

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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: 001-38443

Cogent Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

275 Wyman Street, 3rd Floor
Waltham, Massachusetts

(Address of principal executive offices)

46-5308248

(I.R.S. Employer
Identification Number)

02451

(Zip code)

(617) 945-5576

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 Par Value	COGT	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 checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input 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

As of November 8, 2024, there were 110,461,729 shares of the registrant's Common Stock, \$0.001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position,

business strategy and plans, and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “should,” “expects,” “might,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential,” “seek,” “would” or “continue,” or the negative of these terms or other similar expressions. The forward looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in Item 1A. “Risk Factors.” Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Some of the key factors that could cause actual results to differ from our expectations include:

- the potential impacts of raising additional capital, including dilution to our existing stockholders, restrictions on our operations or requirements that we relinquish rights to our technologies or product candidates;
- the success, cost, and duration of our product development activities and clinical trials, including the enrollment rates in our clinical trials;
- the timing of our planned regulatory submissions to the FDA for our bezuclastinib product candidate and any other product candidates we may develop;
- our ability to obtain and maintain regulatory approval for our bezuclastinib product candidate and any other product candidates we may develop, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the potential for our identified research priorities to advance our bezuclastinib product candidate or for our teams to discover and develop additional product candidates;
- the ability to license additional intellectual property rights relating to our bezuclastinib product candidate or future product candidates from third-parties and to comply with our existing or future license agreements and/or collaboration agreements;
- our ability to commercialize our bezuclastinib product candidate and future product candidates in light of the intellectual property rights of others;
- our ability to obtain funding for our operations, including funding necessary to complete further discovery, development and commercialization of our existing and future product candidates;
- the scalability and commercial viability of our manufacturing methods and processes;
- the commercialization of our product candidates, if approved;
- our ability to attract collaborators with development, regulatory, and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- the pricing and reimbursement of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;

- the impact of adverse business and economic conditions including inflationary pressures, general economic slowdown or a recession, high interest rates, changes in monetary policy, banking institution instability and the prospect of a shutdown of the U.S. federal government;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the development and success of competing therapies that are or may be under development in clinical trials or become available commercially;
- our ability to attract and retain key scientific and management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our use of the proceeds from the private placements, sales of our preferred stock and public offerings of our common stock from time to time; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our bezuclastinib product candidate and future product candidates.

While we may elect to update these forward-looking statements at some point in the future, whether as a result of any new information, future events, or otherwise, we have no current intention of doing so except to the extent required by applicable law.

Cogent Biosciences, Inc.
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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

COGENT BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)
(unaudited)

	September 30,	December 31,
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 97,045	\$ 53,229
Short-term marketable securities	238,474	212,481
Prepaid expenses and other current assets	6,009	5,061
Total current assets	341,528	270,771
Long-term marketable securities	10,029	7,460
Operating lease, right-of-use assets	20,580	21,998
Property and equipment, net	7,017	8,344
Other assets	4,862	4,864
Total assets	\$ 384,016	\$ 313,437
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 15,061	\$ 10,655
Accrued expenses and other current liabilities	36,467	26,127
Operating lease liabilities	1,520	1,386
Total current liabilities	53,048	38,168
Operating lease liabilities, net of current portion	16,309	17,467
Total liabilities	69,357	55,635
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 8,979,420 shares authorized; no shares issued or outstanding	—	—
Series A non-voting convertible preferred stock, \$0.001 par value; 1,000,000 shares authorized; 70,465 and 74,465 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	56,515	60,035
Series B non-voting convertible preferred stock, \$0.001 par value; 20,580 shares authorized; 6,868 and no shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	54,085	—
Common stock, \$0.001 par value; 300,000,000 shares authorized; 110,458,249 and 86,124,249 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	110	86
Additional paid-in capital	994,609	801,059
Accumulated other comprehensive income	896	246
Accumulated deficit	(791,556)	(603,624)
Total stockholders' equity	314,659	257,802
Total liabilities and stockholders' equity	\$ 384,016	\$ 313,437

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

COGENT BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 63,614	\$ 50,127	\$ 170,613	\$ 125,036
General and administrative	11,800	9,453	31,592	24,866
Total operating expenses	75,414	59,580	202,205	149,902
Loss from operations	(75,414)	(59,580)	(202,205)	(149,902)
Other income:				
Interest income	4,779	4,198	14,229	9,207
Other income, net	1	—	44	950
Change in fair value of CVR liability	—	—	—	1,700
Total other income, net	4,780	4,198	14,273	11,857
Net loss	\$ (70,634)	\$ (55,382)	\$ (187,932)	\$ (138,045)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.64)	\$ (0.64)	\$ (1.85)	\$ (1.79)
Weighted average common shares outstanding, basic and diluted	110,165,580	86,165,951	101,435,402	77,274,580
Comprehensive loss:				
Net loss	\$ (70,634)	\$ (55,382)	\$ (187,932)	\$ (138,045)
Other comprehensive income (loss):				
Net unrealized gains (losses) on marketable securities	1,088	(75)	650	(68)
Total other comprehensive income (loss)	1,088	(75)	650	(68)
Comprehensive loss	\$ (69,546)	\$ (55,457)	\$ (187,282)	\$ (138,113)

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

COGENT BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)
(unaudited)

	Series A Non-Voting Convertible Preferred Stock		Series B Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2023	74,465	\$ 60,035	—	\$ —	86,124,249	\$ 86	\$ 801,059	\$ 246	\$ (603,624)	\$ 257,802
Issuance of Series B non-voting convertible preferred stock and common stock, net of issuance costs of \$11.6 million, in connection with the Private Placement	—	—	12,280	87,364	17,717,997	18	126,034	—	—	213,416
Exchange of common stock for Series B non-voting convertible preferred stock	—	—	8,300	74,754	(8,300,000)	(8)	(74,746)	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	71,150	—	356	—	—	356
Unrealized losses on marketable securities	—	—	—	—	—	—	—	(285)	—	(285)
Stock-based compensation expense	—	—	—	—	—	—	9,393	—	—	9,393
Net loss	—	—	—	—	—	—	—	—	(58,348)	(58,348)
Balances at March 31, 2024	74,465	60,035	20,580	162,118	95,613,396	96	862,096	(39)	(661,972)	422,334
Conversion of Series B non-voting convertible preferred stock into common stock	—	—	(13,712)	(107,980)	13,712,000	13	107,967	—	—	—
Change in estimate on Private Placement issuance costs	—	—	—	(53)	—	—	(76)	—	—	(129)
Issuance of common stock from exercises	—	—	—	—	17,828	—	109	—	—	109
Unrealized losses on marketable securities	—	—	—	—	—	—	—	(153)	—	(153)
Stock-based compensation expense	—	—	—	—	—	—	10,012	—	—	10,012
Net loss	—	—	—	—	—	—	—	—	(58,950)	(58,950)
Balances at June 30, 2024	74,465	60,035	6,868	54,085	109,343,224	109	980,108	(192)	(720,922)	373,223
Conversion of Series A non-voting preferred stock into common stock	(4,000)	(3,520)	—	—	1,000,000	1	3,519	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	105,743	—	561	—	—	561
Issuance of common stock from exercises	—	—	—	—	9,282	—	63	—	—	63
Unrealized gains on marketable securities	—	—	—	—	—	—	—	1,088	—	1,088
Stock-based compensation expense	—	—	—	—	—	—	10,358	—	—	10,358
Net loss	—	—	—	—	—	—	—	—	(70,634)	(70,634)
Balances at September 30, 2024	70,465	\$ 56,515	6,868	\$ 54,085	110,458,249	\$ 110	\$ 994,609	\$ 896	\$ (791,556)	\$ 314,659

	Series A Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2022	81,050	\$ 65,830	69,893,434	\$ 70	\$ 601,153	\$ (104)	\$ (411,214)	\$ 255,735
Conversion of Series A non-voting preferred stock into common stock	(4,000)	(3,520)	1,000,000	1	3,519	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	39,228	—	313	—	—	313
Issuance of common stock upon exercise of stock options	—	—	14,128	—	132	—	—	132
Unrealized gains on marketable securities	—	—	—	—	—	120	—	120
Stock-based compensation expense	—	—	—	—	5,850	—	—	5,850
Net loss	—	—	—	—	—	—	(38,587)	(38,587)
Balances at March 31, 2023	<u>77,050</u>	<u>62,310</u>	<u>70,946,790</u>	<u>71</u>	<u>610,967</u>	<u>16</u>	<u>(449,801)</u>	<u>223,563</u>
Issuance of common stock in underwritten public offering, net of offering costs of 10.7 million	—	—	14,375,000	14	161,775	—	—	161,789
Issuance of common stock upon exercise of stock options	—	—	12,375	—	102	—	—	102
Unrealized losses on marketable securities	—	—	—	—	—	(113)	—	(113)
Stock-based compensation expense	—	—	—	—	7,163	—	—	7,163
Net loss	—	—	—	—	—	—	(44,076)	(44,076)
Balances at June 30, 2023	<u>77,050</u>	<u>62,310</u>	<u>85,334,165</u>	<u>85</u>	<u>780,007</u>	<u>(97)</u>	<u>(493,877)</u>	<u>348,428</u>
Conversion of Series A non-voting preferred stock into common stock	(2,585)	(2,275)	646,250	1	2,274	—	—	—
Issuance of common stock upon exercise of stock options	—	—	97,184	—	731	—	—	731
Issuance of common stock under Employee Stock Purchase Plan	—	—	46,650	—	439	—	—	439
Unrealized losses on marketable securities	—	—	—	—	—	(75)	—	(75)
Stock-based compensation expense	—	—	—	—	8,757	—	—	8,757
Net loss	—	—	—	—	—	—	(55,382)	(55,382)
Balances at September 30, 2023	<u>74,465</u>	<u>\$ 60,035</u>	<u>86,124,249</u>	<u>\$ 86</u>	<u>\$ 792,208</u>	<u>\$ (172)</u>	<u>\$ (549,259)</u>	<u>\$ 302,898</u>

