to us due to our status as an EGC and a SRC. These requirements include, but are not limited to:

- the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002;
- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- the requirement that we provide more detailed disclosures regarding executive compensation; and
- the requirement that we hold a non-binding advisory vote on executive compensation and obtain stockholder approval of any golden parachute payments not previously approved.

We expect that the loss of EGC and SRC status and compliance with the additional requirements of being a large accelerated filer will increase our legal, accounting and financial compliance costs and costs associated with investor relations activities, and cause management and other personnel to divert attention from operational and other business matters to devote substantial time to public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities, which would require additional financial and management resources.

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

Use of Proceeds from IPO of Common Stock

On January 7, 2021, our Registration Statement on Form S-1, as amended (Registration No. 333-251512), was declared effective by the Securities and Exchange Commission (the “SEC”) for our initial public offering (“IPO”). The aggregate net proceeds to us from our IPO, after underwriting discounts and offering expenses, were \$264.5 million. As of September 30, 2024, we estimate that we have used all of the net proceeds from the IPO to fund the preclinical and clinical development of our product candidates, the hiring of additional personnel, the costs of operating as a public company, and other general corporate purposes.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Description
3.1	<u>Second Amended and Restated Certificate of Incorporation of the Registrant, as amended by the Certificate of Amendment, effective as of April 15, 2024 (incorporated by reference to Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2024).</u>
3.2	<u>Third Amended and Restated Bylaws of the Registrant, effective as of April 15, 2024 (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed with the SEC on April 16, 2024).</u>
3.3	<u>Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on January 19, 2023).</u>
31.1*	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2*	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1**	<u>Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents.
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).

* Filed herewith.

**Furnished herewith

SIGNATURES

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

Cullinan Therapeutics, Inc.

Date: November 7, 2024

By: /s/ Nadim Ahmed

Name: Nadim Ahmed

Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2024

By: /s/ Mary Kay Fenton

Name: Mary Kay Fenton

Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Nadim Ahmed, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Cullinan Therapeutics, Inc. (the “registrant”);
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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 7, 2024

By: /s/ Nadim Ahmed

Nadim Ahmed
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mary Kay Fenton, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Cullinan Therapeutics, Inc. (the “registrant”);
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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 7, 2024

By: /s/ Mary Kay Fenton
Mary Kay Fenton
Chief Financial Officer
(Principal Financial and Accounting Officer)

**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 Cullinan Therapeutics, Inc. (the “Company”) on Form 10-Q for the period ending September 30, 2024 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:

- (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 7, 2024

By: /s/ Nadim Ahmed
Nadim Ahmed
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2024

By: /s/ Mary Kay Fenton
Mary Kay Fenton
Chief Financial Officer
(Principal Financial and Accounting Officer)
