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, 2022

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	**46-5308248**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
275 Wyman Street, 3rd Floor Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip code)**

(617) 945-5576
(Registrant's telephone number, including area code)

200 Cambridge Park Drive, Suite 2500
Cambridge, Massachusetts 02140
(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of November 11, 2022, there were 69,893,434 shares of the registrant's Common Stock, $0.001 par value per share, outstanding.

Summary of the Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- Our business is highly dependent on the success of our bezuclastinib program and our ability to discover and develop additional product candidates. We may not be successful in our efforts to develop bezuclastinib or expand our pipeline of drug candidates.
- Since the number of patients that we have dosed to date in our clinical trials is small, the results from such clinical trials may be less reliable than results achieved in larger clinical trials.
- Clinical trials are expensive, time-consuming, and difficult to design and implement.
- The current pandemic of the novel coronavirus, or COVID-19, and the future outbreak of other highly infectious or contagious diseases, could seriously harm our development efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- We may choose not to develop a potential product candidate, or we may suspend, deprioritize or terminate one or more discovery programs or preclinical or clinical product candidates or programs.
- Regulatory authorities, including the U.S. Food and Drug Administration ("FDA"), may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.
- The impact on our business of healthcare legislation and other changes in the healthcare industry and in healthcare spending is currently unknown and may adversely affect our business model.
- We contract with third parties for the manufacture of our product candidates for preclinical development and clinical trials. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- The third parties upon whom we rely for the supply of the API and drug product used in bezuclastinib are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.
- We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.
- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.
- We will require substantial additional funding. If we fail to obtain additional financing when needed, or on attractive terms, we may be unable to complete the development and commercialization of our product candidates
- The price of our stock may be volatile, and you could lose all or part of your investment.

The summary risk factors described above should be read together with the text of the full risk factors in *Item 1A. "Risk Factors"* and the other information set forth in this Quarterly Report on Form 10-Q, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

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 strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth 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;
- business interruptions resulting from the coronavirus disease ("COVID-19") outbreak or similar public health crises, which could cause a disruption to the development of our product candidates and adversely impact our business;
- the success, cost, and duration of our product development activities and clinical trials;
- the timing of our planned regulatory submissions to the FDA for our bezuclastinib product candidate, also known as CGT9486;
- 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;
- 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.

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, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 140,568	$ 219,684
Marketable securities	148,526	$ —
Prepaid expenses and other current assets	6,068	2,949
Restricted cash	1,255	—
Total current assets	296,417	222,633
Operating lease, right-of-use asset	23,832	2,771
Property and equipment, net	6,543	1,706
Restricted cash	—	1,255
Other assets	4,768	3,727
Total assets	$ 331,560	$ 232,092
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,093	$ 3,483
Accrued expenses and other current liabilities	14,384	8,210
CVR liability (Note 3)	3,060	3,060
Operating lease liability	2,014	2,324
Total current liabilities	23,551	17,077
Operating lease liability, net of current portion	18,067	831
Total liabilities	41,618	17,908
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 9,000,000 shares authorized; no shares issued or outstanding	—	—
Series A non-voting convertible preferred stock, $0.001 par value; 1,000,000 shares authorized; 81,050 and 103,289 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	65,830	85,400
Common stock, $0.001 par value; 150,000,000 shares authorized; 69,857,972 shares and 43,805,922 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	70	44
Additional paid-in capital	595,801	399,713
Accumulated other comprehensive loss	(163)	—
Accumulated deficit	(371,596)	(270,973)
Total stockholders' equity	289,942	214,184
Total liabilities and stockholders' equity	$ 331,560	$ 232,092

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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	29,936	14,798	84,885	35,399
General and administrative	6,885	5,021	19,209	14,512
Total operating expenses	36,821	19,819	104,094	49,911
Loss from operations	(36,821)	(19,819)	(104,094)	(49,911)
Other income:				
Interest income	1,500	115	1,879	360
Other income, net	259	620	1,592	1,847
Change in fair value of CVR liability	—	—	—	343
Total other income, net	1,759	735	3,471	2,550
Net loss	$ (35,062)	$ (19,084)	$ (100,623)	$ (47,361)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.50)	$ (0.48)	$ (1.84)	$ (1.25)
Weighted average common shares outstanding, basic and diluted	69,576,359	39,848,943	54,780,041	37,741,526
Comprehensive loss:				
Net loss	$ (35,062)	$ (19,084)	$ (100,623)	$ (47,361)
Other comprehensive loss				
Net unrealized losses on marketable securities	(163)	—	(163)	—
Total other comprehensive loss	(163)	—	(163)	—
Comprehensive loss	$ (35,225)	$ (19,084)	$ (100,786)	$ (47,361)

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		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2021	103,289	$ 85,400	43,805,922	$ 44	$ 399,713	$ —	$ (270,973)	$ 214,184
Conversion of Series A non-voting preferred stock into common stock	(7,955)	(7,000)	1,988,750	2	6,998	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	18,995	—	129	—	—	129
Issuance of common stock upon exercise of stock options	—	—	5,599	—	9	—	—	9
Stock-based compensation expense	—	—	—	—	4,175	—	—	4,175
Net loss	—	—	—	—	—	—	(30,634)	(30,634)
Balances at March 31, 2022	95,334	78,400	45,819,266	46	411,024	—	(301,607)	187,863
Issuance of common stock and pre-funded warrants in underwritten public offering, net of offering costs of $10.8 million	—	—	17,899,698	18	161,897	—	—	161,915
Conversion of Series A non-voting preferred stock into common stock	(7,955)	(7,000)	1,988,750	2	6,998	—	—	—
Stock-based compensation expense	—	—	—	—	4,534	—	—	4,534
Net loss	—	—	—	—	—	—	(34,927)	(34,927)
Balances at June 30, 2022	87,379	71,400	65,707,714	66	584,453	—	(336,534)	319,385
Conversion of Series A non-voting preferred stock into common stock	(6,329)	(5,570)	1,582,250	2	5,568	—	—	$ —
Pre-funded warrant exercise	—	—	2,424,242	2	22	—	—	$ 24
Issuance of common stock under Employee Stock Purchase Plan	—	—	30,005	—	222	—	—	222
Issuance of common stock upon exercise of stock options	—	—	113,761	—	914	—	—	914
Net unrealized losses on marketable securities	—	—	—	—	—	(163)	—	(163)
Stock-based compensation expense	—	—	—	—	4,622	—	—	4,622
Net loss	—	—	—	—	—	—	(35,062)	(35,062)
Balances at September 30, 2022	81,050	65,830	69,857,972	70	595,801	(163)	(371,596)	289,942

	Series A Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances at December 31, 2020	132,244	$ 110,881	32,347,905	$ 32	$ 322,454	$ (198,700)	$ 234,667
Conversion of Series A non-voting preferred stock into common stock	(18,409)	(16,200)	4,602,250	5	16,195	—	—
Issuance of common stock to settle CVR liability	—	—	212,429	—	2,043	—	2,043
Issuance of common stock for services	—	—	31,683	—	260	—	260
Stock-based compensation expense	—	—	—	—	1,521	—	1,521
Net loss	—	—	—	—	—	(11,728)	(11,728)
Balances at March 31, 2021	113,835	$ 94,681	37,194,267	$ 37	$ 342,473	$ (210,428)	$ 226,763
Conversion of Series A non-voting preferred stock into common stock	(10,546)	(9,281)	2,636,500	3	9,278	—	—
Stock-based compensation expense	—	—	—	—	2,590	—	2,590
Net loss	—	—	—	—	—	(16,549)	(16,549)
Balances at June 30, 2021	103,289	$ 85,400	39,830,767	$ 40	$ 354,341	$ (226,977)	$ 212,804
Issuance of common stock upon exercise of stock options	—	—	15,758	—	24	—	24
Issuance of common stock under Employee Stock Purchase Plan	—	—	4,497	—	31	—	31
Stock-based compensation expense	—	—	—	—	3,463	—	3,463
Net loss	—	—	—	—	—	(19,084)	(19,084)
Balances at September 30, 2021	103,289	$ 85,400	39,851,022	$ 40	$ 357,859	$ (246,061)	$ 197,238

