UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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)

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, $0.001 Par Value	**COGT**	**The Nasdaq Global Select Market**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of Common Stock held by non-affiliates of the registrant computed by reference to the price of the registrant's Common Stock as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $567.8 million (based on the last reported sale price on the Nasdaq Global Select Market as of such date).

As of March 10, 2023, there were 69,946,790 shares of the registrant's Common Stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this report, to the extent not set forth herein, is incorporated herein by reference from our definitive proxy statement relating to the 2023 Annual Meeting of Stockholders, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the annual period to which this report relates.

Cogent Biosciences, Inc.
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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.
- 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.
- If unacceptable side effects are identified during the development of our drug candidates, we may need to abandon or limit such development.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- As difficulties arise enrolling patients in our clinical trials, clinical development activities could be delayed or otherwise adversely affected.
- 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.
- Clinical trials are expensive, time-consuming, and difficult to design and implement.
- 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.
- 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.
- 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.
- 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, discovery, manufacturing and supply 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.
- 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.
- 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.
- 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 Annual Report on Form 10-K, 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.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy and plans, and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "should," "expects," "might," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential," "seek," "would" or "continue," or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K 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 Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described in the "Risk Factors" section and elsewhere in this Annual Report on Form 10-K. 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 COVID-19 pandemic 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, including the enrollment rates in our clinical trials;
- the timing of our planned regulatory submissions to the FDA for our bezuclastinib product candidate;
- 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

Unless the context otherwise requires, we use the terms "Cogent," "company," "we," "us," and "our" to refer to Cogent Biosciences, Inc. and, where appropriate, our subsidiaries.

ITEM 1. BUSINESS

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 most advanced program is bezuclastinib (also known as CGT9486), a selective tyrosine kinase inhibitor 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. This mast cell accumulation results in an orphan disease called Systemic Mastocytosis ("SM"). Exon 17 mutations have also been found in 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 Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases, and is initially targeting FGFR2 and ErbB2.

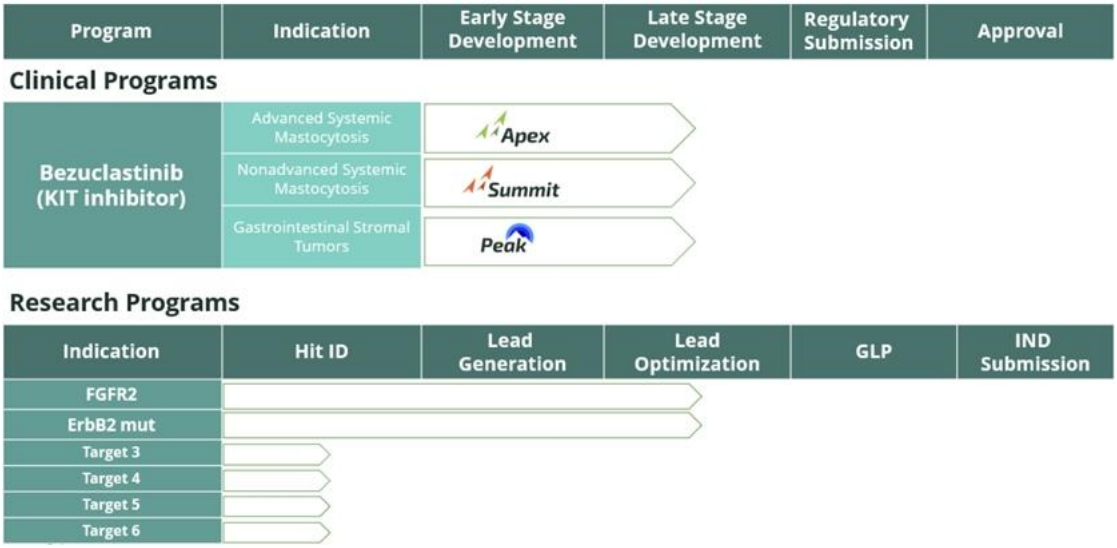
We have assembled a management team with extensive experience in the research, development, manufacturing and commercialization of pharmaceutical products, specifically including numerous successful precision medicines for genetically defined diseases. With the support of our board of directors and their expertise, we believe that the Company is well positioned to develop and commercialize novel precision medicines. Beginning with bezuclastinib, our mission is to develop and commercialize pharmaceutical products that improve the lives of patients fighting rare, genetically driven diseases.

Our Strategy

Our vision is to discover, develop, and commercialize best-in-class therapies that have a meaningful impact for patients with genetically defined diseases. The principal components of our strategy include:

- Explore the clinical utility of bezuclastinib in patients with Advanced Systemic Mastocytosis ("AdvSM");
- Explore the clinical utility of bezuclastinib in patients with Non-Advanced Systemic Mastocytosis ("Non-AdvSM");
- Explore the clinical utility of bezuclastinib in combination with sunitinib in patients with GIST;
- Prepare to commercialize bezuclastinib should any or all of the planned clinical trials demonstrate clinical benefit for patients with high unmet medical need;
- Advance our FGFR2 and ErbB2 preclinical programs, as well as our other undisclosed preclinical programs; and
- Discover and develop additional precision medicines for patients with genetically defined diseases.