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

COGENT BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (187,932)	\$ (138,045)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,825	1,672
Stock-based compensation expense	29,763	21,770
Amortization of operating leases, right-of-use assets	1,418	1,122
Change in fair value of CVR liability	—	(1,700)
Net amortization (accretion) of premiums (discounts) on marketable securities	(5,015)	(871)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(948)	(2,477)
Other assets	(2)	(117)
Accounts payable	4,406	4,026
Accrued expenses and other current liabilities	10,295	5,542
Operating lease liability	(1,024)	(476)
Net cash used in operating activities	<u>(147,214)</u>	<u>(109,554)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(498)	(2,481)
Purchases of marketable securities	(242,879)	(297,888)
Maturities and sales of marketable securities	219,982	192,056
Net cash used in investing activities	<u>(23,395)</u>	<u>(108,313)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock and Series B Preferred Stock in connection with the Private Placement, net of offering costs \$11.6 million	213,336	—
Proceeds from issuance of shares of common stock, net of offering costs of \$10.7 million	—	161,819
Proceeds from issuance of stock from employee stock purchase plan	917	752
Proceeds from issuance of common stock upon stock option exercises	172	965
Net cash provided by financing activities	<u>214,425</u>	<u>163,536</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	43,816	(54,331)
Cash, cash equivalents and restricted cash at beginning of period	53,229	141,141
Cash, cash equivalents and restricted cash at end of period	<u>\$ 97,045</u>	<u>\$ 86,810</u>
Supplemental disclosure of noncash investing and financing information:		
Offering costs included in accounts payable and accrued expenses	\$ 45	\$ 30
Property & equipment included in accounts payable and accrued expenses	\$ —	\$ 51
Conversion of Series A Preferred Stock into common shares	\$ 3,520	\$ 5,795
Conversion of Series B Preferred Stock into common shares	\$ 107,980	\$ —

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

COGENT BIOSCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Nature of the Business and Basis of Presentation

Cogent Biosciences, Inc. (“Cogent” or the “Company”) is a clinical-stage biotechnology company focused on developing precision therapies for genetically defined diseases. Cogent’s approach is to design rational precision therapies that treat the underlying cause of disease and improve the lives of patients. Cogent’s most advanced program is bezuclastinib, also known as CGT9486, a highly selective tyrosine kinase inhibitor that is designed to potently inhibit the KIT D816V mutation as well as other mutations in KIT exon 17. In the vast majority of cases, KIT D816V is responsible for driving Systemic Mastocytosis (“SM”), a serious and rare disease caused by unchecked proliferation of mast cells. Exon 17 mutations are also found in patients with advanced gastrointestinal stromal tumors (“GIST”), a type of cancer with strong dependence on oncogenic KIT signaling. Bezuclastinib is a highly selective and potent KIT inhibitor with the potential to provide a new treatment option for these patient populations. In addition to bezuclastinib, the Company’s research team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases initially targeting mutations in FGFR2, ErbB2, PI3K α and KRAS.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s drug development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses since inception, including a net loss of \$187.9 million for the nine months ended September 30, 2024. As of September 30, 2024, the Company had an accumulated deficit of \$791.6 million. The Company expects to continue to generate operating losses in the foreseeable future. As of the issuance date of the interim condensed consolidated financial statements, the Company expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from issuance of the condensed consolidated financial statements.

The Company expects that it will continue to incur significant expenses in connection with its ongoing business activities. The Company will need to seek additional funding through equity offerings, debt financings, collaborations, licensing arrangements or other marketing and distribution arrangements, partnerships, joint ventures, combinations or divestitures of one or more of its assets or businesses. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborative arrangements or divest its assets. The terms of any financing may adversely affect the holdings or the rights of the Company’s stockholders. Arrangements with collaborators or others may require the Company to relinquish rights to certain of its technologies or product candidates. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate its research and development programs or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations.

The Company’s condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”).

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The consolidated balance sheet at December 31, 2023 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying condensed unaudited consolidated financial statements as of September 30, 2024 and for the three and nine months ended September 30, 2024 and 2023 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) for interim financial statements. Certain information and footnote disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and the notes thereto for the year ended December 31, 2023 included in the Company’s Annual Report on Form 10-K on file with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company’s financial position as of September 30, 2024 and results of operations for the three and nine months ended September 30, 2024 and 2023 and cash flows for the nine months ended September 30, 2024 and 2023 have been made. The Company’s results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2024.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Mono, Inc. and Kiq Bio LLC. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of stock-based awards. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.

Marketable Securities

The Company’s marketable securities, consisting of debt securities, are classified as available-for-sale. Available-for-sale marketable debt securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders’ equity until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included in other income (expense). The Company reviews its portfolio of available-for-sale debt securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost have resulted from a credit-related loss or other factors. If the decline in fair value is due to credit-related factors, a loss is recognized in net income, and if the decline in fair value is not due to credit-related factors, the loss is recorded in other comprehensive income (loss).

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07 Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures related to reportable segment disclosure requirements. The pronouncement improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses, and requires disclosure of incremental segment information on an annual and interim basis. The pronouncement is effective for annual periods beginning after December 15, 2023. The Company is evaluating the impact of the ASU on its financial statements.

In December 2023, the FASB issued ASU 2023-09 Income Taxes (Topic 740): Improvements to Income Tax Disclosures related to income tax disclosure requirements. The pronouncement enhances the transparency and decision usefulness of income tax disclosures. The pronouncement is effective for annual periods beginning after December 15, 2024. The Company is evaluating the impact of the ASU on its financial statements.

3. Marketable Securities and Fair Value of Financial Assets and Liabilities

The following table summarizes the Company's marketable securities (*in thousands*):

	September 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury bills and notes (due within one year)	\$ 237,658	\$ 816	\$ —	\$ 238,474
U.S. Treasury bills and notes (due after one through five year)	9,949	80	—	10,029
	<u>\$ 247,607</u>	<u>\$ 896</u>	<u>\$ —</u>	<u>\$ 248,503</u>

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury bills and notes (due within one year)	\$ 212,274	\$ 213	\$ (6)	\$ 212,481
U.S. Treasury bills and notes (due after one through five year)	7,421	39	—	7,460
	<u>\$ 219,695</u>	<u>\$ 252</u>	<u>\$ (6)</u>	<u>\$ 219,941</u>

As of September 30, 2024, the Company held no securities that were in an unrealized loss position. As of December 31, 2023, the Company held 9 securities that were in an unrealized loss position. The aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months as of December 31, 2023 was \$34.7 million and there were no securities held by the Company in an unrealized loss position for more than twelve months. The Company has the intent and ability to hold such securities until recovery. As a result, the Company did not record any charges for impairments for its marketable debt securities for the three and nine months ended September 30, 2024 and for the year ended December 31, 2023.

The following tables present the Company's fair value hierarchy for its financial assets and liabilities, which are measured at fair value on a recurring basis (*in thousands*):

	Fair Value Measurements at September 30, 2024 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 89,567	\$ —	\$ —	\$ 89,567
Marketable securities:				
U.S. Treasury bills and notes	\$ —	\$ 248,503	\$ —	\$ 248,503
Total assets	<u>\$ 89,567</u>	<u>\$ 248,503</u>	<u>\$ —</u>	<u>\$ 338,070</u>

	Fair Value Measurements at December 31, 2023 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 46,184	\$ —	\$ —	\$ 46,184
Marketable securities:				
U.S. Treasury bills and notes	\$ —	\$ 219,941	\$ —	\$ 219,941
Total assets	<u>\$ 46,184</u>	<u>\$ 219,941</u>	<u>\$ —</u>	<u>\$ 266,125</u>

Money market funds were valued using quoted prices in active markets, which represent a Level 1 measurement in the fair value hierarchy. U.S. Treasury bills and notes were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy.

During the three and nine months ended September 30, 2024 and 2023, there were no transfers between Level 1, Level 2 and Level 3.

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (*in thousands*):

	September 30, 2024	December 31, 2023
Accrued employee compensation and benefits	\$ 7,727	\$ 9,874
Accrued external research and development expense	20,466	10,252
Accrued external manufacturing costs	4,312	3,302
Accrued professional and consulting services	3,656	2,258
Other	306	441
Total	<u>\$ 36,467</u>	<u>\$ 26,127</u>

5. Preferred Stock, Series A and Series B Non-Voting Convertible Preferred Stock and Common Stock

The Company's authorized capital stock consists of 300,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share, 1,000,000 of which are designated as Series A Preferred Stock, 20,580 of which are designated as Series B Preferred Stock and 8,979,420 of which shares of preferred stock are undesignated.

Series A Non-Voting Convertible Preferred Stock

On July 6, 2020, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock") with the Secretary of State of the State of Delaware (the "Series A Certificate of Designation") in connection with the Company's acquisition of Kiq Bio LLC and concurrent private placement of Series A Preferred Stock. The Series A Certificate of Designation provides for the issuance of shares of Series A Preferred Stock, par value \$0.001 per share.