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,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (100,623)	$ (47,361)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	422	79
Stock-based compensation expense	13,331	7,834
Amortization of operating leases, right-of-use assets	4,519	1,366
Change in fair value of CVR liability	—	(343)
Net amortization (accretion) of premiums (discounts) on marketable securities	(456)	—
Right-of-use asset impairment	(396)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,119)	(1,894)
Other assets	(1,041)	(2,036)
Accounts payable	610	3,617
Accrued expenses and other current liabilities	5,781	2,268
Operating lease liability	(8,258)	(1,516)
Net cash used in operating activities	(89,230)	(37,986)
Cash flows from investing activities:		
Purchases of property and equipment	(4,896)	(1,286)
Purchases of marketable securities	(148,233)	—
Net cash used in investing activities	(153,129)	(1,286)
Cash flows from financing activities:		
Proceeds from issuance of shares of common stock and pre-funded warrants, net of offering costs of $10.8 million	161,945	—
Proceeds from issuance of stock from employee stock purchase plan	351	31
Proceeds from issuance of common stock upon stock option exercises	923	24
Proceeds from pre-funded warrant exercises	24	—
Payment to CVR Holders	—	(85)
Net cash (used in) provided by financing activities	163,243	(30)
Net (decrease) increase in cash, cash equivalents and restricted cash	(79,116)	(39,302)
Cash, cash equivalents and restricted cash at beginning of period	220,939	243,445
Cash, cash equivalents and restricted cash at end of period	$ 141,823	$ 204,143
Supplemental disclosure of cash flow information:		
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 25,184	$ —
Supplemental disclosure of noncash investing and financing information:		
Offering costs included in accounts payable and accrued expenses	$ 30	$ —
Property & equipment included in accounts payable and accrued expenses	$ 363	$ —
Conversion of Series A Convertible Preferred stock into common shares	$ 19,570	$ 25,481
Issuance of shares in partial settlement of CVR liability	$ —	$ 2,043

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

1. Nature of the Business and Basis of Presentation

Cogent Biosciences, Inc. ("Cogent" or the "Company") is a 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 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 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 FGFR2 and ErbB2. The Company was incorporated in March 2014 under the laws of the State of Delaware. On October 2, 2020 the Company filed an amendment to its certificate of incorporation to change its name from Unum Therapeutics Inc. to Cogent Biosciences, Inc. The name change became effective on October 6, 2020. In connection with the name change, the Company's common stock began trading under the ticker symbol "COGT" and the new CUSIP for the Company's common stock is 19240Q 201.

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, the impact of COVID-19, 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 $100.6 million for the nine months ended September 30, 2022. As of September 30, 2022, the Company had an accumulated deficit of $371.6 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 and 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, 2021 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited condensed consolidated financial statements as of September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021 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, 2021 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, 2022 and results of operations for the three and nine months ended September 30, 2022 and 2021 and cash flows for the nine months ended September 30, 2022 and 2021 have been made. The Company's results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022.

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 revenue and 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, the valuation of the CVR liability 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 Adopted Accounting Pronouncements

In August 2020, the FASB issued *ASU 2020-06 Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)* related to the measurement and disclosure requirements for convertible instruments and contracts in an entity's own equity. The pronouncement simplifies and adds disclosure requirements for the accounting and measurement of convertible instruments and the settlement assessment for contracts in an entity's own equity. The Company adopted ASU 2020-06 on January 1, 2022. The adoption of this guidance did not have a material impact on the Company's condensed consolidated 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, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury bills (due within one year)	$ 148,689	$ 5	$ (168)	$ 148,526
	$ 148,689	$ 5	$ (168)	$ 148,526

The Company did not hold any marketable securities as of December 31, 2021.

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, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 117,982	$ —	$ —	$ 117,982
Marketable securities:				
U.S. Treasury bills and notes	$ —	$ 148,526	$ —	$ 148,526
Total Assets	$ 117,982	$ 148,526	$ —	$ 266,508
Liabilities:				
CVR Liability	$ —	$ —	$ 3,060	$ 3,060
Total Liabilities	$ —	$ —	$ 3,060	$ 3,060

	Fair Value Measurements at December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
CVR Liability	$ —	$ —	$ 3,060	$ 3,060
Total Liabilities	$ —	$ —	$ 3,060	$ 3,060

Money market funds 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.

On July 6, 2020, the Company issued a non-transferrable contingent value right ("CVR"), which was distributed to stockholders of record as of the close of business on July 6, 2020, and prior to the issuance of any shares to acquire Kiq Bio LLC ("Kiq") (the "Kiq Acquisition") or sold to the Private Investment in Public Equity ("PIPE") investors. Holders of the CVR are entitled to receive common shares and/or cash payments from proceeds received by the Company, if any, related to the disposition of its legacy cell therapy assets for a period of three years from July 2020. In accordance with the terms of the CVR agreement, the payment to CVR holders will be made in shares or cash, depending on the timing of the receipt of the sales proceeds by the Company. For sales proceeds received by the Company prior to December 31, 2020, CVR holders were entitled to receive payment in the form of common shares of the Company. For sales proceeds received by the Company after December 31, 2020 and prior to July 2023, CVR holders are entitled to receive payment in cash.

The Company classifies the CVR as a liability on its condensed consolidated balance sheet. The fair value of the CVR liability was determined using the probability weighted discounted cash flow method to estimate future cash flows associated with the sale of the legacy cell therapy assets, including the Bolt-on Chimeric Receptor ("BOXR") technology and Autologous Cell Therapy Industrial Automation technology (collectively, the "BOXR Platform"), Antibody-Coupled T cell Receptor technology and other fixed assets based on assumptions at the date of the CVR issuance and each subsequent quarterly period end, less certain permitted deductions. For sales proceeds received by the Company prior to December 31, 2020, the number of common shares to be received by CVR holders was determined by dividing the proceeds received by the Company by the closing price of the Company's common stock on July 6, 2020 of $8.80. The closing price of the Company's common stock at each measurement date through February 2021 was used to determine the fair value of the share payments included in the CVR liability. The liability measured at the date of CVR issuance was recorded as a common stock dividend, returning capital to the legacy stockholders of record as of the close of business on July 6, 2020. Changes in fair value of the liability are recognized as a component of Other income (expense) in the condensed consolidated statement of operations and comprehensive loss. The CVR liability was valued based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. On August 28, 2020, the Company sold the BOXR Platform and subsequently sold additional fixed assets, triggering a payment to CVR holders. In November 2020, the Company issued 707,938 shares of common

stock in partial settlement of the CVR liability. In February 2021, the Company issued an additional 212,429 shares of common stock and paid $0.1 million in partial settlement of the CVR liability. Any settlement of the remaining CVR liability will be a cash settlement.

The following table sets forth a summary of the changes in the fair value of the Company's CVR liability *(in thousands)*:

Balance at December 31, 2020	$	5,531
Change in fair value		(343)
CVR settlement		(2,128)
Balance at December 31, 2021	$	3,060
Change in fair value		—
CVR settlement		—
Balance at September 30, 2022	$	3,060

During the three and nine months ended September 30, 2022 and 2021, 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, 2022	December 31, 2021
Accrued employee compensation and benefits	$ 4,069	$ 3,389
Accrued external research and development expense	4,860	1,953
Accrued external manufacturing costs	1,536	1,556
Accrued professional and consulting services	2,722	1,077
Other	1,197	235
Total	$ 14,384	$ 8,210

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

The Company's authorized capital stock consists of 150,000,000 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 and 9,000,000 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 "Certificate of Designation") in connection with the Kiq Acquisition and the PIPE. The 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 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) prior to the stockholder approval of the Conversion Proposal or 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 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. Cumulatively, through September 30, 2022, 82,275 shares of Series A Preferred Stock, or 50.4% of the issued Series A Preferred Stock, have been converted into 20,568,750 shares of common stock. The 81,050 shares of Series A Preferred Stock outstanding as of September 30, 2022 are convertible into 20,262,500 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, 2022.