Our Pipeline



Bezuclastinib Overview

Bezuclastinib is designed to target mutations within the KIT receptor tyrosine kinase, including KIT D816V. As a Type I inhibitor, bezuclastinib is designed to selectively bind the active conformation of mutant KIT. In preclinical studies, bezuclastinib has demonstrated comparable potency relative to other FDA-approved KIT mutant inhibitors, and clear selectivity for KIT mutations versus other kinase targets frequently associated with other KIT inhibitors including, but not limited to, FLT3, VEGFR, PDGFRα and CSF1R. In preclinical studies of bezuclastinib, limited blood-brain-barrier penetration was observed, and there have been no clinically significant CNS toxicities identified either preclinically or clinically. This preclinical profile of selectivity against kinases that have been associated with off-target toxicities and limited blood-brain-barrier penetration differentiate bezuclastinib from other KIT mutant inhibitors, and support the potential for a best-in-class clinical profile. The figures below provide a summary of potency and selectivity preclinical data.

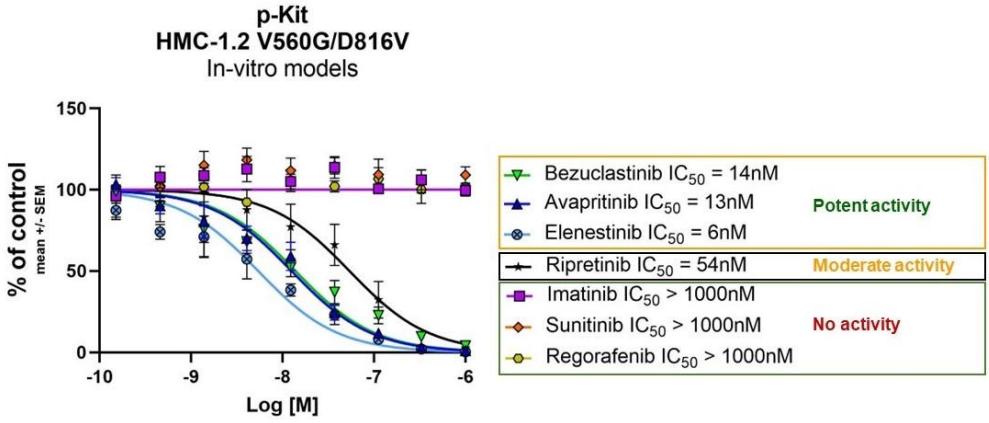


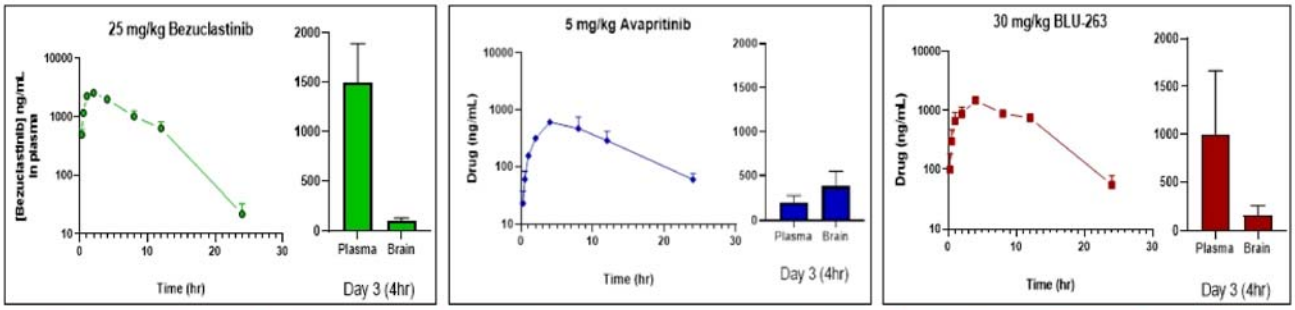
Figure 1. Potent Inhibitor of KIT Activation Loop Mutants, Including D816V
HMC-1.2 human mast cells were treated with indicated inhibitors for 1 hour (n = 3 biological replicates) Readout is phosphorylated c-Kit (Human Phospho c-Kit ELISA, R&D Systems)