Holders of Series A Preferred Stock are entitled to receive dividends on shares of Series A Preferred Stock equal, on an as-if-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of the common stock. Except as otherwise required by law, the Series A Preferred Stock does not have voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock, (b) alter or amend the Series A Certificate of Designation, (c) amend its certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (d) increase the number of authorized shares of Series A Preferred Stock, (e) at any time while at least 40% of the originally issued Series A Preferred Stock remains issued and outstanding, consummate a Fundamental Transaction (as defined in the Series A Certificate of Designation) or (f) enter into any agreement with respect to any of the foregoing. The Series A Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company.

Each share of Series A Preferred Stock is convertible at any time at the option of the holder thereof, into 250 shares of common stock, subject to certain limitations, including that a holder of Series A Preferred Stock is prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (to be established by the holder between 4.9% and 19.9%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion.

Series B Non-Voting Convertible Preferred Stock

On February 13, 2024, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) for a private placement (the “Private Placement”) with certain institutional and accredited investors (each, a “Purchaser” and collectively, the “Purchasers”), pursuant to which the Purchasers purchased (i) an aggregate of 17,717,997 shares of the Company’s common stock at a price per share of \$7.50, and (ii) 12,280 shares of the Company’s Series B Preferred Stock, at a price per share of \$7,500.00. Net proceeds were approximately \$213.4 million after deducting placement fees and offering costs. On February 14, 2024, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of the Series B Non-Voting Convertible Preferred Stock (“Series B Preferred Stock”) with the Secretary of State of the State of Delaware (the “Series B Certificate of Designation”) in connection with the Private Placement. The Series B Certificate of Designation provided for the issuance of up to 12,280 shares of Series B Preferred Stock, par value \$0.001 per share. Subsequently, on March 21, 2024, the Company entered into exchange agreements (the “Exchange Agreements”) with certain of the Purchasers (the “Exchange Stockholders”), pursuant to which the Exchange Stockholders agreed to exchange an aggregate of 8,300,000 shares of the Company’s common stock, for an aggregate of 8,300 shares of the Company’s Series B Preferred Stock (the “Exchange”). On March 21, 2024, in connection with the Exchange, the Company filed a Certificate of Amendment to the Series B Certificate of Designation (the “Certificate of Amendment”) to increase the number of authorized shares of Series B Preferred Stock from 12,280 to 20,580.

Holders of shares of Series B Preferred Stock are entitled to receive dividends on shares of Series B Preferred Stock equal to, on an as-if-converted-to-common stock basis, and in the same form as dividends actually paid on shares of the common stock. Except as otherwise required by law, the Series B Preferred Stock does not have voting rights. However, as long as any shares of Series B Preferred Stock are outstanding, the Company will not, without the affirmative vote of each of the holders of the then outstanding shares of the Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock, (b) alter or amend the Series B Certificate of Designation, or (c) amend its certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series B Preferred Stock. The Series B Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company.

On June 10, 2024, following approval by the stockholders of the Company of an increase in the number of authorized shares of common stock at the Company's 2024 annual meeting of stockholders, each share of Series B Preferred Stock automatically converted into 1,000 shares of common stock, subject to certain limitations, including that a holder of Series B Preferred Stock was prohibited from converting shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would have beneficially owned more than a specified percentage (established by the holder between 0% and 19.9%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion. Pursuant to the terms of the Series B Certificate of Designation, on June 10, 2024, 13,712 shares of Series B Preferred Stock automatically converted to 13,712,000 shares of common stock.

Cumulatively, through September 30, 2024, 92,860 shares of Series A Preferred Stock, or 56.9% of the previously issued Series A Preferred Stock, have been converted into 23,215,000 shares of common stock. The 70,465 shares of Series A Preferred Stock outstanding as of September 30, 2024 are convertible into 17,616,250 shares of common stock. Cumulatively, through September 30, 2024, 13,712 shares of the Series B Preferred Stock, or 66.6% of the previously issued Series B Preferred Stock, have been converted into 13,712,000 shares of common stock. The 6,868 shares of Series B Preferred Stock outstanding as of September 30, 2024 are convertible into 6,868,000 shares of common stock.

No other classes of preferred stock have been designated and no other preferred shares have been issued or are outstanding as of September 30, 2024.

Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company’s stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors. In the event of the Company’s liquidation, dissolution or winding up, holders of the Company’s common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

On May 6, 2022, the Company filed a shelf registration statement on Form S-3 with the SEC. The shelf registration statement allows the Company to sell from time-to-time up to \$300.0 million of common stock, preferred stock, debt securities, warrants or units comprised of any combination of these securities, for its own account in one or more offerings. The terms of any offering under the shelf registration statement will be established at the time of such offering and will be described in a prospectus supplement filed with the SEC prior to the completion of any such offering.

Additionally, on May 6, 2022, pursuant to the Form S-3, the Company entered into a Sales Agreement (the “Sales Agreement”) with Guggenheim Securities, LLC (“Guggenheim Securities”), pursuant to which the Company may issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to \$75.0 million through Guggenheim Securities, as the sales agent. As of September 30, 2024, no shares have been sold under the Sales Agreement.

On June 13, 2022, the Company completed an underwritten public offering of 17,899,698 shares of its common stock at a public offering price of \$8.25 per share (including the exercise in full by the underwriters of their 30-day option to purchase up to 2,730,000 additional shares of common stock) and, in lieu of common stock to certain investors, pre-funded warrants to purchase 3,030,302 shares of its common stock at a purchase price of \$8.24 per underlying share. The net proceeds from the offering were approximately \$161.9 million, after deducting the underwriting discounts and commissions of \$10.4 million and offering expenses of \$0.4 million.

Each pre-funded warrant entitles the holder to purchase shares of common stock at an exercise price of \$0.01 per share and is exercisable at any time beginning on the date of issuance. These warrants were recorded as a component of stockholders’ equity within additional paid-in capital. Per the terms of the warrant agreement, a holder of the outstanding warrant is not entitled to exercise any portion of the pre-funded warrant if, upon giving effect to such exercise, would cause the aggregate number of shares of common stock beneficially owned by such holder (together with its affiliates and any other person whose beneficial ownership of common stock would be aggregated with the holder) to exceed 9.99% of the total number of then issued and outstanding shares of common stock, as such percentage ownership is determined in accordance with the terms of the pre-funded warrant and subject to such holder’s rights under the pre-funded warrant to increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days’ prior notice from such holder. As of September 30, 2024, 2,424,242 pre-funded warrants have been exercised and 606,060 pre-funded warrants remain outstanding.

On February 10, 2023, the Company filed a Form S-3ASR with the SEC (“2023 Shelf Registration”) for the issuance of common stock, preferred stock, warrants, rights, debt securities and units, which became effective immediately upon filing. At the time any of the securities covered by the 2023 Shelf Registration are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

In June 2023, the Company completed an underwritten public offering of 14,375,000 shares of its common stock at a public offering price of \$12.00 per share (including the exercise in full by the underwriters of their 30-day option to purchase up to 1,875,000 additional shares of common stock). The net proceeds from the offering were approximately \$161.8 million, after deducting the underwriting discounts and commissions of \$10.3 million and offering expenses of \$0.4 million.

In February 2024, in connection with the Private Placement, the Company issued (i) an aggregate of 17,717,997 shares of the Company’s common stock at a price per share of \$7.50, and (ii) 12,280 shares of the Company’s Series B Preferred Stock, at a price per share of \$7,500.00. Net proceeds were approximately \$213.4 million after deducting placement fees and offering costs. In March 2024, in connection with the Exchange, the Exchange Stockholders exchanged an aggregate of 8,300,000 shares of the Company’s common stock, for an aggregate of 8,300 shares of the Company’s Series B Preferred Stock.

At our 2024 annual meeting of stockholders on June 5, 2024, the Company’s stockholders approved an amendment to the Company’s Third Amended and Restated Certificate of Incorporation (the “Certificate of Incorporation”) (the “Amendment”), to increase the number of authorized shares of common stock from 150,000,000 to 300,000,000 and the Company filed a Certificate of Amendment to the Certificate of Incorporation with the Secretary of State of the State of Delaware to effect the Amendment, which became effective immediately upon such filing. Pursuant to the terms of the Series B Certificate of Designation, on June 10, 2024, 13,712 shares of Series B Preferred Stock automatically converted to 13,712,000 shares of common stock, and 6,868 shares of Series B Preferred Stock remain outstanding as of September 30, 2024.

6. Stock-Based Compensation

2018 Stock Option and Incentive Plan

The Company’s 2018 Stock Option and Incentive Plan, (the “2018 Plan”), which became effective on March 27, 2018, provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights. The number of shares initially reserved for issuance under the 2018 Plan was 700,180. Additionally, the shares of common stock that remained available for issuance under the previously outstanding 2015 Stock Incentive Plan (the “2015 Plan”) became available under the 2018 Plan. The number of shares reserved for the 2018 Plan automatically increases on each January 1 by 4% of the number of shares of the Company’s common stock outstanding on the immediately preceding December 31 or a lesser number of shares determined by the Company’s board of directors. At the Company’s 2021 annual stockholder meeting, the Company’s stockholders approved the amendment and restatement of the 2018 Stock Plan to increase the number of shares of common stock issuable under the 2018 Plan by 6,000,000 shares. At the Company’s 2023 annual stockholder meeting, the Company’s stockholders approved the amendment and restatement of the 2018 Plan to increase the number of shares of common stock issuable under the 2018 Plan by an additional 6,000,000 shares.

The shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by the Company under the 2018 Plan or the 2015 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan. The number of authorized shares reserved for issuance under the 2018 Plan was increased by 3,444,970 shares effective as of January 1, 2024. As of September 30, 2024, 2,432,053 shares of common stock remain available for issuance under the 2018 Plan.