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 February 8, 2021, 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 $200.0 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. On May 6, 2022, the Company filed an Amendment to its February 8, 2021 S-3 Registration Statement to terminate the effectiveness of the registration statement and to remove from registration all securities registered but not sold under the registration statement.

Additionally, on February 8, 2021, pursuant to the Form S-3, the Company entered into a Sales Agreement (the "SVB Sales Agreement") with SVB Leerink LLC ("SVB Leerink"), 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 SVB Leerink as the sales agent. Cumulatively, the Company has sold 3,954,900 shares of common stock under the SVB Sales Agreement with offering prices ranging between $9.25 and $10.30 per share for net proceeds of approximately $38.0 million. The Company terminated the existing SVB Sales Agreement, effective as of May 5, 2022. The Company did not incur any termination penalties as a result of the termination of the SVB Sales Agreement. No shares were sold under the SVB Sales Agreement.

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, 2022, 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, 2022, 2,424,242 pre-funded warrants have been exercised.

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. The number of authorized shares reserved for issuance under the 2018 Plan was increased by 1,752,237 shares effective as of January 1, 2022. 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.

On June 16, 2021, 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. Upon stockholder approval, in accordance with *ASC 718- Compensation- Stock Compensation*, a grant date was established for accounting purposes with respect to 3,402,768 options previously granted to employees and non-employee directors during the year ended December 31, 2021, which were subject to stockholder approval of the amendment and restatement of the 2018 Plan.

As of September 30, 2022, 1,034,467 shares of common stock remain available for issuance under the 2018 Plan.

Inducement Plan

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, 2022, 728,995 shares of common stock remain available for issuance under the Inducement Plan.

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, 2022. In January 2022, 18,995 shares were issued to employees under the ESPP. In July 2022, 30,005 shares were issued to employees under the ESPP. As of September 30, 2022, 412,919 shares remain available for issuance under the ESPP.

Stock-Based Compensation

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,	
	2022	2021	2022	2021
Research and development expenses	$ 2,049	$ 1,436	$ 6,080	$ 2,650
General and administrative expenses	2,573	2,027	7,251	5,184
Total	$ 4,622	$ 3,463	$ 13,331	$ 7,834

As of September 30, 2022, total unrecognized compensation cost related to the unvested stock-based options was $49.0 million, which is expected to be recognized over a weighted average period of 2.74 years.

7. Commitments and Contingencies

Operating Leases

Corporate Headquarters- Waltham, MA

On March 19, 2022, the Company and Cimpress USA Incorporated (the "Cimpress") entered into a sublease agreement (the "Waltham Sublease") pursuant to which the Company subleases approximately 17,749 square feet of office space in Waltham, MA, which serves as the Company's corporate headquarters. The Waltham Sublease became effective on May 5, 2022.

The Waltham Sublease has a term of four years and four months, commencing June 1, 2022 and expiring September 30, 2026. The Company will pay Cimpress base rent at an initial rate of $42.50 per square foot per year. Rent will be payable in equal monthly installments and subject to $1.00 per square foot annual increases over the term. Additionally, the Company is responsible for reimbursing Cimpress for the Company's share of the building's property taxes and operating expenses. In connection with the Waltham Sublease, the Company provided a cash security deposit to the landlord in an amount of $0.4 million which is recorded in Other Assets in the condensed consolidated balance sheet as of September 30, 2022.

The lease commencement date occurred in May 2022, following landlord consent, as the Company gained access to the space under the terms of the lease. The Company has recorded a right-of-use asset and lease liability for this lease component of $2.9 million at the lease commencement date.

Research Facility- Boulder, CO

On July 6, 2021, the Company entered into a lease agreement (the "Original Lease") pursuant to which the Company leases approximately 38,075 square feet (the "Initial Premises") in Boulder, CO, which will include office and laboratory space. Subsequently, on March 29, 2022, the Company entered into the First Amendment to the lease agreement (the "First Amendment" and together with the Original Lease, the "Boulder Lease") pursuant to which the Company leases approximately 6,582 square feet of additional office space on the second floor (the "Expansion Premises").

Per the terms of the Original Lease, the landlord will contribute an aggregate of approximately $6.9 million toward the cost of landlord assets (the "Improvements"), as well as an additional amount of up to approximately $2.3 million in the form of a tenant improvement loan at an annual interest rate of 6%. Any monies borrowed under the tenant improvement loan are required to be repaid over the Boulder Lease term. Additionally, under the terms of the First Amendment, the landlord will provide an additional tenant improvement allowance (the "Additional Allowance") of $0.6 million, of which $0.3 million will be used in the Initial Premises toward the cost of landlord assets. The remaining $0.3 million Additional Allowance is to be used for work to be performed in the Expansion Premises for the construction of lessee assets. The Company incurred net construction costs of approximately $7.0 million for the development of the Initial Premises at the Boulder location.

The Boulder Lease has an initial term of 12 years with the option to extend for three successive five-year terms. Boulder Lease payments will begin in June 2023 after an initial free rent period. Rent will be payable in equal monthly installments and subject to annual increases over the term. Additionally, the Company is responsible for reimbursing the landlord for its share of the building's property taxes and operating expenses. The Boulder Lease is an operating lease. In connection with the Boulder Lease, the Company provided a cash security deposit to the landlord in an amount of $0.7 million which is recorded in Other Assets in the condensed consolidated balance sheet as of September 30, 2022.

The Company has recorded the initial right-of-use assets and lease liabilities for the lease components of $22.3 million as of the lease commencement dates.

Former Corporate Headquarters- Cambridge, MA

The Company leases office and laboratory space in Cambridge, MA under a non-cancelable operating lease (the "Cambridge Lease") that expires in April 2023.

In August 2020, the Company entered into a sublease (the "Cambridge Sublease Agreement") for a significant portion of the leased premises for the remaining term of the lease. Under the terms of the Cambridge Sublease Agreement, the sublessee leased approximately 70% of the facility and is responsible for the corresponding percentage of operating lease costs and variable lease costs. Variable lease costs include common area maintenance and other operating charges.

The Company recorded a right-of-use impairment charge of $0.4 million during the three and nine months ended September 30, 2022, following the move of the Corporate Headquarters from Cambridge, MA to Waltham, MA.

The elements of the lease expense, net of sublease income, were as follows (in thousands):

	Nine Months Ended September 30, 2022
Lease cost	
Operating lease cost	$ 7,286
Variable lease cost (1)	736
Sublease Income	(1,962)
Total lease cost	$ 6,060
Other information	
Cash paid for amounts included in the measurement of lease liabilities	$ 8,022
Weighted average remaining lease term	10.70
Weighted average discount rate	8.07%

(1) The variable lease costs for the nine months ended September 30, 2022 include common area maintenance and other operating charges.

Future minimum lease payments under the Cambridge and Boulder operating leases commenced as of September 30, 2022 are as follows (in thousands):

Year Ending December 31,	
2022 (remaining 3 months)	2,510
2023	2,544
2024	2,780
2025	2,841
2026	2,697
Thereafter	19,678
Total future minimum lease payments	33,050
Less: imputed interest	12,706
Less: tenant improvement allowance receivable	263
Total operating lease liability	$ 20,081
Included in the condensed consolidated balance sheet:	
Current operating lease liability	$ 2,014
Operating lease liability, net of current portion	18,067
Total operating lease liability	$ 20,081

Under the terms of the Cambridge Lease, the Company issued a $1.3 million letter of credit to the landlord as collateral for the leased facility. The underlying cash collateralizing this letter of credit has been classified as current restricted cash in the accompanying condensed consolidated balance sheets. This is a refundable deposit and not a lease payment. Under the terms of the Cambridge Sublease Agreement, the sublessee obtained a letter of credit for $1.3 million for the benefit of the Company. This has been excluded from the undiscounted cash flows above.

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. ("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 Company's review of the progression of the Peak study and discussions with Plexxikon, the first clinical milestone was deemed to have been achieved, resulting in payment of $2.5 million to Plexxikon in June 2022. As of September 30, 2022, no other milestone payments have been made or accrued.

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 validate claim of a licensed Plexxikon patent covering a subject product in such country or (ii) the 10^{th} 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, 2022 or its consolidated financial statements as of December 31, 2021.