Compound	Cell IC_{50} (nM)				
	PDGFRα	PDGFRß	CSF1R	FLT3	KDR
Bezuclastinib	>10,000	>10,000	>10,000	>1000	>1000
Avapritinib	53	10	249	305	>1000
BLU-263	21	6	161	345	>1000
Ripretinib	20	34	312	534	110
Imatinib	75	247	1027	>1000	>1000
Sunitinib	23	14	313	1	4
Regorafenib	138	1180	473	237	101

Key: Fold change from on-target KIT activity

≤ 10x | 10x-30x | 30x-50x | 50x-100x | > 100x

Figure 2. Selectivity Against Related Kinases



$t_{1/2}$ (h)	C_{max} (ng/mL)	AUC_{last} (ng·hr/mL)	Brain:Plasma ratio
7	2592 ± 364	21509 ± 2558	**0.07**

$t_{1/2}$ (h)	C_{max} (ng/mL)	AUC_{last} (ng·hr/mL)	Brain:Plasma ratio
13	672 ± 102	6980 ± 1156	**2.0**

$t_{1/2}$ (h)	C_{max} (ng/mL)	AUC_{last} (ng·hr/mL)	Brain:Plasma ratio
4	1470 ± 222	16200 ± 414	**0.18**

Figure 3. Bezuclastinib Demonstrates Minimal Brain Penetration

We licensed the exclusive worldwide rights to develop and commercialize bezuclastinib from Plexxikon Inc., a member of the Daiichi Sankyo Group ("Plexxikon"). Under the terms of the license agreement, Plexxikon received an upfront payment and is eligible for additional development and regulatory milestone payments along with mid- to high- single-digit royalty payments.

Bezuclastinib, a potential best-in-class KIT mutant inhibitor, has demonstrated promising clinical activity and safety results in a completed Phase 1/2 clinical trial in patients with GIST and in an on-going Phase 2 clinical trial in patients with AdvSM, supporting accelerated timelines for further development. In 2021, we initiated three clinical trials designed to explore the safety and efficacy of bezuclastinib in patients with AdvSM, Non-AdvSM and GIST. Currently, all three clinical trials are actively recruiting patients.

In 2022, we introduced a new formulation of bezuclastinib, which is currently being used in our clinical trial for patients with GIST and which we expect to incorporate into our SM trials in 2023. In 2022, we also filed a provisional patent application seeking to protect the new formulation of bezuclastinib, which could potentially provide exclusivity through at least 2043.

Clinical Trials and Disease Overviews

Bezuclastinib – SM

SM is driven by KIT D816V mutations causing a perpetual 'on' state within mast cells, a type of white blood cell, leading to proliferation and accumulation in various internal organs and bone marrow. Key biomarkers of SM include but are not limited to, elevated serum tryptase, high mass cell burden in bone marrow and the KIT D816V variant allele frequency. As a highly selective and potent KIT inhibitor, bezuclastinib has the potential to provide a new treatment option for patients with SM. SM occurs when mast cells inappropriately accumulate in various internal organs in the body. Approximately 90% of patients present with Non-AdvSM and 10% of patients present with AdvSM a rare, very aggressive form of SM. There are three subtypes of AdvSM: aggressive SM ("ASM"), SM with associated hematologic neoplasm ("SM-AHN") and mast cell leukemia ("MCL").

Patients diagnosed with Non-AdvSM, a life-long illness with chronic symptoms including headaches, urticaria pigmentosa, skin lesions, skin redness and warmth (flushing), abdominal pain, bloating, vomiting, diarrhea, and gastroesophageal reflux ("GERD"), that significantly impact the patient's quality of life. Many patients are also at high risk for severe, life-threatening anaphylactic reactions to various triggers such as insect bites or stings. Patients with Non-AdvSM suffer from a poor quality of life and without any currently approved therapies, are in need of new treatment options.

Patients with AdvSM may suffer from a multitude of debilitating symptoms such as anemia, thrombocytopenia, ascites, bone fractures, gastrointestinal abnormalities, and enlargement of the liver, spleen, and lymph nodes, which ultimately lead to organ failure and early death. Patients with AdvSM have a significantly diminished lifespan with a median survival of less than 3.5 years.

Based on the characteristics of bezuclastinib, we are pursuing development of the compound in both patients living with AdvSM and patients with Non-AdvSM, the vast majority of whom have a KIT D816V mutation. Emerging clinical data for other kinase inhibitors with activity against KIT D816V have shown that SM patients are highly sensitive to inhibition of the target. Bezuclastinib was specifically designed to selectively inhibit KIT mutations, including KIT D816V.

The underlying SM patient population is not yet well understood. The prevalence of SM in the United States is estimated to be up to 30,000 patients, with the prevalence of Non-AdvSM being approximately 25,000 patients. We believe there is a significant unmet medical need for clinically active, well tolerated treatment options for this patient population. We believe bezuclastinib is well suited to meet this need and target the direct underlying cause of SM.