Inducement Awards

On October 22, 2020, the board of directors adopted the Cogent Biosciences, Inc. 2020 Inducement Plan (the “Inducement Plan”). The board of directors also adopted a form of non-qualified stock option agreement for use with the Inducement Plan. A total of 3,750,000 shares of common stock have been reserved for issuance under the Inducement Plan, subject to adjustment for stock dividends, stock splits, or other changes in Cogent’s common stock or capital structure. On November 5, 2020, the Company filed a Registration Statement on Form S-8 related to the 3,750,000 shares of its common stock reserved for issuance under the Inducement Plan. As of September 30, 2024, 577,995 shares of common stock remain available for issuance under the Inducement Plan.

In connection with the appointment of the Chief Commercial Officer on May 25, 2024, the Company granted additional “inducement” equity awards in accordance with Listing Rule 5635(c)(4) of the corporate governance rules of the Nasdaq Stock Market, separate from the awards available for grant under the Inducement Plan. The awards consist of (i) nonqualified options to purchase 525,000 shares of Cogent common stock with a 10-year term, an exercise price equal to the closing price of Cogent’s common stock on the first day of his employment, and a 4-year vesting schedule with 25% vesting on the 1-year anniversary of the grant date and the remainder vesting in equal monthly installments over the subsequent 36 months, and (ii) up to 214,000 performance-based restricted stock units (“PSUs”) with terms consistent with the PSUs granted in June 2023 and outlined below. In August 2024, the Company filed a registration statement on Form S-8 related to the up to 739,000 shares of its common stock reserved for issuance under these inducement awards to the Chief Commercial Officer.

2018 Employee Stock Purchase Plan

The Company’s 2018 Employee Stock Purchase Plan (the “ESPP”) became effective on March 28, 2018, at which time a total of 78,500 shares of common stock were reserved for issuance. In addition, the number of shares of common stock that may be issued under the ESPP automatically increases on each January 1 through January 1, 2027, by the least of (i) 125,000 shares of common stock, (ii) 1% of the number of shares of the Company’s common stock outstanding on the immediately preceding December 31 or (iii) such lesser number of shares as determined by the ESPP administrator. The number of authorized shares reserved for issuance under the ESPP was increased by 125,000 shares effective as of January 1, 2024. As of September 30, 2024, 391,497 shares remain available for issuance under the ESPP.

Performance-based restricted stock units

In February 2023, the board of directors approved grants in aggregate of up to 2,500,000 PSUs under the 2018 Plan, which grants were subject to forfeiture in the event that the Company’s stockholders did not approve an increase to the number of shares reserved for issuance under the 2018 Plan (the “2023 Pool Increase”). On June 7, 2023, stockholders approved the 2023 Pool Increase and a grant date was established for accounting purposes for these PSUs in accordance with ASC 718 Compensation- Stock Compensation. An award holder can generally receive between 0% and 200% of the target award based on achievement of specified stock price hurdles and/or research and development milestones over a three-year performance period ending in February 2026. Any PSUs earned will vest, if at all, in a single tranche in February 2026 subject to a condition of continuing employment through the end of the performance period. The Company granted an additional 214,000 PSUs to the Chief Commercial Officer upon his start date with the same terms and conditions as the awards granted in 2023. The fair value of the market-based awards was estimated on the date of grant for accounting purposes using a Monte Carlo simulation model. The fair value of the performance-based awards was based on the closing share price of the Company’s common stock on the accounting grant date. As of September 30, 2024, one of each of the research performance milestones and the development performance milestones was achieved and another one of the development performance milestones was determined to be probable of achievement.

Stock-Based Compensation

The following table summarizes stock-based compensation expense during the three and nine months ended September 30, 2024 (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Stock-based compensation expense by type of award:				
Time-based stock options	\$ 7,880	\$ 6,795	\$ 22,824	\$ 19,124
Employee stock purchase plan	160	106	482	306
Time-based restricted stock units	57	—	153	—
Performance-based restricted stock units	2,261	1,856	6,304	2,340
Total	<u>\$ 10,358</u>	<u>\$ 8,757</u>	<u>\$ 29,763</u>	<u>\$ 21,770</u>

The Company recorded stock-based compensation expense in the following expense categories of its condensed consolidated statements of operations and comprehensive loss (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expenses	\$ 4,801	\$ 4,005	\$ 13,953	\$ 10,510
General and administrative expenses	5,557	4,752	15,810	11,260
Total	<u>\$ 10,358</u>	<u>\$ 8,757</u>	<u>\$ 29,763</u>	<u>\$ 21,770</u>

As of September 30, 2024, total unrecognized compensation cost related to the unvested time-based stock options and time-based restricted stock units was \$49.7 million and \$0.2 million, respectively, which is expected to be recognized over a weighted average period of 2.52 years and 0.92 years, respectively.

As of September 30, 2024, the total minimum amount of unrecognized compensation cost related to the stock price hurdles for the unvested PSUs was \$10.8 million based on the maximum achievement of 200% of the target award, which is expected to be recognized ratably over a weighted average period of 1.37 years.

If any additional research or development milestones become probable of achievement, the Company will recognize incremental stock compensation expense of up to \$2.6 million through a cumulative catch up adjustment in the period of change in probability. The Company recorded incremental expense of \$0.6 million as a result of the change in probability for three of the milestones during the nine months ended September 30, 2024.

7. Commitments and Contingencies

License Agreements

Plexxikon License Agreement

In July 2020, the Company obtained an exclusive, sublicensable, worldwide license (the "License Agreement") to certain patents and other intellectual property rights to research, develop and commercialize bezuclastinib. Under the terms of the License Agreement, the Company is required to pay Plexxikon Inc., a member of the Daiichi Sankyo Group ("Plexxikon"), aggregate payments of up to \$7.5 million upon the satisfaction of certain clinical milestones and up to \$25.0 million upon the satisfaction of certain regulatory milestones. During the second quarter of 2022, as a result of the progression of the PEAK study, the first clinical milestone was achieved, resulting in payment of \$2.5 million to Plexxikon in June 2022. As of September 30, 2024, no other milestone payments have been made or are considered probable of occurring.

The Company is also required to pay Plexxikon tiered royalties ranging from a low-single digit percentage to a high-single digit percentage on annual net sales of products. These royalty obligations last on a product-by-product basis and country-by-country basis until the latest of (i) the date on which there is no valid claim of a licensed Plexxikon patent covering a subject product in such country or (ii) the 10th anniversary of the date of the first commercial sale of the product in such country. In addition, if the Company sublicenses the rights under the License Agreement, the Company is required to pay a certain percentage of the sublicense revenue to Plexxikon ranging from mid-double digit percentages to mid-single digit percentages, depending on whether the sublicense is entered into prior to or after certain clinical trial events.

The license agreement will expire on a country-by-country and licensed product-by-licensed product basis until the later of the last to expire of the patents covering such licensed products or services or the 10-year anniversary of the date of first commercial sale of the licensed product in such country. The Company may terminate the license agreement within 30 days after written notice in the event of a material breach. The Company may also terminate the agreement upon written notice in the event of the Company's bankruptcy, liquidation or insolvency. In addition, the Company has the right to terminate this agreement in its entirety at will upon 90 days' advance written notice to Plexxikon.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that will 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 condensed consolidated financial statements as of September 30, 2024 or its consolidated financial statements as of December 31, 2023.

Legal Proceedings

The Company is not currently party to 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. The Company expenses as incurred the costs related to such legal proceedings.

8. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	\$ (70,634)	\$ (55,382)	\$ (187,932)	\$ (138,045)
Net loss attributable to common stockholders	\$ (70,634)	\$ (55,382)	\$ (187,932)	\$ (138,045)
Denominator:				
Weighted average common shares outstanding, basic and diluted	110,165,580	86,165,951	101,435,402	77,274,580
Net loss per common share, basic and diluted	\$ (0.64)	\$ (0.64)	\$ (1.85)	\$ (1.79)

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive and would result in a reduction to net loss per share. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated above because including them would have had an anti-dilutive effect:

	September 30,	
	2024	2023
Stock options to purchase common stock	21,221,213	15,519,578
Performance-based restricted stock units subject to vesting	2,714,000	2,500,000
Time-based restricted stock units subject to vesting	80,000	—
Series A Preferred Stock	17,616,250	18,616,250
Series B Preferred Stock	6,868,000	—
	48,499,463	36,635,828

In accordance with ASC Topic 260, Earnings Per Share, the outstanding pre-funded warrants are included in the computation of basic and diluted net loss per share because the exercise price is negligible (\$0.01 per share) and they are fully vested and exercisable at any time after the original issuance date.

9. Retirement Plan

The Company has a defined-contribution plan under Section 401(k) of the Internal Revenue Code (the “401(k) Plan”). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The 401(k) Plan allows for discretionary matching contributions of 100% of the first 4% of elective contributions, which vest immediately. Contributions under the plan were approximately \$0.3 million and \$0.2 million for the three months ended September 30, 2024 and 2023, respectively. Contributions under the plan were approximately \$1.2 million and \$0.9 million for the nine months ended September 30, 2024 and 2023, respectively.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the caption “Risk Factors” in this Quarterly Report on Form 10-Q.