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,	
	2022	2021	2022	2021
Numerator:				
Net loss	$ (35,062)	$ (19,084)	$ (100,623)	$ (47,361)
Net loss attributable to common stockholders	$ (35,062)	$ (19,084)	$ (100,623)	$ (47,361)
Denominator:				
Weighted average common shares outstanding, basic and diluted	69,576,359	39,848,943	54,780,041	37,741,526
Net loss per common share, basic and diluted	$ (0.50)	$ (0.48)	$ (1.84)	$ (1.25)

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,	
	2022	2021
Stock options to purchase common stock	12,471,244	8,156,538
Series A Preferred Stock	20,262,500	25,822,250
	32,733,744	33,978,788

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 $0.1 million and $0.5 million for the three and nine months ended September 30, 2022, respectively. Contributions under the plan were approximately $0.1 million and $0.3 million for the three and nine months ended September 30, 2021, respectively.

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

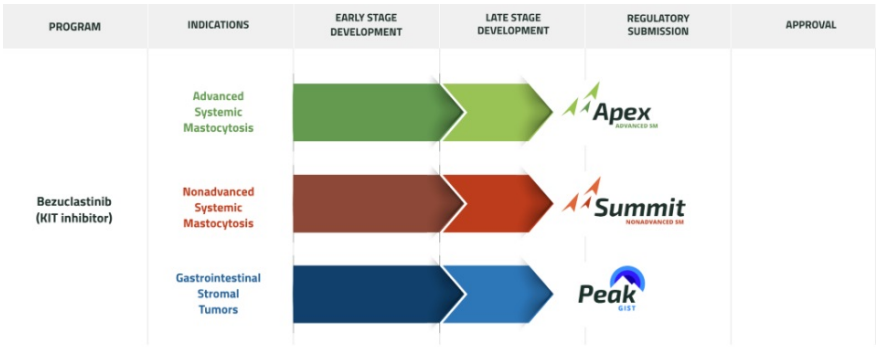
The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K. Some of the information 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 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 lead drug candidate, bezuclastinib, is designed to target exon 17 mutations found within the KIT receptor tyrosine kinase, including KIT D816V. When KIT D816V remains in a perpetual 'on' state it causes mast cells, a type of white blood cell, to accumulate in various internal organs including the bone marrow. The result is an orphan disease called Systemic Mastocytosis ("SM"). Exon 17 mutations have also been found in advanced Gastrointestinal Stromal Tumors ("GIST"), which have a strong dependence on oncogenic KIT signaling. Bezuclastinib is a highly selective and potent KIT inhibitor with the potential to provide a powerful new treatment option for patients with both of these diseases. 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 FGFR2 and ErbB2.

Pipeline

Our current pipeline is below:



Bezuclastinib

Bezuclastinib is a selective tyrosine kinase inhibitor that is designed to potently inhibit the KIT D816V mutation as well as other mutations in KIT exon 17. KIT D816V is responsible for driving systemic mastocytosis, a serious disease caused by unchecked proliferation of mast cells. Exon 17 mutations are also found in patients with GIST, a type of cancer with strong dependence on oncogenic KIT signaling

We are pursuing the development of bezuclastinib in patients living with GIST based on our study of more than 50 advanced solid tumor and GIST patients in a Phase 1/2 clinical trial, with the vast majority of those patients living with advanced GIST. GIST is a disease frequently driven by KIT mutations, and resistance to currently available therapeutics is frequently associated with the emergence of other KIT mutations. Anti-tumor activity for bezuclastinib was observed in both single agent and combination settings, including in combination with sunitinib, an approved treatment option for GIST patients. Clinical data from this trial have been published in the Journal of American Medical Association and have been presented at several scientific conferences, including most recently by Cogent at the 2020 annual Connective Tissue Oncology Society ("CTOS") meeting, and previously by Plexxikon Inc. ("Plexxikon"), a member of the Daiichi Sankyo Group, at the 2018 annual American Society of Clinical Oncology meeting and the 2017 annual CTOS meeting. Within the group of 15 heavily pre-treated GIST patients who received the combination of bezuclastinib and sunitinib, and who had not received prior treatment with bezuclastinib, the confirmed objective response rate was twenty percent, including two partial responses and one complete response, while the estimated median progression free survival ("mPFS") for this group was twelve months. Four subjects continued to receive bezuclastinib via individual patient INDs beyond the conclusion of the trial. In October 2021, we presented preclinical data in a virtual poster at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics that identified bezuclastinib as a differentiated, potent and selective KIT mutant inhibitor with unique selectivity for KIT D816V and minimal evidence of brain penetration that avoids targeting PDGFR isoforms. In April 2022, we presented additional preclinical data at the 2022 American Associated for Cancer Research annual meeting ("AACR") demonstrating that bezuclastinib potently inhibits A loop-mutations exquisitely selective against other closely related kinases, and differentiates bezuclastinib by its lack of brain penetration. These data support that bezuclastinib inhibits KIT downstream signaling and may drive tumor regressions at clinically achievable doses.

We are continuing the development bezuclastinib in GIST in our PEAK study. 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 has granted orphan drug designation to bezuclastinib for the treatment of GIST.

In November 2021, through a partnership with Serán Biosciences, we announced the development of an optimized formulation of bezuclastinib, which was used in the PEAK lead-in study. Based on the data from the PEAK lead-in study we have initiated the randomized portion of PEAK using a 600 mg dose of a new formulation of bezuclastinib, which in the lead-in portion of the study demonstrated clinical exposure equivalent to the 1,000 mg original formulation used in our GIST Phase 1/2 clinical trial. Initial safety and pharmacokinetic data from the PEAK lead-in study will be presented at the CTOS annual meeting in November 2022. We expect to present initial efficacy data from the PEAK lead-in study in the first half of 2023.

Along with the development of bezuclastinib in GIST, we are continuing the development of bezuclastinib in patients living with Advanced Systemic Mastocytosis ("AdvSM") and Non-Advanced Systemic Mastocytosis ("Non-AdvSM"). 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, there are no available approved therapies, and 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.

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 initial clinical data from the ongoing APEX trial at the 2022 European Hematology Association Annual Congress. As of the data cutoff date of May 24, 2022, 11 out of 11 patients treated with bezuclastinib achieved at least a 50% reduction in serum tryptase, with a median reduction of 89%, regardless of prior KIT D816V inhibitor treatment; 8 of 8 bone marrow biopsy-assessed patients achieved at least a 50% bone marrow mast cell reduction and decreases in blood KIT D816V variant allele fraction. Bezuclastinib was generally well-tolerated at all doses and all patients remained on study. We believe that this early data demonstrates a favorable initial safety and tolerability profile with no reported periorbital or peripheral edema, cognitive effects or intracranial bleeding events. The majority of adverse events were Grade 1/2 and seen in no more than one patient with one serious adverse event and no Grade 4 events reported. We plan to present updated APEX clinical data in an oral presentation at the American Society of Hematology Annual Meeting in December 2022.

SUMMIT is our randomized, double-blind, placebo-controlled, global multi-center Phase 2 clinical trial for patients with Non-AdvSM. The study is designed to evaluate the safety and efficacy of bezuclastinib in patients with moderate to severe Indolent Systemic Mastocytosis or Smoldering Systemic Mastocytosis. Based on the performance of bezuclastinib's new formulation in the PEAK lead-in trial, as well as in a healthy normal volunteer study, the SUMMIT trial protocol will be amended to allow for the new formulation to be introduced during the dose exploration phase. We expect to report initial data from the SUMMIT trial in the second half of 2023.

Worldwide rights to develop and commercialize bezuclastinib are exclusively licensed from 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. In April 2022, as a result of our review of the progression of the Peak study and discussions with Plexxikon, the first clinical milestone was deemed to have been achieved, triggering a payment of $2.5 million to Plexxikon in Q2 2022.

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 intend to file a provisional patent application seeking to protect our new formulation of bezuclastinib, which could potentially provide exclusivity through at least 2043.