APEX (AdvSM)

We are currently enrolling Part 1 of APEX, our global, open-label, multi-center, Phase 2 clinical trial in patients with AdvSM evaluating the safety, efficacy, pharmacokinetic, and pharmacodynamic profiles of bezuclastinib. We expect to provide an update on the planned initiation of APEX Part 2 based on clinical data from approximately 25-30 patients in APEX Part 1 in mid-2023.

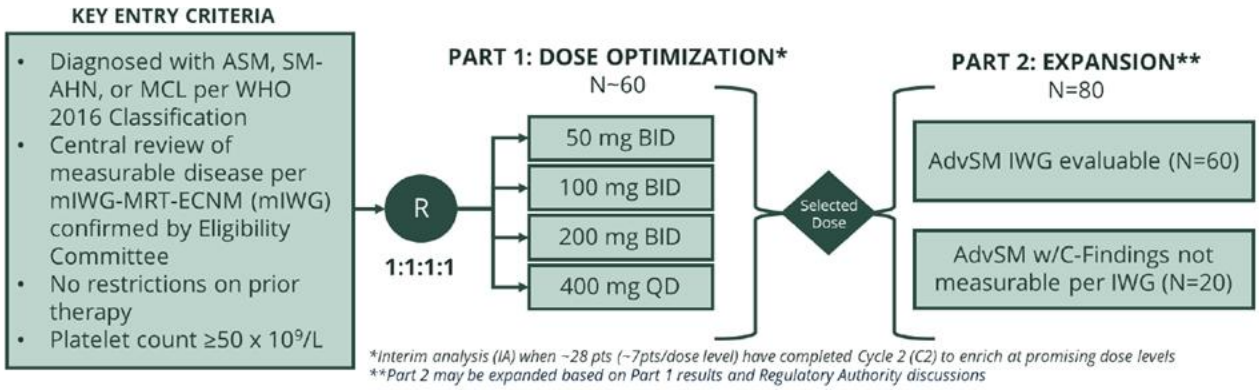


Figure 4. APEX study design graphic

In December 2022, at the 64th American Society of Hematology (ASH) Annual Meeting, we reported positive updated clinical data from the ongoing APEX trial. As of the data cutoff date of October 26, 2022, 16 patients had been treated in Part 1 at one of four dose levels (50 mg BID, 100 mg BID, 200 mg BID or 400 mg QD). Eleven patients were evaluable for response per the modified IWG-MRT-ECNM criteria, and 12 patients were evaluable for response using pure pathological response (PPR) criteria. An objective response rate (ORR) of 89% (including centrally adjudicated confirmed and unconfirmed responses) was achieved in TKI therapy naïve patients, including 67% of patients achieving complete remission (CR), CR with partial hematologic remission (CRh), partial remission (PR) and 22% achieving CR or CRh. An ORR of 73% was achieved in all patients, regardless of prior treatment, and 75% ORR was achieved by PPR criteria, regardless of prior treatment. Additionally, results of key markers of clinical activity were reported from 16 patients.

Best Response, n (%) * β (confirmed and unconfirmed)	Total (n=11)	mIWG-MRT-ECNM per CRRC Assessment (TKI‡ Therapy Naïve) (n=9)	mIWG-MRT-ECNM per CRRC Assessment (Prior TKI‡ Exposure) (n=2)
Overall response rate			
CR + CRh + PR + CI†	**8 (73)**	8 (89)	0 (0)
CR + CRh + PR	**6 (55)**	6 (67)	0 (0)
Complete Response (CR + CRh)	**2 (18)**	2 (22)	0 (0)
Partial Response (PR)	**4 (36)**	4 (44)	0 (0)
Clinical Improvement (CI)	**2 (18)**	2 (22)	0 (0)
Stable Disease (SD)	**3 (27)**	1 (11)	2 (100)

Best Response, n (%) α	Total (n=12)	PPR per Investigator Assessment (TKI‡ Therapy Naïve) (n=10)	PPR per Investigator Assessment (Prior TKI‡ Therapy) (n=2)
Overall response rate (CR + PR)	**9 (75)**	7 (70)	2 (100)
Complete Response (CR)	**3 (25)**	3 (30)	0 (0)
Partial Response (PR)	**6 (50)**	4 (40)	2 (100)
Stable Disease (SD)	**3 (25)**	3 (30)	0 (0)

- Median duration on treatment = 27 weeks (range: 0.3-40)
- First confirmed CRh by mIWG documented as early as 8 weeks and first confirmed CR as early as 20 weeks

Figure 5. Early Responses Observed by mIWG-MRT-ECNM and PPR Criteria (Source: ASH conference 2022)