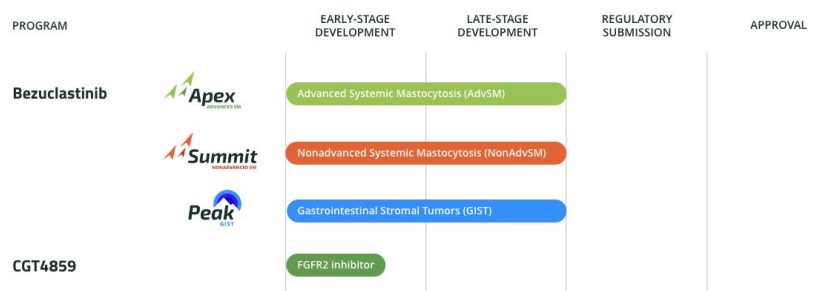
Overview

We are a clinical-stage biotechnology company focused on developing precision therapies for genetically defined diseases. Our approach is to design rational precision therapies that treat the underlying cause of disease and improve the lives of patients. Our most advanced program is bezuclastinib, also known as CGT9486, a highly selective tyrosine kinase inhibitor that is designed to potently inhibit the KIT D816V mutation as well as other mutations in KIT exon 17. In the vast majority of cases, KIT D816V is responsible for driving Systemic Mastocytosis (“SM”), a serious and rare disease caused by unchecked proliferation of mast cells. Exon 17 mutations are also found in patients with advanced gastrointestinal stromal tumors (“GIST”), a type of cancer with strong dependence on oncogenic KIT signaling. Bezuclastinib is a highly selective and potent KIT inhibitor with the potential to provide a new treatment option for these patient populations. We are developing bezuclastinib in patients living with Advanced Systemic Mastocytosis (“AdvSM”), Non-Advanced Systemic Mastocytosis (“Non-AdvSM”) and GIST. In addition to bezuclastinib, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases initially targeting mutations in FGFR2, ErbB2, PI3K α and KRAS.

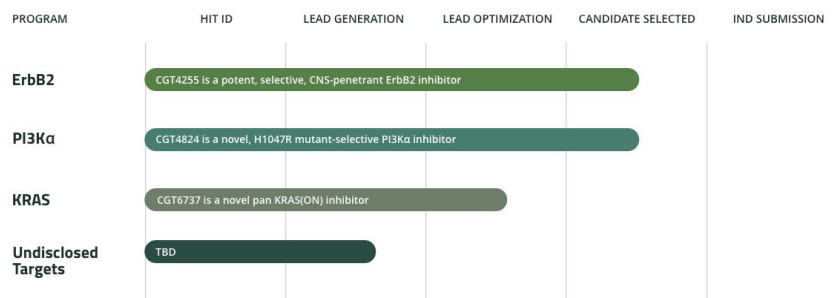
The following is an illustration of the status of our current clinical and pre-clinical programs:

Our Pipeline

CLINICAL PROGRAMS



RESEARCH PROGRAMS



Bezuclastinib- SM

The vast majority of AdvSM and Non-AdvSM patients have a KIT D816V mutation. Patients with AdvSM have a significantly diminished lifespan with a median survival of less than 3.5 years. For patients with Non-AdvSM, while their lifespan is not impacted by the disease, these patients suffer from a poor quality of life and new treatment options are badly needed. The FDA has granted orphan drug designation to bezuclastinib for the treatment of Mastocytosis.

SUMMIT (Non-AdvSM)

SUMMIT is our randomized, global, multicenter, double-blind, placebo-controlled, multi-part Phase 2 clinical trial for patients with Non-AdvSM. The study is designed to explore the safety and efficacy of bezuclastinib in patients with moderate to severe Non-AdvSM, which includes Indolent Systemic Mastocytosis (“ISM”), Smoldering Systemic Mastocytosis (“SSM”) and Bone Marrow Mastocytosis. SUMMIT Part 1 completed enrollment in the third quarter of 2023, including over enrollment at 54 patients across Part 1a and Part 1b. SUMMIT Part 2 is a registration-directed study that is currently enrolling and expected to include 159 patients.

From the data collected in Part 1 of SUMMIT and in accordance with FDA guidelines, we have developed a novel patient reported outcomes measure (“PROM”) called Mastocytosis Symptom Severity Daily Diary (“MS2D2”). Based on literature review, patient and physician interviews, and data from SUMMIT Part 1, we believe our MS2D2 is a reliable, valid and fit-for-purpose PROM. The MS2D2 Total Symptom Score (“TSS”) is comprised of 11 items, and scored on a 0-110 scale. We expect that a comparison of week 24 mean absolute change from baseline in MS2D2 TSS between bezuclastinib and placebo will serve as the measurement of the primary endpoint of the SUMMIT Part 2 study. In June 2024, we announced a positive discussion with the FDA and that we reached alignment with the FDA on the use of MS2D2 in Part 2 of SUMMIT. We expect to complete enrollment in SUMMIT Part 2 in the first quarter of 2025, with top-line results expected in the second half of 2025.

In February 2024, we presented data from SUMMIT Part 1b at the 2024 American Academy of Allergy, Asthma and Immunology (“AAAAI”). Thirty four patients were enrolled in Part 1b and were treated with either bezuclastinib or placebo plus best supportive care. Patients were enrolled with the following sub-types: 33 patients with ISM and one patient with SSM. One patient had received prior avapritinib. These patients were evaluated for signs of clinical activity over 12 weeks, including well-accepted biomarkers of disease burden. Based on the totality of the results from SUMMIT Part 1, the data support 100 mg QD as the optimal dose of bezuclastinib in Part 2 of SUMMIT for patients with Non-AdvSM (“RP2D”).

At the RP2D and as of the cut-off date of December 18, 2023, 100% of patients with baseline tryptase ≥ 20 ng/mL achieved < 20 ng/mL at week 12 versus 0% of placebo patients. Additionally, 100% of patients with detectable baseline KIT D816V variant allele fraction (“VAF”) achieved $\geq 50\%$ reduction in KIT D816V VAF at week 12 versus 0% of placebo patients and 86% of patients with evaluable bone marrow samples achieved $\geq 50\%$ reduction in bone marrow mast cell burden at week 12 versus 40% of placebo patients.

Patients enrolled in SUMMIT Part 1b were evaluated for signs of clinical activity over 12 weeks using multiple PRO measures, including MS2D2 and the Mast Cell Quality-of-Life (“MC-QoL”). At the RP2D, patients reported a 51% mean improvement in overall symptom severity MS2D2 TSS from baseline at week 12 for bezuclastinib 100 mg versus 18% improvement for placebo. Additionally, patients at the RP2D reported a statistically significant reduction in total symptom severity after 12 weeks when compared to placebo (-23.78 vs. -9.03; $p=0.0003$) and 70% of patients at the RP2D achieved $\geq 50\%$ reduction in MS2D2 TSS at Week 12 versus 8% placebo patients. Patients at the RP2D reported a 49% mean improvement in quality of life (MC-QoL) versus 24% for placebo. Additionally, patients at the RP2D reported a statistically significant improvement in quality of life after 12 weeks when compared to placebo (-24.86 vs. -12.39, $p=0.046$).

The majority of treatment emergent adverse events were low grade and reversible with no bleeding or cognitive impairment events reported across cohorts. There were no dose reductions in the 100 mg cohort and two dose reductions in the 150 mg cohort (Grade 1 ALT and Grade 2 abdominal pain). Only one serious adverse event (“SAE”) was reported across both cohorts, which occurred in the 150mg cohort, when a patient experienced ALT/AST increase that led to discontinuation. SUMMIT Part 2 is currently ongoing using the RP2D.

In June 2024, we presented additional data from SUMMIT Part 1 at the 2024 European Hematology Association (“EHA”) Congress. As of the cutoff date, December 18, 2023, patients in Part 1 treated at the recommended dose of 100 mg bezuclastinib demonstrated $>90\%$ reductions across all markers of mast cell burden. Additional data also show meaningful reduction in symptom severity and objective measures of disease, including a substantial reduction in mast cell reactions ($>50\%$) and patients’ most severe symptoms as measured by MS2D2, clinically meaningful reduction in all individual MS2D2 TSS symptoms and across domains, as well as additional symptoms including dizziness, diarrhea severity, and brain fog, and clinically meaningful improvement in skin symptoms as well as objective reduction in skin lesions. Consistent with results previously reported, as of the December 18, 2023 cutoff date, the RP2D demonstrates a favorable safety and tolerability profile. There were no bleeding or cognitive impairment adverse events reported and no SAEs reported.

APEX (AdvSM)

APEX is our global, open-label, multi-center, Phase 2 clinical trial in patients with AdvSM evaluating the safety, efficacy, pharmacokinetic, and pharmacodynamic profiles of bezuclastinib. In June 2022, we reported positive interim clinical data from Part 1 of the APEX trial at the 2022 EHA Congress, and we presented updated positive clinical data from Part 1 in an oral presentation at the American Society of Hematology (“ASH”) Annual Meeting in December 2022. In April 2023, we initiated the registration-directed Part 2 of the APEX trial at 150 mg daily dose of bezuclastinib. We remain on track to deliver top-line results from the APEX trial by mid-2025.

In December 2023, at the 2023 ASH meeting, we reported additional positive clinical data from Part 1 of the APEX trial. As of the data cutoff date of September 25, 2023, 32 patients had been treated in Part 1 at one of four dose levels of the original formulation (50 mg BID, 100 mg BID, 200 mg BID or 400 mg QD). Patients were enrolled with the following sub-types: seven patients with ASM, 23 patients with SM-AHN, and two patients with MCL. As of the cut-off date of September 25, 2023, 32 patients enrolled were evaluated for signs of clinical activity and 27 patients were evaluable for response per the modified IWG-MRT-ECNM criteria. An objective response rate (“ORR”) of 52% (including complete remission (“CR”), CR with partial hematologic remission (“CRh”), partial remission (“PR”)) was achieved, including a 56% ORR for TKI-treatment-naïve patients. An ORR of 75% was achieved by pure pathological response (“PPR”) criteria, including an ORR of 86% for TKI-treatment-naïve patients. All patients receiving the 100mg BID achieved PR or better and remain on trial with 3 patients at ≥ 30 cycles of treatment. The 150mg QD dose of our optimized formulation selected for APEX Part 2 is expected to deliver patient exposures consistent with the 100mg BID dose of the original formulation used in Part 1. An additional APEX cohort was also initiated in the third quarter of 2023 and is designed to allow concomitant administration of bezuclastinib with azacitadine in patients with SM with an associated hematologic neoplasm.