Research programs

During the second quarter of 2021, we announced the formation of the Cogent Research Team, a highly experienced discovery and research group. Based in Boulder, Colorado, the Cogent Research Team 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. 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. Preclinical data presented at EORTC-NCI-AACR in October of 2022, detailed our next-generation fibroblast growth factor receptor 2 ("FGFR2") program. The current series retains potency across all primary, gatekeeper and molecular brake resistance mutations. The disclosure includes an overview of ongoing optimization of the Cogent lead series, pharmacokinetic and pharmacodynamic assessment of an FGFR1-sparing novel molecule, as well as robust efficacy in model of FGFR2 clinical resistance (N549K). We remain on track for an IND in 2023 for a potentially best-in-class, FGFR1-sparing, pan-FGFR2 mutation tyrosine kinase inhibitor with IND enabling studies in early 2023.

We are also advancing a novel, ErbB2 mutant program, which is focused on actionable and underserved mutations in a variety of solid tumor indications. Currently available oral ErbB2 inhibitors struggle to provide broad mutant coverage while sparing EGFR activity. Our exemplar molecule demonstrates robust cellular inhibition of all key resistance and primary driver mutations, while sparing wild type EGFR target engagement. Preclinical data presented at EORTC-NCI-AACR in October of 2022, focused on a single advanced exemplar compound, which demonstrated dose ascendable pharmacokinetics, robust tumor phospho-ErbB2 suppression (L755S), and superior tumor growth inhibition when compared to the clinical competitor tucatinib.

For both FGFR and ErBB2, we see an opportunity to provide a more robust molecular response compared to existing therapies.

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 $100.6 million for the nine months ended September 30, 2022 compared to net losses of $47.4 million for the nine months ended September 30, 2021. As of September 30, 2022, we had an accumulated deficit of $371.6 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, including through the creation of the Cogent Research Team in Boulder, CO, and build out our lab facility in Boulder, CO;
- 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, 2022, we had cash, cash equivalents and marketable securities of $289.1 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 into 2025.

The COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel strain of coronavirus, or COVID-19, as a pandemic, which has spread throughout the United States and worldwide. We could be materially and adversely affected by the risks, or the public perception of the risks, related to an epidemic, pandemic, outbreak, or other public health crisis, such as the recent outbreak of COVID-19 or variants thereof. We continue to monitor the pandemic and have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address the COVID-19 pandemic. The spread of COVID-19 has caused us to modify our business practices, including implementing a work-from-home policy for all employees who are able to perform their duties remotely and restricting all nonessential travel, and we expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees, the patients we serve and other business partners in light of COVID-19. Given the fluidity of the COVID-19 pandemic however, we do not yet know the full extent of the potential impact of COVID-19 on our business operations. The ultimate extent of the impact of any epidemic, pandemic, outbreak, or other public health crisis on our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of such epidemic, pandemic, outbreak, or other public health crisis and actions taken to contain or prevent the further spread, among others. Accordingly, we cannot predict with certainty the extent to which our business, financial condition and results of operations will be affected. We will continue to work diligently with our partners and stakeholders to continue advancing our product candidate under regulatory review as well as in our clinical studies to the extent safe to do so for patients, caregivers and healthcare practitioners, and ensuring the continuity of our manufacturing and supply chain.

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;
- 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, 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.

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 headquarters facilities.

Change in Fair Value of the CVR liability

This consists of changes in the fair value of the 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 research and development 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, 2021. We reevaluate the utilization of net operating loss carryforwards and tax credits at each reporting period. As of December 31, 2021, we had U.S. federal and state net operating loss carryforwards of $128.8 million and $47.1 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2035. Of the federal net operating loss carryforwards at December 31, 2021, $125.5 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, 2021, we also had U.S. federal and state research and development tax credit carryforwards of $3.1 million and $0.8 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2040 and 2035, respectively.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development 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, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Operating expenses:			
Research and development	29,936	14,798	15,138
General and administrative	6,885	5,021	1,864
Total operating expenses	36,821	19,819	17,002
Loss from operations	(36,821)	(19,819)	(17,002)
Other income:			
Interest income	1,500	115	1,385
Other income, net	259	620	(361)
Total other income, net	1,759	735	1,024
Net loss	$ (35,062)	$ (19,084)	$ (15,978)

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Direct external research and development expenses:			
Bezuclastinib	$ 12,824	$ 6,686	6,138
Preclinical research and discovery	4,310	1,446	2,864
Unallocated expenses:			
Personnel related (including stock-based compensation)	9,289	5,218	4,071
Laboratory supplies, facility related and other	3,513	1,448	2,065
Total research and development expenses	$ 29,936	$ 14,798	$ 15,138

Total research and development expense increased by $15.1 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 and the increase was 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 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 $0.6 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021. This is further driven by increased lab supplies and other facilities costs to support the build-out of the Cogent Research Team.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2022 were $6.9 million, compared to $5.0 million for the three months ended September 30, 2021. 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 $0.5 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021.

Interest Income

Interest income for the three months ended September 30, 2022 was $1.5 million, compared to $0.1 million for the three months ended September 30, 2021 . The increase is due to higher average invested balances in cash equivalents and marketable securities.

Other Income, Net

Other income, net was $0.3 million in the three months ended September 30, 2022, compared to $0.6 million for the three months ended September 30, 2021. Other income represents sublease income recognized resulting from the sublease of a portion of our former corporate headquarters space, partially offset by the right-of-use asset impairment charge recorded for this space.

Change in Fair Value of CVR Liability

There was no change in fair value of the CVR liability for the three months ended September 30, 2022. Any settlement of the remaining liability will be a cash settlement.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 84,885	35,399	49,486
General and administrative	19,209	14,512	4,697
Total operating expenses	104,094	49,911	54,183
Loss from operations	(104,094)	(49,911)	(54,183)
Other income:			
Interest income	1,879	360	1,519
Other income, net	1,592	1,847	(255)
Change in fair value of CVR liability	—	343	(343)
Total other income, net	3,471	2,550	921
Net loss	$ (100,623)	$ (47,361)	$ (53,262)

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Direct external research and development expenses:			
Bezuclastinib	$ 42,357	$ 19,300	23,057
Preclinical research and discovery	9,280	1,877	7,403
Unallocated expenses:			
Personnel related (including stock-based compensation)	25,238	10,408	14,830
Laboratory supplies, facility related and other	8,010	3,814	4,196
Total research and development expenses	$ 84,885	$ 35,399	$ 49,486

Total research and development expense increased by $49.5 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 and the increase was 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 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, 2022 compared to the nine months ended September 30, 2021. This is further driven by increased lab supplies and other facilities costs to support the build-out of the Cogent Research Team.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2022 were $19.2 million, compared to $14.5 million for the nine months ended September 30, 2021. 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 $2.1 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021.

Interest Income

Interest income for the nine months ended September 30, 2022 was $1.9 million, compared to $0.4 million for the nine months ended September 30, 2021. The increase is due to higher average invested balances in cash equivalents and marketable securities.

Other Income, Net

Other income, net was $1.6 million in the nine months ended September 30, 2022, compared to $1.8 million for the nine months ended September 30, 2021. Other income represents sublease income recognized resulting from the sublease of a portion of our former corporate headquarters space, partially offset by the right-of-use asset impairment charge recorded for this space.

Change in Fair Value of CVR Liability

There was no change in fair value of the CVR liability for the nine months ended September 30, 2022. Any settlement of the remaining liability will be a cash settlement.

Liquidity and Capital Resources

We have incurred certain costs related to the COVID-19 outbreak as a result of taking necessary precautions for essential personnel to operate safely both in person as well as remotely. Costs incurred include items like incremental payroll costs, consulting support, IT infrastructure and facilities related costs. The estimated impact of COVID-19 is currently unknown. The final impact may vary based on the duration of the current social and economic conditions. To the extent the COVID-19 pandemic continues, it may materially impact our financial condition, liquidity or results of operations in the future. We do not currently believe the accumulated costs will present a material impact to our financial liquidity or position.

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, 2022, 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.