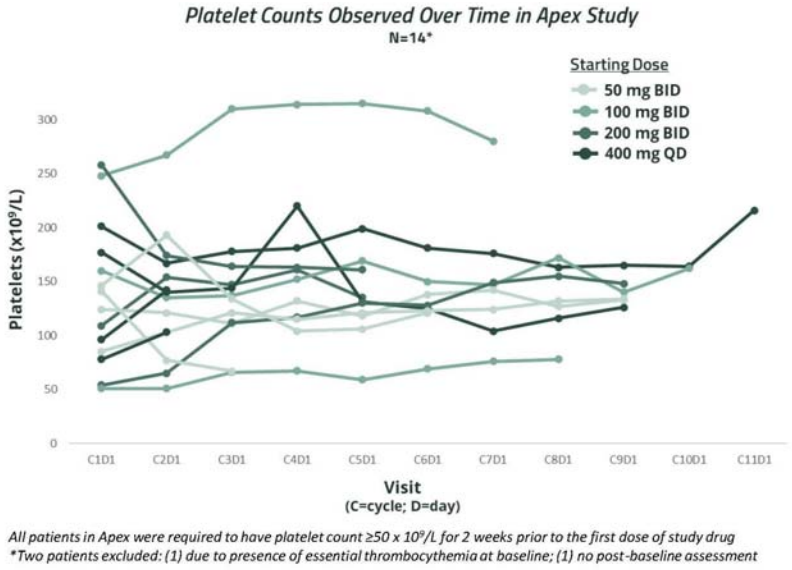


Figure 6. Platelet counts observed over time in APEX study (Source: ASH conference 2022)

As of the cut-off date of October 26, 2022, 14 out of 16 patients treated with bezuclastinib achieved at least a 50% reduction in serum tryptase, with a median reduction of 85%, regardless of prior KIT D816V inhibitor treatment; 13 of 13 patients with at least two cycles of treatment achieved at least a 50 % reduction in bone marrow mast cell aggregates, with 10 of these patients achieving complete clearance of bone marrow mast cell aggregates. Also, 11 of 12 patients with baseline D816V mutation and at least two cycles of treatment achieved at least a 50% reduction in blood KIT D816V variant allele fraction by droplet digital polymerase chain reaction. Bezuclastinib was generally well-tolerated at all doses. The majority of adverse events were Grade 1/2 and occurred in no more than one patient. Grade 3 events reported as at least possibly related to bezuclastinib were neutropenia (2 patients), thrombocytopenia (1 patient), anemia (1 patient) and hypersensitivity/mediator flare (1 patient). Importantly, there were no related cognitive effects or bleeding events reported, which have been associated with other KIT inhibitors. Limited low-grade edema was observed, and analysis of platelet counts in bezuclastinib-treated patients showed a limited effect of bezuclastinib on platelet counts.

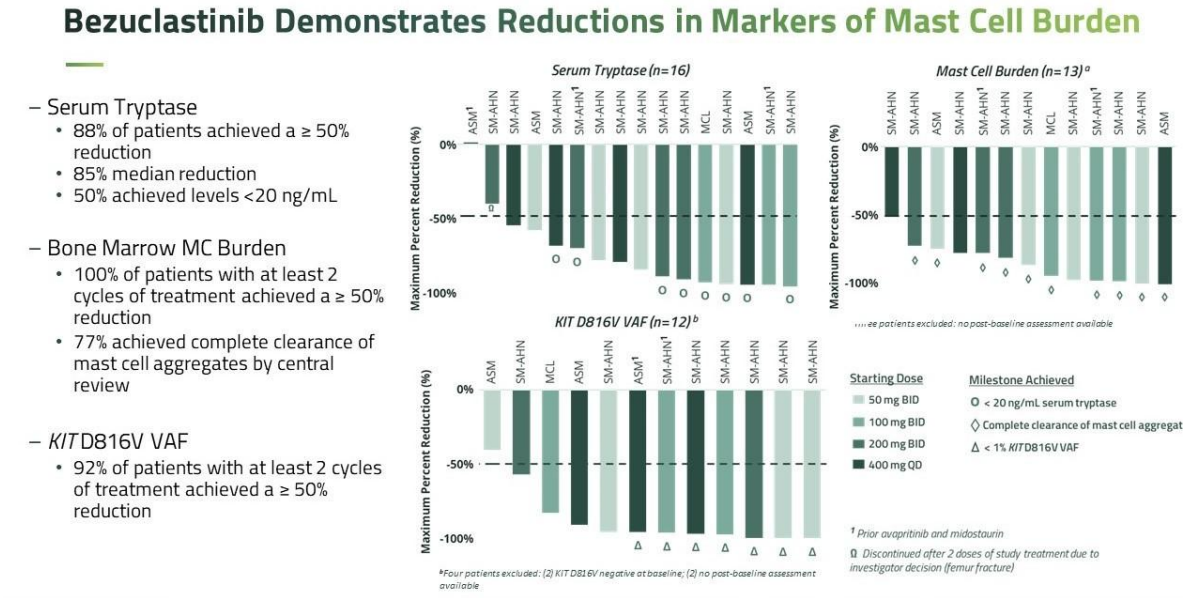


Figure 7. Reductions in markers of mast cell burden (Source: ASH conference 2022)