Bezuclastinib- GIST

We are also pursuing the development of bezuclastinib in combination with sunitinib as a potential second line treatment for patients living with GIST. GIST is a cancer frequently driven by KIT mutations, and resistance to currently available therapeutics is frequently associated with the emergence of other KIT mutations. First-line therapy for the vast majority of GIST patients is imatinib, followed by sunitinib monotherapy as the current second-line therapy for the majority of patients that eventually develop resistance to imatinib.

PEAK (GIST)

PEAK is our randomized open-label, global Phase 3 clinical trial designed to evaluate the safety, tolerability, and efficacy of bezuclastinib in combination with sunitinib compared to sunitinib alone in patients with locally advanced, unresectable or metastatic GIST who have received prior treatment with imatinib. The FDA and EMA have granted orphan drug designation to bezuclastinib for the treatment of GIST. Patient enrollment for the pivotal portion of the PEAK trial was completed in the third quarter of 2024. Based on strong global patient interest, a total of 413 patients were enrolled in the trial. In addition, we completed a pre-planned interim futility analysis, and the Independent Data Monitoring Committee (“IDMC”) recommended continuing the PEAK study without modification. This pre-specified analysis was based on an assessment of progression-free survival (“PFS”) as determined by independent central review and did not include the option for early stopping due to efficacy. Top line results are expected by the end of 2025.

In June 2024, we presented updated positive clinical data from the lead-in portion of PEAK Part 1 at the 2024 American Society of Clinical Oncology (“ASCO”) meeting. As of the cutoff date, April 1, 2024, the 42 patients in Part 1 have been on study for a median of 15.3 months. The median progression-free survival (“mPFS”) during treatment with bezuclastinib and sunitinib was 10.2 months in all of these heavily pre-treated GIST patients. In a subset of second-line GIST patients with only prior imatinib, which most closely resembles patients currently enrolling in the Phase 3 registration-enabling PEAK study, the data demonstrate a mPFS of 19.4 months. In addition, the objective response rate (“ORR”) in all patients treated with bezuclastinib and sunitinib was 27.5% and in the subset of second-line patients the ORR was 33.3%, per investigator assessment. Combination treatment resulted in a disease control rate of 80% in all patients and 100% in second-line patients with prior imatinib only. As of the data cutoff, the combination of bezuclastinib and sunitinib does not appear to add to the severity of adverse events known to be associated with sunitinib monotherapy and is well-tolerated. The majority of treatment-emergent adverse events (“TEAEs”) were low-grade and reversible and discontinuations due to TEAEs remain limited.

In May 2024, we also announced the initiation of a new advanced Phase 2 clinical trial of bezuclastinib plus sunitinib in later line GIST patients that is being sponsored by the Sarcoma Alliance for Research through Collaboration and in collaboration with The Life Raft Group and Dana-Farber Cancer Institute. The open label, single arm Phase 2 trial is designed to evaluate the mPFS as well as the safety and tolerability of bezuclastinib plus sunitinib in 40 patients with GIST who have previously progressed on sunitinib. This trial is focused on later line patients that are not eligible for PEAK and have limited treatment options.

Worldwide rights to develop and commercialize bezuclastinib are exclusively licensed from Plexxikon Inc., a member of the Daiichi Sankyo Group (“Plexxikon”). Under the terms of the license agreement, Plexxikon received an upfront payment and is eligible for additional development milestones of up to \$7.5 million upon the satisfaction of certain clinical milestones and up to \$25.0 million upon the satisfaction of certain regulatory milestones. During the second quarter of 2022, as a result of the progression of the PEAK study, the first clinical milestone was achieved, resulting in payment of \$2.5 million to Plexxikon in June 2022. As of September 30, 2024, no other milestone payments have been made. Patents protecting bezuclastinib include composition of matter claims which have been issued in the US and other key territories and provide exclusivity through 2033 and potentially beyond through patent term extensions. In addition, we filed a patent application in 2023 seeking to protect our optimized formulation of bezuclastinib that is currently being used in all three of our on-going clinical trials, which could potentially provide exclusivity through at least 2043.

CGT4859

Our research team is building a pipeline of small molecule inhibitors, with our first efforts aimed toward targeting currently undrugged mutations in fibroblast growth factor receptor (“FGFR”). FGFR mutations are well-established oncogenic drivers in multiple diseases, but approved medicines fail to capture the full landscape of FGFR altered tumor types, with FGFR1-mediated hyperphosphatemia serving as the most common dose-limiting toxicity for pan-FGFR inhibitors. We have selected our FGFR2 clinical candidate, CGT4859. In April 2023, we reported preclinical data at the American Association for Cancer Research (“AACR”) 2023 Annual Meeting providing the first published evidence of CGT4859 a reversible, selective FGFR2 inhibitor with coverage of activating and emerging resistance mutations that spares inhibition of FGFR1. Preclinical data demonstrate a profile that delivers equipotent coverage across both key gatekeeper and molecular brake mutations (V564X, N549X) in FGFR2, while avoiding any evidence of FGFR1-linked hyperphosphatemia at efficacious plasma concentrations. In October 2023, we presented updated preclinical data at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. Preclinical data demonstrate a profile that exhibits low nanomolar potency on WT FGFR2 and FGFR2 mutations and is selective against the kinome, as well as a panel of ion channels and receptors. Exploratory pharmacokinetics studies conducted across species showed CGT4859 to be a low-clearance compound with high oral bioavailability. Further, in a mutant-driven mouse model, CGT4859 demonstrated dose-responsive tumor growth inhibition with complete regressions at 5 mg/kg PO and was well-tolerated. In addition, as a reversible inhibitor, the Cogent program retains enzymatic potency against potential cysteine 491 mutations. We initiated a Phase 1 study of CGT4859 in patients with FGFR2 mutations, including advanced cholangiocarcinoma, in the third quarter of 2024. The trial will explore the safety, tolerability and clinical activity of escalating doses of CGT4859 with a goal of selecting an active and well tolerated dose for further clinical investigation. Preliminary results from this trial are expected in 2025.

Research programs

The Cogent Research Team, based in Boulder, Colorado, is focused on pioneering best-in-class, small molecule therapeutics to expand our pipeline and deliver novel precision therapies for patients living with unmet medical needs. For ErbB2, PI3K and KRAS we see opportunities to provide a more robust molecular response compared to existing therapies.

ErbB2

Our research team is also advancing a novel, ErbB2 mutant program, which is focused on actionable and underserved mutations in a variety of solid tumor indications. In April 2023, we reported preclinical data at AACR describing a series of novel compounds which potently inhibit several key ErbB2 mutations, including YVMA insertions, while sparing inhibition of EGFR. An exemplar compound from these series demonstrates advantages versus tucatinib, an approved benchmark compound, on tumor growth inhibition in a peripheral ErbB2 L755S driven mutant model, as well as in an ErbB2 driven intracranial model. Recent program advances with a novel chemotype have further improved ErbB2 mutational potency and selectivity and improved human whole blood stability to nearly 24 hours, suggesting a favorable profile for optimal clinical efficacy. Updated data was presented in November 2023 at the San Antonio Breast Cancer Symposium (“SABCS”) and at AACR in April 2024. The updated data presented shows that CGT4255 demonstrated low nM potency against ErbB2 wild-type and oncogenic ErbB2 mutations with greater than 100-fold selectivity over wild-type-EGFR. In addition to impressive selectivity across a broad range of kinases, receptors and ion channels, CGT4255 has exceptional half-life in human whole blood and liver cytosol fractions. Dose ascending PK data in mice showed low clearance and high oral bioavailability at all doses, with best-in-class 80% brain penetrance at 100 mg/kg. Maximum inhibition of ErbB2 was observed at a 30 mg/kg PO dose in both NIH/3T3 ErbB2-YVMA and ErbB2-L755S tumor models, with complete regressions at 100 mg/kg PO BID in the NIH3T3 ErbB2-L755S TGI model and was well tolerated. These advances continue to highlight a favorable profile for optimal clinical efficacy. We selected our ErbB2 clinical candidate and initiated IND-enabling studies in mid-2024.

PI3K α

Our research team is also developing a potential best-in-class, wild-type-sparing, PI3K α inhibitor that provides coverage for the H1047R mutation, which affects >30,000 cancer patients each year. The phosphoinositide 3-kinase (“PI3K”) pathway is a key cell cycle regulating pathway that has an established role in tumor growth and development. PI3K α mutations are highly prevalent in many solid tumors and are present in 36% of all breast cancer patients. The approved agents for these patients often lead to dose limitations, resulting from activity against wild-type PI3K α . Preclinical data was presented at the 2024 EORTC-NCI-AACR International Symposium on Molecular Targets and Cancer Therapeutics (“EORTC-NCI-AACR”) in October 2024 and highlighted that CGT6297 is an allosteric inhibitor of PI3K, was well-tolerated in the tumor growth inhibition efficacy models and has been profiled based on its selectivity for H1047R over WT PI3K. CGT6297 demonstrated low nM potency in H1047R mutant PI3K cell lines, differentiated dose ascending PK in mice with high bioavailability and low clearance. CGT4824 also showed >95% inhibition of pAKT in a H1047R PD model, importantly without increases in insulin or C-peptide. Its efficacy profile was superior to a clinically-relevant dose of Alpelisib in the NCI H1048 mouse tumor growth inhibition model. CGT6297 has been selected as our clinical candidate for the PI3K 1047 mutation focused project. IND-enabling studies are expected to be initiated in 2025.