As of September 30, 2022, the Company has 90,726,532 shares outstanding on a fully diluted and as-converted basis, including the 69,857,972 shares of common stock outstanding, the 606,060 pre-funded warrants that are exercisable for shares of common stock, and the 81,050 shares of Series A Preferred stock, which are convertible into 20,262,500 shares of common stock.

As of September 30, 2022, we had cash, cash equivalents and marketable securities of $289.1 million, which we believe will be sufficient to fund our operating expenses and capital expenditure requirements into 2025.

Cash Flows

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

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Cash used in operating activities	$ (89,230)	$ (37,986)
Cash used in investing activities	(153,129)	(1,286)
Net cash (used in) provided by financing activities	163,243	(30)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (79,116)	$ (39,302)

Operating Activities

During the nine months ended September 30, 2022, operating activities used $89.2 million of cash, primarily resulting from our net loss of $100.6 million and net cash used in changes in our operating assets and liabilities of $6.0 million, partially offset by net noncash charges of $17.4 million. Net cash used in changes in our operating assets and liabilities for the nine months ended September 30, 2022 consisted primarily of a $3.1 million increase in prepaid expenses other current assets, a $1.0 million increase in other assets, and a $8.3 million decrease in the operating lease liability partially offset by a $6.4 million increase in accounts payable and accrued expenses and other current liabilities.

During the nine months ended September 30, 2021, operating activities used $38.0 million of cash, primarily resulting from our net loss of $47.4 million, partially offset by net cash provided by changes in our operating assets and liabilities of $1.8 million and by net noncash charges of $7.6 million. Net cash provided by changes in our operating assets and liabilities for the nine months ended September 30, 2021 consisted primarily of a $5.9 million increase in accounts payable and accrued expenses and other current liabilities, and a $1.3 million decrease in the right-of-use asset, partially offset by a $1.9 million increase in prepaid expenses and other current assets, a $2.0 million increase in other assets and a $1.5 million decrease in the operating lease liability.

Investing Activities

During the nine months ended September 30, 2022, net cash used in investing activities was $153.1 million which consisted of purchases of property and equipment and marketable securities.

During the nine months ended September 30, 2021, net cash used in investing activities was $1.3 million which consisted primarily of purchases of property and equipment.

Financing Activities

During the nine months ended September 30, 2022, net cash provided by financing activities was $163.2 million, which consisted of $161.9 million in proceeds from the issuance of common stock and pre-funded warrants in an underwritten public offering, net of paid offering costs, proceeds from the issuance of common stock under the Employee Stock Purchase Plan, proceeds from the issuance of common stock upon stock option exercises and proceeds from pre-funded warrant exercises.

During the nine months ended September 30, 2021, net cash used in financing activities was $0.1 million, which consisted of the proceeds from the issuance of common stock upon stock option exercises and from the issuance of common stock under the Employee Stock Purchase Plan.

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, including the impact of COVID-19 on our ongoing and planned research and development efforts;
- 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;

- the cost and timing of completion of the build out of our new office and laboratory facility in Boulder, CO;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates; and
- the impact of COVID-19 on the operations of key governmental agencies, such as the FDA, which may delay the development of our current product candidates or any future product candidates.

Based on our current plans, we believe that our existing cash, cash equivalents and marketable securities of $289.1 million as of September 30, 2022 will enable us to fund our operating expenses and capital expenditure requirements into 2025. 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. The Company 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, 2022, 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.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 (“JOBS Act”) permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are a smaller reporting company, as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended, for this reporting period and are not required to provide the information required under this item.

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, 2022. 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, 2022, 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, 2022 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.

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as our other filings with the Securities and Exchange Commission, before deciding whether to invest in our common stock. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to the Discovery and Development of Our Drug Candidates

Our business is highly dependent on the success of our bezuclastinib program and our ability to discover and develop additional product candidates. We may not be successful in our efforts to develop bezuclastinib or expand our pipeline of drug candidates.

Our business and future success depend on our ability to develop, obtain regulatory approval for and then successfully commercialize bezuclastinib and any other product candidates that we may discover and develop. We are pursuing clinical development of bezuclastinib to target SM and GIST through our APEX, SUMMIT and PEAK clinical trials. There is no guarantee that any or all of these trials will be successful. Even if our trials are successful, bezuclastinib will require regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we are able to generate any revenue from product sales, if ever.

Through the development of the research team, we are also working to build a pipeline of other product candidates. Researching, developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding beyond the net proceeds from the public offering and private placement of our securities and consideration received from our collaborative agreements and is prone to the risks of failure inherent in medical product development. Even if we are successful in continuing to build and expand our pipeline, we cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process, or that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

If unacceptable side effects are identified during the development of our drug candidates, we may need to abandon or limit such development.

If our drug candidates are associated with unacceptable side effects in preclinical or clinical trials or have characteristics that are unexpected, we may need to abandon their development, limit development to more narrow uses or subpopulations in which the unacceptable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective or highlight these risks, side effects, or other characteristics in the approved product label. In pharmaceutical development, many drugs that initially show promise in early-stage testing for treating cancer may later be found to cause side effects that prevent further development of the drug. Currently marketed therapies for the treatment of cancer are generally limited to some extent by their toxicity. In addition, some of our drug candidates would be chronic therapies or used in pediatric populations, for which safety concerns may be particularly important. Use of our drug candidates as monotherapies may also result in adverse events consistent in nature with other marketed therapies. In addition, if used in combination with other therapies in the future, our drug candidates may exacerbate adverse events associated with the therapy. If unexpected side effects are identified during development, we may be required to develop a Risk Evaluation and Mitigation Strategy ("REMS") to mitigate those serious safety risks, which could impose significant distribution and/or use restrictions on our products.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The development and commercialization of new pharmaceutical and biotechnology products is highly competitive. We face competition with respect to our current clinical-stage drug candidates and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our drug candidates. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have superior dosing regimens, have fewer or less severe side effects, are approved for broader indications or patient populations, are approved for specific sub-populations, are more convenient or are less expensive than bezuclastinib or any other products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than any approval we may obtain for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals, and marketing and selling approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

We may choose not to develop a potential product candidate, or we may suspend, deprioritize or terminate one or more discovery programs or preclinical or clinical product candidates or programs.

At any time and for any reason, we may determine that one or more of our discovery programs or preclinical or clinical product candidates or programs does not have sufficient potential to warrant the allocation of resources toward such program or product candidate. Accordingly, we may choose not to develop a potential product candidate or elect to suspend, deprioritize or terminate one or more of our discovery programs or preclinical or clinical product candidates or programs. If we suspend, deprioritize or terminate a program or product candidate in which we have invested significant resources, we will have expended resources on a program or product candidate that will not provide a full return on our investment and may have missed the opportunity to have allocated those resources to potentially more productive uses, including existing or future programs or product candidates.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, but we may not realize any resulting benefits.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. In particular, we may seek to enter into collaborations with our bezuclastinib program and other collaborations to progress the clinical development of the bezuclastinib program. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval. Further, collaborations involving our product candidates are subject to numerous technical, business, and legal risks. Even if we are successful in entering into a collaboration with respect to the development and/or commercialization of one or more product candidates, there is no guarantee that the collaboration will be successful.

The incidence and prevalence for target patient populations of our drug candidates have not been established with precision. If the market opportunities for our drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue potential and ability to achieve profitability will be adversely affected.

The precise incidence and prevalence for GIST and SM are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug candidates, are based on estimates, which are inherently uncertain. The total addressable market opportunity for bezuclastinib , and any other drug candidates we may produce will ultimately depend upon, among other things, the diagnosis criteria included in the final label for our future approved drugs for sale for these indications, acceptance by the medical community and patient access, drug pricing, and reimbursement. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drug, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

The commercial success of any future approved drugs, including bezuclastinib, will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

If bezuclastinib and any future approved drugs do not achieve an adequate level of acceptance by physicians, patients, third-party payors, and others in the medical community, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of bezuclastinib and of any current or future drug candidates, if approved for commercial sale, will depend on a number of factors, including the availability, perceived advantages, and relative cost, safety, and efficacy of alternative and competing treatments; and the prevalence and severity of any side effects, adverse reactions, misuse, or any unfavorable publicity in these areas, in particular compared to alternative treatments. Even if a potential drug displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the drug will not be known until after it is launched.