SUMMIT (Non-AdvSM)

We are also currently enrolling Part 1 of SUMMIT, a randomized, double-blind, placebo-controlled, global Phase 2 clinical trial. The study is designed to explore the safety and efficacy of bezuclastinib in patients with moderate to severe Indolent Systemic Mastocytosis ("ISM") or Smoldering Systemic Mastocytosis ("SSM"), collectively considered as Non-AdvSM. 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 has been amended to allow for the new formulation to be introduced during the dose optimization phase. We expect to present initial clinical data in patients with Non-AdvSM in the second half of 2023. Clinical data is expected to include safety/tolerability, pharmacokinetics and measures of clinical activity. The below figure shows the current SUMMIT clinical trial design. In March 2023, Cogent received approvals from European regulatory authorities to initiate the SUMMIT trial in patients with Non-AdvSM. Beginning in April 2023, we expect to start activating clinical trial sites across major countries in the European Union.

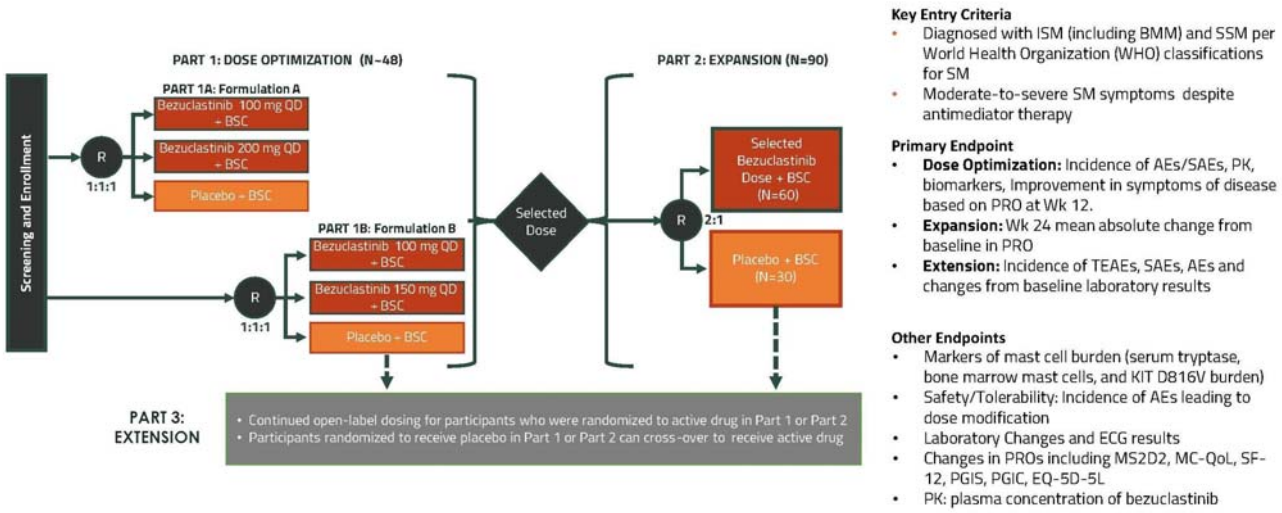


Figure 8. SUMMIT study design graphic

Bezuclastinib – GIST

GIST is characterized by uncontrolled cell growth in the interstitial cells of the gastrointestinal ("GI") tract. At diagnosis, about 80% of GIST patients' tumors are the result of primary KIT mutations. Imatinib is the current standard of care for treating GIST patients in the first line setting, with a median PFS of 19 months. However, the majority of GIST patients eventually develop resistance to imatinib due to secondary KIT mutations, most notably in exon 17 and exon 13. There are an estimated 2,000 to 3,500 patients with imatinib-resistant GIST eligible for treatment each year in the United States. We believe there is a significant unmet medical need for clinically active, well tolerated treatment options for this patient population and results from our clinical trial of bezuclastinib in combination with sunitinib demonstrated the potential for this novel combination to address the underlying drivers of imatinib resistance. The FDA has granted orphan drug designation to bezuclastinib for the treatment of GIST.

Bezuclastinib is designed to be a potent and selective inhibitor of KIT exon 17 mutations. By combining bezuclastinib with sunitinib, a tyrosine kinase inhibitor known to inhibit KIT exon 13 mutations, we believe this combination has the potential to offer a new, active treatment option for imatinib resistant GIST patients.