KRAS

Our research team is also developing a potent and selective KRAS inhibitor. Mutations in KRAS are among the most prevalent mutations found in cancer, occurring most often in colorectal cancer, non-small cell lung cancer and pancreatic cancer. Preclinical data was presented at the EORTC-NCI-AACR meeting and highlighted our internally-developed pan KRAS(ON) inhibitor with selectivity over HRAS and NRAS and picomolar (pM) activity across KRAS mutations without the potential liabilities of molecules in the class. Following oral administration, CGT6737 demonstrated robust PK/PD and tumor growth inhibition with 90% PD inhibition in mouse xenograft models. Lead optimization of CGT6737 is ongoing.

Financial Operations Overview

Since our inception in 2014, we have focused significant efforts and financial resources on establishing and protecting our intellectual property portfolio, conducting research and development of our product candidates, manufacturing drug product material for use in preclinical studies and clinical trials, staffing our company, and raising capital. We do not have any products approved for sale and have not generated any revenue from product sales. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were \$187.9 million for the nine months ended September 30, 2024 compared to net losses of \$138.0 million for the nine months ended September 30, 2023. As of September 30, 2024, we had an accumulated deficit of \$791.6 million. We expect to continue to incur significant expenses and operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- initiate and increase enrollment for our existing and planned clinical trials for our product candidates;
- continue to discover and develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional research, clinical, scientific, and commercial personnel;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain regulatory approval; and
- add operational, financial, and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2024, we had cash, cash equivalents and marketable securities of \$345.5 million. Based on our current plans, we expect that our current cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements through clinical readouts from ongoing SUMMIT, PEAK, and APEX registration-directed trials and into late 2026.

Components of Our Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- expenses incurred in connection with the discovery, preclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants, contractors and contract research organizations (“CROs”);
- the cost of manufacturing drug products for use in our preclinical studies and clinical trials, including under agreements with third parties, such as consultants, contractors and contract manufacturing organizations (“CMOs”);
- employee-related expenses, including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions;
- laboratory supplies and animal care;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance; and
- payments made under third-party licensing agreements.

We expense research and development costs as incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Certain of our direct research and development expenses are tracked on a program-by-program basis and consist of costs, such as fees paid to consultants, contractors, CMOs, and CROs in connection with our discovery, preclinical and clinical development activities. We do not allocate employee costs, costs associated with the manufacture of bezuclastinib, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical and preclinical development activities in the near term and in the future. At this time, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of our preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;

- the progress of the development efforts of parties with whom we have entered, or may enter, into collaboration arrangements;
- our ability to maintain our current research and development programs and to establish new ones;
- the enrollment rates in our clinical trials;
- our ability to establish new licensing or collaboration arrangements;
- the future productivity of the Cogent Research Team in Boulder, CO and its ability to discover new product candidates and build our pipeline;
- the successful completion of clinical trials with safety, tolerability, and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the success in establishing and operating a manufacturing facility, or securing manufacturing supply through relationships with third parties;
- our ability to obtain and maintain patents, trade secret protection, and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved;
- the acceptance of our product candidates, if approved, by patients, the medical community, and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our therapies following approval.

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance, commercial and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, investor and public relations, accounting, and audit services. We anticipate that our general and administrative expenses will increase in the future as a result of the costs associated with the expansion of operations to support our on-going discovery, preclinical and clinical activities and current and future commercialization activities.

Interest Income

Interest income consists of interest earned on our cash equivalents and marketable securities balances.

Other Income, Net

Other income consists of miscellaneous income and expense unrelated to our core operations, primarily income from subleasing a portion of our former headquarters facilities.

Change in Fair Value of the CVR liability

This consists of changes in the fair value of the contingent value right (“CVR”) liability.

Income Taxes

Since our inception, we have not recorded any current or deferred tax benefit for the net losses we have incurred in each year or for our tax credits generated, as we believe, based upon the weight of available evidence, that it is more likely than not that our net operating loss carryforwards and tax credits will not be realized. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2023. We reevaluate the utilization of net operating loss carryforwards and tax credits at each reporting period. As of December 31, 2023, we had U.S. federal and state net operating loss carryforwards of \$195.7 million and \$110.6 million, respectively, which may be available to offset future taxable income and begin to expire in 2035. Of the federal net operating loss carryforwards at December 31, 2023, \$192.4 million is available to be carried forward indefinitely but we are permitted to offset a maximum of 80% of taxable income per year. As of December 31, 2023, we had U.S. federal and state research and development tax credit carryforwards of \$14.0 million and \$3.1 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2040 and 2035, respectively. The Company also had federal orphan drug tax credits of \$12.4 million which may be available to offset future income tax liabilities and begin to expire in 2041.

Utilization of the U.S. federal and state net operating loss carryforwards and tax credit carryforwards may be subject to annual limitation under Section 382 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period.

We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

Results of Operations

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

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Change
	2024	2023	
	(in thousands)		
Operating expenses:			
Research and development	\$ 63,614	\$ 50,127	\$ 13,487
General and administrative	11,800	9,453	2,347
Total operating expenses	75,414	59,580	15,834
Loss from operations	(75,414)	(59,580)	(15,834)
Other income:			
Interest income	4,779	4,198	581
Other income, net	1	—	1
Total other income, net	4,780	4,198	582
Net loss	\$ (70,634)	\$ (55,382)	\$ (15,252)

Research and Development Expenses

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

	Three Months Ended September 30,		Change
	2024	2023	
	(in thousands)		
Direct external research and development expenses:			
Bezuclastinib	\$ 34,740	\$ 27,965	\$ 6,775
Preclinical research and discovery	7,626	4,425	3,201
Unallocated expenses:			
Personnel related (including stock-based compensation)	16,928	13,850	3,078
Laboratory supplies, facility related and other	4,320	3,887	433
Total research and development expenses	\$ 63,614	\$ 50,127	\$ 13,487

Total research and development expense increased by \$13.5 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023, driven by higher external research and development costs associated with the manufacture and development of bezuclastinib, including costs associated with the accelerated enrollment of the SUMMIT and PEAK trials and ongoing cost of the APEX trial, and the continued development and progression of our research pipeline. Additionally, there was an increase in unallocated expenses driven by higher personnel costs due to an increase in headcount, including stock-based compensation expense which increased by \$0.8 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2024 were \$11.8 million, compared to \$9.5 million for the three months ended September 30, 2023. The increase in general and administrative expenses was primarily due to higher personnel costs driven by an increase in headcount, including stock-based compensation expense which increased by \$0.8 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023, and initial commercial readiness activities initiated in the third quarter of 2024.

Interest Income

Interest income for the three months ended September 30, 2024 was \$4.8 million, compared to \$4.2 million for the three months ended September 30, 2023. The increase is due to higher average interest rates and invested balances in cash equivalents and marketable securities.

Other Income, Net

Other income, net for the three months ended September 30, 2024 was less than \$0.1 million and represented miscellaneous income. Other income, net for the three months ended September 30, 2023 was nil.

Comparison of the nine months ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		Change
	2024	2023	
	(in thousands)		
Operating expenses:			
Research and development	\$ 170,613	\$ 125,036	\$ 45,577
General and administrative	31,592	24,866	6,726
Total operating expenses	<u>202,205</u>	<u>149,902</u>	<u>52,303</u>
Loss from operations	<u>(202,205)</u>	<u>(149,902)</u>	<u>(52,303)</u>
Other income:			
Interest income	14,229	9,207	5,022
Other income, net	44	950	(906)
Change in fair value of CVR liability	—	1,700	(1,700)
Total other income, net	<u>14,273</u>	<u>11,857</u>	<u>2,416</u>
Net loss	<u>\$ (187,932)</u>	<u>\$ (138,045)</u>	<u>\$ (49,887)</u>

Research and Development Expenses

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

	Nine Months Ended September 30,		Change
	2024	2023	
	(in thousands)		
Direct external research and development expenses:			
Bezuclastinib	\$ 90,797	\$ 61,276	\$ 29,521
Preclinical research and discovery	19,708	13,761	5,947
Unallocated expenses:			
Personnel related (including stock-based compensation)	48,127	38,479	9,648
Laboratory supplies, facility related and other	11,981	11,520	461
Total research and development expenses	<u>\$ 170,613</u>	<u>\$ 125,036</u>	<u>\$ 45,577</u>

Total research and development expense increased by \$45.6 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023, driven by higher external research and development costs associated with the manufacture and development of bezuclastinib, including costs associated with the APEX, SUMMIT and PEAK trials, and the continued development and progression of our research pipeline. Additionally, there was an increase in unallocated expenses driven by higher personnel costs due to an increase in headcount, including stock-based compensation expense which increased by \$3.4 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2024 were \$31.6 million, compared to \$24.9 million for the nine months ended September 30, 2023. The increase in general and administrative expenses was primarily due to higher personnel costs driven by an increase in headcount, including stock-based compensation expense which increased by \$4.6 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023, and initial commercial readiness activities initiated in the third quarter of 2024.

Interest Income

Interest income for the nine months ended September 30, 2024 was \$14.2 million, compared to \$9.2 million for the nine months ended September 30, 2023. The increase is due to higher average invested balances in cash equivalents and marketable securities.