Clinical trials are expensive, time-consuming, and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. We are unable to predict when or if our drug or any of our drug candidates will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, interim or preliminary results of a clinical trial do not necessarily predict final results, and results for one indication may not be predictive of the success in additional indications. In particular, the small number of patients in our early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy, or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our drug or drug candidates. Our product development costs will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured, or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates and may harm our business and results of operations.

Since the number of patients that we have dosed to date in our clinical trials is small, the results from such clinical trials may be less reliable than results achieved in larger clinical trials.

A study design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of trials with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the study results less reliable than studies with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. In our current and any future clinical trials, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we may have seen in prior clinical trials or preclinical studies.

As difficulties arise enrolling patients in our clinical trials, clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. As an example, clinical trial site start-up and patient enrollment in our Phase 2 SUMMIT trial has been slower than originally forecast. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including: the patient eligibility criteria defined in the protocol; the size of the patient population required for analysis of the trial's primary endpoints; and our ability to recruit clinical trial investigators with the appropriate competencies and experience.

In addition, our clinical trials compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Additional delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, may be interpreted differently if additional data are disclosed, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or "top-line" data from our clinical trials, which may be based on a preliminary analysis of then-available data in a summary or "top-line" format, and the results and related findings may change as more patient data become available, may be interpreted differently if additional data are disclosed at a later time and are subject to audit and verification procedures that could result in material changes in the final data. If additional results from our clinical trials are not viewed favorably, our ability to obtain approval for and commercialize our drug candidates, our business, operating results, prospects, or financial condition may be harmed and our stock price may decrease.

We may not be able to file investigational new drug applications ("IND"s) or IND amendments or clinical trial authorization applications ("CTA"s) to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or other regulatory authorities may not permit us to proceed.

Our timing of filing INDs or CTAs on our product candidates is dependent on further research. We cannot be sure that submission of an IND or CTA will result in the FDA or other regulatory authority allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials.

We have limited experience as a company conducting clinical trials.

We have limited experience as a company in conducting clinical trials. In part because of this lack of experience, we cannot be certain that our ongoing clinical trials will be completed on time or if the planned clinical trials will begin or be completed on time, if at all.

Our updated bezuclastinib formulation is unproven and may not work as intended in clinical trials.

In November 2021 we announced an updated formulation of bezuclastinib which is intended to reduce the number of daily tablets required, thereby potentially improving the overall patient experience. This formulation is currently being used in our PEAK trial, as well as a Phase 1 clinical study evaluating the pharmacokinetics, relative bioavailability and food effects of bezuclastinib in healthy adults. The formulation is unproven to date, and there is no guarantee that it will be successful.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks and regulatory requirements related to operating in foreign countries if we obtain the necessary approvals. Risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products.

The current pandemic of the novel coronavirus, or COVID-19, and the future outbreak of other highly infectious or contagious diseases, could seriously harm our development efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.

The extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of such pandemic, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among others. The rapid development and fluidity of this situation precludes any prediction as to the full adverse impact of the COVID-19 pandemic. Nevertheless, the COVID-19 pandemic has already affected and may continue to adversely affect our business, financial condition and results of operations, including the below:

- Our operating plan currently includes efforts to advance bezuclastinib through further clinical development. We currently rely on third parties to, among other things, help conduct our clinical trials, manufacture raw materials, manufacture our product candidates and supply other goods and services to run our business. If our clinical trial sites or any third party in our supply chain for materials is adversely impacted by restrictions resulting from the COVID-19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our development timelines may be delayed and our supply chain may be disrupted, limiting our ability to enroll patients and manufacture our product candidate and conduct our research and development operations.
- The trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

Risks Related to Our Reliance on Third Parties

We currently rely and for the foreseeable future will continue to rely on third parties to conduct our clinical trials and to assist with various research and discovery activities. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates or discover new product candidates.

We depend and will depend upon independent investigators and collaborators, such as medical institutions, contract research organizations ("CROs"), commercial manufacturing organizations ("CMO"s) and strategic partners to conduct our preclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. We and these third parties are required to comply with good clinical practices ("GCP"s), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, failure or any failure by these third parties to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf.

If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

We also rely on third party vendors and collaborators to support our research and discovery efforts and to help expand our drug candidate pipeline, including certain third parties located in China, and we expect to continue to use such third parties. A natural disaster, epidemic or pandemic disease outbreaks, including the COVID-19 pandemic, trade war, political unrest or other local events could disrupt the business or operations of these third parties and thus negatively impact our research and discovery capabilities.

We contract with third parties for the manufacture of our drug candidates for preclinical development and clinical trials. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our drug candidates for preclinical development and clinical testing, as well as for the commercial manufacture of our current and future drugs. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not have long-term supply agreements with our contract manufacturers, and purchase our required drug supply, including the API and drug product used in our drug candidates, on a purchase order basis with certain contract manufacturers. In addition, we may be unable to establish or maintain any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish and maintain agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks. In addition, our drug candidates may compete with other drug candidates for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

For our other potential products, if we are not able to negotiate commercial supply terms with any such third-party manufacturers, we may be unable to commercialize our products if they were to be approved, and our business and financial condition would be materially harmed. If we are forced to accept unfavorable terms for our relationships with any such third-party manufacturer, our business and financial condition would be materially harmed.

Third-party manufacturers may not be able to comply with the FDA's cGMP regulations or similar regulatory requirements outside of the U.S. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of drug candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Third-party manufacturers' failure to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, also could result in patient injury or death, product shortages, delays or failures in product testing or delivery, cost overruns, or other problems that could seriously harm our business. Third-party manufacturers often encounter difficulties involving production yields, quality control, and quality assurance, as well as shortages of qualified personnel.

The third parties upon whom we rely for the supply of the API and drug product used in bezuclastinib are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The API and drug product used in bezuclastinib are currently supplied to us from single-source suppliers. Our ability to successfully develop our drug candidates and supply our drug candidates for clinical trials, depends in part on our ability to obtain the API and drug product for these drugs in accordance with regulatory requirements and in sufficient quantities for clinical testing. We will need to enter into arrangements to establish redundant or second-source supply of some of the API and drug product. If any of our suppliers ceases its operations for any reason or is unable or unwilling to supply API or drug product in sufficient quantities or on the timelines necessary to meet our needs, including as a result of the COVID-19 pandemic, it could significantly and adversely affect our business, the supply of our current or future drug candidates or any future approved drugs and our financial condition.

For bezuclastinib and any other product candidates, we intend to identify and qualify additional manufacturers to provide such API and drug product prior to submission of a New Drug Application ("NDA") to the FDA and/or a Marketing Authorization Application ("MAA") to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance and they may subordinate our needs in the future to their other customers.

While we seek to maintain adequate inventory of the API and drug product used in our current or future drug candidates and any future approved drugs, any interruption or delay in the supply of components or materials, or our inability to obtain such API and drug product from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

Risks Related to Regulatory Approval of Our Drug Candidates and Other Legal Compliance Matters

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We currently have one drug candidate in clinical development and its risk of failure is high. We are unable to predict when or if any of our drug candidates will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans.

While bezuclastinib is a highly potent and selective KIT D816V inhibitor that is being developed to treat SM and GIST patients, we may find that patients treated with bezuclastinib have or develop mutations that confer resistance to treatment. If patients have or develop resistance to treatment with our drug candidates, we may be unable to successfully complete our clinical trials, and may not be able to obtain regulatory approval of, and commercialize, our drug candidates.

Our product development costs will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our drug candidates. We may utilize companion diagnostics in our planned clinical trials in the future in order to identify appropriate patient populations for our drug candidates. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

Regulatory authorities, including the FDA, may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

We are conducting clinical trials with our lead product candidate, bezuclastinib, in patients with GIST, AdvSM and NonAdvSM. The FDA may not agree with our regulatory plans for initial registration of bezuclastinib in some or all of these indications and may require additional clinical trials to be conducted prior to approval. Our clinical trial results may also not support approval.