The safety profile of bezuclastinib was clinically evaluated in approximately 50 GIST patients both as a single agent and as part of a combination therapy. Clinical data from this trial were published in the Journal of American Medical Association ("JAMA") and were presented at several scientific conferences, including most recently by us at the 2020 annual Connective Tissue Oncology Society ("CTOS") meeting, and previously by Plexxikon at the 2018 annual American Society of Clinical Oncology ("ASCO") meeting and the 2017 annual CTOS meeting. In November 2020, we presented final results from a Phase 1/2 trial testing the combination of bezuclastinib with sunitinib in 18 heavily pre-treated GIST patients at 2020 CTOS. In the subset of 15 patients who had not been previously treated with bezuclastinib as a single-agent, the estimated mPFS reached 12 months , the confirmed ORR was 20% and the clinical benefit rate (CR+PR+SD) was 80%, with 27% of patients remaining on therapy out 27-34 months. Importantly, there were no dose limiting toxicities in the three dose levels tested, and the most common Treatment Emergent Adverse Events that were grade 3 or higher included anemia (5 patients, 27.8%), hypophosphatemia (3 patients, 16.7%), diarrhea, fatigue, hypertension, and lymphopenia (each 2 patients, 11.1%). Four subjects continued to receive bezuclastinib via individual patient INDs beyond the conclusion of the trial.

Demographics and Prior Therapy: Heavily Pretreated GIST Patients treated in Phase 1/2 Trial Testing the Combination of Bezuclastinib with Sunitinib

	Total (N=18)	Dose Level 1 (n=3)	Dose Level 2 (n=5)	Dose Level 3 (n=10)
Age, Median (range)	62 (44 – 78)	57 (46 – 68)	55 (44 – 78)	62 (53 – 65)
Sex, male, n (%)	9 (50)	0	3 (60)	6 (60)
Prior Regimens, Median (range)	3 (1 – 6)	2 (1 – 2)	3 (1 – 6)	4 (1 – 5)
Imatinib, n (%)	18 (100)	3 (100)	5 (100)	10 (100)
Sunitinib, n (%)	13 (72)	1 (33)	4 (80)	8 (80)
Regorafenib, n (%)	12 (67)	0	4 (80)	8 (80)
Ripretinib, n (%)	5 (28)	1 (33)	1 (20)	3 (30)
≥ 3 prior lines, n (%)	12 (67)	0	4 (80)	8 (80)
Prior treatment with CGT9486 (previously enrolled on another arm)	**3 (17)**	0	0	**3 (30)**

DL 1 = CGT9486 500 mg + Sunitinib 25 mg; DL 2 = CGT9486 1000 mg + Sunitinib 25 mg; DL3 = CGT9486 1000 mg + Sunitinib 37.5 mg
All doses PO once daily

Figure 9. GIST Phase 1/2 trial demographics (Source: 2020 CTOS annual meeting)

Durable Responses in Patients Treated with Bezuclastinib + Sunitinib

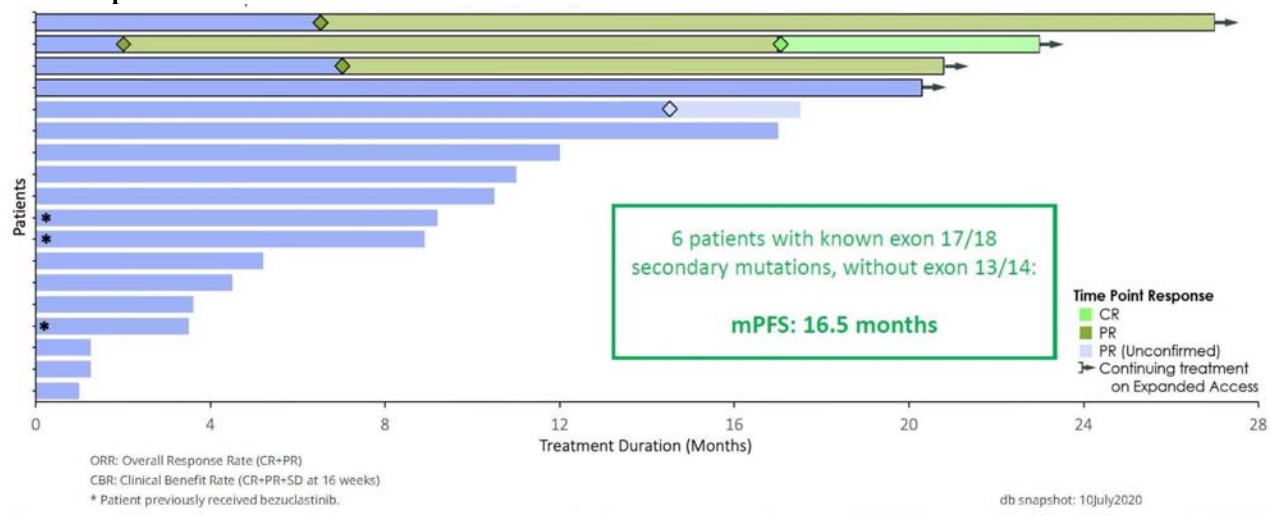


Figure 10. Patient Responses in GIST Phase 1/2 trial (Source: 2020 CTOS annual meeting)

PEAK (GIST)

We are currently enrolling Part 2 of PEAK, 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.