Other Income, Net

Other income, net for the nine months ended September 30, 2024 was less than \$0.1 million, compared to \$1.0 million for the nine months ended September 30, 2023. For the nine months ended September 30, 2024, other income represented miscellaneous income while for the nine months ended September 30, 2023, other income primarily represented sublease income recognized resulting from the sublease of a portion of our former corporate headquarters space. The decrease in other income, net is driven by the expiration of our former corporate headquarters lease and associated sublease in April 2023.

Change in Fair Value of the CVR liability

The change in fair value of CVR liability for the nine months ended September 30, 2024 was nil, compared to \$1.7 million for the nine months ended September 30, 2023. We recorded a decrease in fair value of the liability of \$1.7 million in the first quarter of 2023, reducing the liability to zero as the probability of additional CVR payments occurring prior to the expiration of CVR term was remote. The CVRs expired on August 6, 2023 and no further payments will be made to CVR holders.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have generated limited revenue to date from funding arrangements with our former collaboration partner. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. We have historically funded our operations primarily through the public offering and private placement of our securities and consideration received from our collaborative agreements.

On May 6, 2022, we filed a shelf registration statement on Form S-3 with the SEC. The shelf registration statement allows us to sell from time-to-time up to \$300.0 million of common stock, preferred stock, debt securities, warrants or units comprised of any combination of these securities, for our own account in one or more offerings. The terms of any offering under the shelf registration statement will be established at the time of such offering and will be described in a prospectus supplement filed with the SEC prior to the completion of any such offering.

Additionally, on May 6, 2022, pursuant to the Form S-3, we entered into a Sales Agreement (the “Sales Agreement”) with Guggenheim Securities, LLC (“Guggenheim Securities”), pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$75.0 million through Guggenheim Securities, as the sales agent. As of September 30, 2024, no shares have been sold under the Sales Agreement.

On June 13, 2022, we completed an underwritten public offering of 17,899,698 shares of our common stock at a public offering price of \$8.25 per share (including the exercise in full by the underwriters of their 30-day option to purchase up to 2,730,000 additional shares of common stock) and, in lieu of common stock to certain investors, pre-funded warrants to purchase 3,030,302 shares of our common stock at a purchase price of \$8.24 per underlying share. The net proceeds from the offering were approximately \$161.9 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

On February 10, 2023, we filed a Form S-3ASR with the SEC (“2023 Shelf Registration”) for the issuance of common stock, preferred stock, warrants, rights, debt securities and units, which became effective immediately upon filing. At the time any of the securities covered by the 2023 Shelf Registration are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

In June 2023, we completed an underwritten public offering of 14,375,000 shares of our common stock at a public offering price of \$12.00 per share (including the exercise in full by the underwriters of their 30-day option to purchase up to 1,875,000 additional shares of common stock). The net proceeds from the offering were approximately \$161.8 million, after deducting the underwriting discounts and commissions and offering expenses.

On February 13, 2024, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) for a private placement (the “Private Placement”) with certain institutional and accredited investors (each, a “Purchaser” and collectively, the “Purchasers”). The closing of the Private Placement occurred on February 16, 2024. Pursuant to the Purchase Agreement, the Purchasers purchased (i) an aggregate of 17,717,997 shares of our common stock at a price per share of \$7.50, and (ii) 12,280 shares of our Series B Non-voting Convertible Preferred Stock (“Series B Preferred Stock”), at a price per share of \$7,500.00. Net proceeds were approximately \$213.4 million after deducting placement fees and offering costs.

As of September 30, 2024, we have 135,548,559 shares outstanding on an as-converted basis, which consists of (i) 110,458,249 shares of common stock outstanding, (ii) pre-funded warrants that are exercisable for 606,060 shares of common stock, (iii) 70,465 shares of Series A Preferred Stock that are convertible into 17,616,250 shares of common stock and (iv) 6,868 shares of Series B Preferred Stock that are convertible into 6,868,000 shares of common stock.

As of September 30, 2024, we had cash, cash equivalents and marketable securities of \$345.5 million, which we believe will be sufficient to fund our operating expenses and capital expenditure requirements through clinical readouts from ongoing SUMMIT, PEAK, and APEX registration-directed trials and into late 2026.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Nine Months Ended September 30,	
	2024	2023
	<i>(in thousands)</i>	
Net cash used in operating activities	\$ (147,214)	\$ (109,554)
Net cash used in investing activities	(23,395)	(108,313)
Net cash provided by financing activities	214,425	163,536
Net increase in cash, cash equivalents and restricted cash	\$ 43,816	\$ (54,331)

Operating Activities

During the nine months ended September 30, 2024, operating activities used \$147.2 million of cash, primarily resulting from our net loss of \$187.9 million, partially offset by net cash provided by changes in our operating assets and liabilities of \$12.7 million and by net noncash charges of \$28.0 million. Changes in our operating assets and liabilities for the nine months ended September 30, 2024 consisted primarily of a \$14.7 million increase in accounts payable and accrued expenses and other current liabilities, partially offset by a \$0.9 million increase in prepaid expenses and other current assets, and a \$1.0 million decrease in the operating lease liability.

During the nine months ended September 30, 2023, operating activities used \$109.6 million of cash, primarily resulting from our net loss of \$138.0 million, partially offset by net cash used in changes in our operating assets and liabilities of \$6.4 million and by net noncash charges of \$22.0 million. Changes in our operating assets and liabilities for the nine months ended September 30, 2023 consisted primarily of a \$9.5 million increase in accounts payable and accrued expenses and other current liabilities partially offset by a \$2.5 million increase in prepaid expenses and other current assets, a \$0.5 million decrease in the operating lease liability and a \$0.1 million increase in other assets.

Investing Activities

During the nine months ended September 30, 2024, net cash used in investing activities was \$23.4 million which consisted of purchases of property and equipment and marketable securities, partially offset by maturities and sales of marketable securities.

During the nine months ended September 30, 2023, net cash used in investing activities was \$108.3 million which consisted of purchases of property and equipment and marketable securities, partially offset by maturities and sales of marketable securities.

Financing Activities

During the nine months ended September 30, 2024, net cash provided by financing activities was \$214.4 million, which consisted of \$213.3 million in proceeds from the issuance of common stock and Series B Preferred Stock in the Private Placement, net of paid offering costs and proceeds from the issuance of common stock under the Employee Stock Purchase Plan.

During the nine months ended September 30, 2023, net cash provided by financing activities was \$163.5 million, which consisted of \$161.8 million in proceeds from the issuance of common stock in an underwritten public offering, net of paid offering costs, proceeds from the issuance of common stock under the Employee Stock Purchase Plan and proceeds from the issuance of common stock upon stock option exercises.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we advance the clinical development of our current and any future product candidates and conduct additional research, development and preclinical activities. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, and completion of preclinical studies and clinical trials for our current and future potential product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or our inability to do so at acceptable prices;
- our inability to establish collaborations, if desired or needed;
- our failure to commercialize our product candidates;

- additions or departures of key scientific or management personnel; and
- unanticipated serious safety concerns related to the use of our product candidates.

Based on our current plans, we believe that our existing cash, cash equivalents and marketable securities of \$345.5 million as of September 30, 2024 will enable us to fund our operating expenses and capital expenditure requirements through clinical readouts from ongoing SUMMIT, PEAK, and APEX registration-directed trials and into late 2026. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We will require additional funding to complete the critical activities planned to support ongoing research and development programs.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce, or terminate our research, product development, or future commercialization efforts, or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Estimates

There have been no material changes in our critical accounting policies during the three months ended September 30, 2024, as compared to those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

A description of our material cash requirements, including commitments for capital expenditures, is described above and disclosed in Note 7 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

Recently Issued 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 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

There have been no material changes to our market risks as described in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on February 26, 2024.

Item 4. Controls and Procedures.**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and President and our Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months 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.

We are not currently subject to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Regardless of the outcome, litigation can have a material adverse effect on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors.

There have been no material changes from our risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on February 26, 2024. The risks described in our Form 10-K are not the only risks facing our Company. Additional risk and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits.

Exhibit Number	Description
31.1*	<u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of 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 Rule 13a-14(a) or Rule 15d-14(a) of 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 pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2*†	<u>Certification of 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.
104*	The cover page for the Company’s Quarterly Report on Form 10-Q has been formatted in Inline XBRL and contained in Exhibit 101

* Filed herewith

(1) Schedules and exhibits have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the Securities and Exchange Commission upon its request; provided, however, that the registrant may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedule or exhibit so furnished.

† The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Cogent Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

COGENT BIOSCIENCES, INC.

Date: November 12, 2024

By: /s/ Andrew Robbins
Andrew Robbins
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2024

By: /s/ John Green
John Green
Chief Financial Officer
(Principal Accounting and Financial 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, Andrew Robbins, certify that:

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

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

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

4. The registrant's other certifying officer 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 12, 2024

By: /s/ Andrew Robbins

Andrew Robbins

Chief Executive Officer and President
(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, John Green, certify that:

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

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

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

4. The registrant's other certifying officer 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 12, 2024

By: /s/ John Green

John Green

Chief Financial Officer

(Principal Accounting and Financial 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 on Form 10-Q of Cogent Biosciences, Inc. (the “Company”) for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Andrew Robbins, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2024

By: /s/ Andrew Robbins
Andrew Robbins
Chief Executive Officer and President
(Principal Executive 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 on Form 10-Q of Cogent Biosciences, Inc. (the “Company”) for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, John Green, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2024

By: /s/ John Green

John Green
Chief Financial Officer
(Principal Accounting and Financial Officer)