In addition, our product candidates could fail to receive regulatory approval for many reasons, including if we are unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications, or that our product candidates' clinical and other benefits outweigh their safety risks.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. We may also submit marketing applications in other countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

If we are unable to successfully develop companion diagnostic tests for our drug candidates that require such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these drug candidates.

We may develop, either by ourselves or with collaborators, in vitro companion diagnostic tests for our drug candidates for certain indications. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory, and logistical challenges. The FDA regulates in vitro companion diagnostics as medical devices that will likely be subject to clinical trials in conjunction with the clinical trials for our drug candidates, and which will require regulatory clearance or approval prior to commercialization. We may rely on third parties for the design, development, and manufacture of companion diagnostic tests for our therapeutic drug candidates that require such tests. If these parties are unable to successfully develop companion diagnostics for these therapeutic drug candidates, or experience delays in doing so, the development of these therapeutic drug candidates may be adversely affected or may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval.

The impact of healthcare legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. In fact, both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, regulations, and policies affecting coverage and reimbursement rates, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in potential coverage and reimbursement levels for our product candidates, if approved and commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect us.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under the regulations of the FDA and other similar foreign regulatory bodies will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.

In general, under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. As a result of the shares issued in July 2020 related to the acquisition of Kiq and the sale of Series A convertible preferred stock, the Company has experienced a change in ownership, as defined by Section 382. As a result of the ownership change, utilization of the federal and state net operating loss carryforwards and research and development tax credit carryforwards is subject to annual limitation under Section 382. Under Section 382, the annual limitation is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. This limitation resulted in the expiration of federal and state net operating loss carryforwards before utilization of $26.9 million and $79.5 million, respectively, and federal and state research and development tax credit carryforwards before utilization of $6.6 million and $2.0 million, respectively. We have written off these gross deferred tax attributes, which were previously fully reserved for, in 2020. As of December 31, 2021, approximately $63.1 million and $3.0 million of federal and state net operating losses, respectively, as well as $10.6 million of future amortization for federal purposes, were subject to the July 6 limitation of $0.3 million per year. A second ownership change occurred in December 2020 as a result of the underwritten public offering of common stock which resulted in a limitation of tax attributes generated from July 7, 2020 to December 1, 2020. The December 1, 2020 ownership change is not expected to have a material impact to the Company's net operating loss carryforwards or research and development tax credit carryforwards as these net operating losses and tax credit carryforwards may be utilized, subject to annual limitation, assuming sufficient taxable income is generated before expiration.

Risks Related to Our Intellectual Property

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. In particular, bezuclastinib and other molecules are subject to a license from Plexxikon. We expect in the future to be party to additional material license or collaboration agreements. Any termination of our current or future licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. These licenses do and future licenses may include provisions that impose obligations and restrictions on us. This could delay or otherwise negatively impact a transaction that we may wish to enter into. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have rights to certain intellectual property, through licenses from third parties and under patent applications that we own or will own, related to bezuclastinib , and certain other product candidates. Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Currently, we have patents issued from our in-licensed portfolio under our license agreement with Plexxikon. in multiple territories, including but not limited to, Australia, Canada, China, Colombia, Europe (validated in Germany, Spain, France, Great Britain, Italy, the Netherlands, as well as various other EU countries), Hong Kong, India, Indonesia, Israel, Japan, Mexico, New Zealand, Peru, the Philippines, Republic of Korea, Russia, Singapore, South Africa, Taiwan, and the United States. We also have patent applications pending in Brazil, Egypt and the United States. We anticipate additional patent applications will be filed both in the United States and in other countries, as appropriate. There is no guarantee that patent applications will provide meaningful protection or result in patents being issued and granted.

Third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we are employing their proprietary technology without authorization. While we do not believe that any claims that could materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

We may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, if we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

An unfavorable outcome of any post-grant proceedings, including interference proceedings, provoked by third parties or brought by the USPTO could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Risks Related to Employee Matters and Managing Growth

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our inability or failure to successfully attract and retain qualified personnel, particularly at the management level, could adversely affect our ability to execute our business plan and harm our operating results. We are highly dependent on our management, scientific and medical personnel, including our Chief Executive Officer and President, our Chief Financial Officer, our Chief Technology Officer, our Chief Scientific Officer, our Chief Medical Officer and our Chief Legal Officer. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. The employment agreements with our key employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice.

We have undergone significant growth across both locations over the past year and we may face challenges in managing our growth.

During the nine-months ended September 30, 2022, we increased our headcount from 77 to 121 full time employees through the expansion of our research, development, manufacturing and G&A infrastructure. To manage these organizational changes and growth, we must continue to enhance our operational, financial and management controls and systems, reporting systems and infrastructure, and policies and procedures. We may not be able to implement enhancements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. We must also continue to recruit, train and retain qualified personnel and we may be unable to do so effectively. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our development timelines may be delayed, our ability to generate revenue could be reduced, and we may not be able to implement our business strategy.

Our business and operations could suffer in the event of system failures or unauthorized or inappropriate use of or access to our systems.

We are increasingly dependent on our information technology systems and infrastructure for our business. We collect, store and transmit sensitive information including intellectual property, proprietary business information and personal information in connection with business operations. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack or unauthorized access and use by third parties with a wide range of motives and expertise, including organized criminal groups, “hacktivists,” patient groups, disgruntled current or former employees and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage or interruption from computer viruses, unauthorized or inappropriate access or use, natural disasters, pandemics (including COVID-19), terrorism, war, and telecommunication and electrical failures. Such events could cause interruption of our operations. For example, the loss of pre-clinical trial data or data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory filings and development efforts, as well as delays in the commercialization of our products, and significantly increase our costs. To the extent that any disruption, security breach or unauthorized or inappropriate use or access to our systems were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, including but not limited to patient, employee or vendor information, we could incur notification obligations to affected individuals and government agencies, liability, including potential lawsuits from patients, collaborators, employees, stockholders or other third parties and liability under foreign, federal and state laws that protect the privacy and security of personal information, and the development and potential commercialization of our product candidates could be delayed.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are a clinical-stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in March 2014. For further information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations."

There can be no assurance that the product candidates under development by us will be approved for sale in the United States or elsewhere. Furthermore, there can be no assurance that if such products are approved, they will be successfully commercialized, which would have an adverse effect on our business prospects, financial condition and results of operation. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require substantial additional funding. If we fail to obtain additional financing when needed, or on attractive terms, we may be unable to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of our product candidates, including our clinical trials for bezuclastinib. If approved, we will require significant additional amounts in order to launch and commercialize our product candidates. We cannot be certain that additional funding will be available on acceptable terms, or at all. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the payment and other obligations under the agreements. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Risks Related to Ownership of our Common Stock

An active trading market for our common stock may not be sustained.

Our common stock began trading on the Nasdaq Global Select Market on March 29, 2018. Given the limited trading history and low volumes of our common stock, there is a risk that an active trading market for our shares may not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell some or all of their shares at attractive prices, at the times and in the volumes that they would like to sell them, or at all.

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to continue to be highly volatile. Market prices for our common stock could be subject to wide fluctuations in response to various factors. In addition, the stock market in general, and The Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. If the market price of our common stock does not exceed your purchase price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval.

Our executive officers, directors, and 5% stockholders beneficially owned approximately 56% of our outstanding common stock as of December 31, 2021. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of our directors, amendments to our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that may be in the best interests of our stockholders.

Future sales and issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, research and development activities, and incurring costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities, or other equity securities, investors may be materially diluted by such sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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*	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
31.2*	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
32.1*†	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
32.2*†	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
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.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase 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

† 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 14, 2022

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

Date: November 14, 2022

By: /s/ John Green
John Green
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 31.1

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 14, 2022

By: /s/ Andrew Robbins

Andrew Robbins

Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

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 14, 2022

By: /s/ John Green

John Green

Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Cogent Biosciences, Inc. (the "Company") for the period ended September 30, 2022 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 14, 2022

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

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Cogent Biosciences, Inc. (the "Company") for the period ended September 30, 2022 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 14, 2022

By: /s/ John Green
John Green
Chief Financial Officer
(Principal Accounting and Financial Officer)