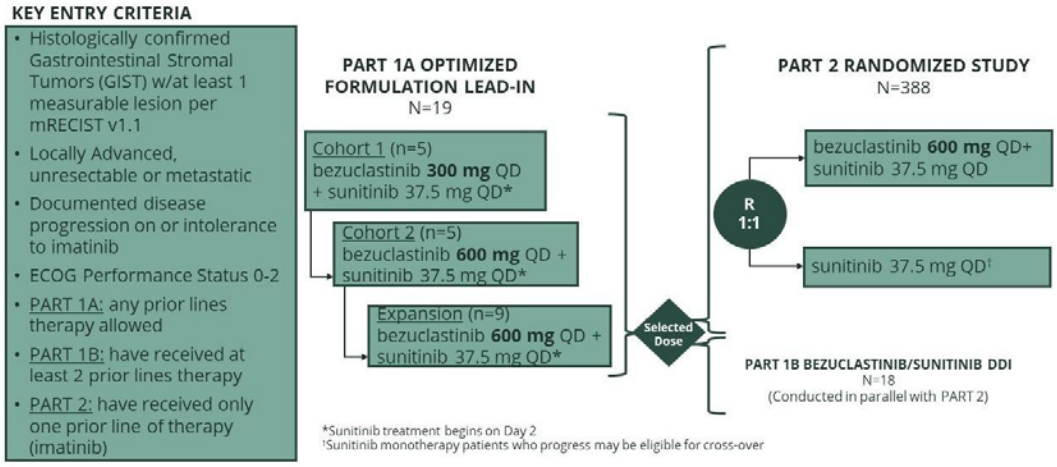


Figure 11. PEAK study design graphic

Based on the data from the PEAK lead-in study we initiated the randomized portion of PEAK using a 600 mg dose of our new formulation of bezuclastinib, supplied as 75 mg tablets, which in the lead-in portion of the study demonstrated clinical exposure comparable 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 was presented at the CTOS annual meeting in November 2022. We expect to present updated clinical data from refractory GIST patients in the lead-in cohort of the Phase 3 PEAK trial of bezuclastinib plus sunitinib during the first half of 2023.

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. Dr. John Robinson, our Chief Scientific Officer, leads the Cogent Research team composed of highly experienced scientists with deep expertise across a broad range of functional specialties including medicinal chemistry, computational chemistry, biology, enzymology and pharmacology.

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. In October 2022, we reported preclinical data at EORTC-NCI-AACR ("ENA") annual meeting on a next-generation fibroblast growth factor receptor 2 ("FGFR2") program, which retains potency across all primary, gatekeeper and molecular brake resistance mutations, including N549K and V564I, while sparing FGFR1 inhibition.

Our research team is also advancing a novel, ErbB2 mutant program, which is focused on actionable and underserved mutations in a variety of solid tumor indications. Currently available oral ErbB2 inhibitors struggle to provide broad mutant coverage while sparing EGFR activity. In October 2022, presented preclinical data at ENA on a novel ErbB2 mutant selective program which demonstrates robust cellular inhibition of all key resistance and primary driver mutations, including L755S, V842I and S310F/Y, while sparing wild type EGFR target engagement.

For both FGFR and ErBB2, we see an opportunity to provide a more robust molecular response compared to existing therapies. We expect to initiate clinical trials for both of these programs in 2024.

Intellectual Property

One key to our success will be our ability to establish and maintain protection for our product candidates and know-how, in order to enforce and defend our intellectual property rights and to operate without infringing on the rights of others. We rely on our know-how, trade secrets and continuing technological innovation as well as on in-licensing of third-party intellectual property to develop and maintain our proprietary position. Our patent portfolio consists of U.S. patents and foreign patents and patent applications that we in-licensed exclusively from Plexxikon, as well as additional patent applications we have filed on our own.

With the acquisition of Kiq Bio LLC (formerly Kiq LLC) ("Kiq") on July 6, 2020, we obtained an exclusive, sublicensable, worldwide license to patents and applications owned by Plexxikon pursuant to a license agreement between Plexxikon and Kiq (the "License Agreement"). The licensed patents and applications under the License Agreement cover bezuclastinib, its therapeutic uses, and methods of making bezuclastinib and intermediates. These patents and applications include issued patents in multiple territories, including, but not limited to, Australia, Brazil, 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. The pending applications also include patent applications pending in Australia, Brazil, Canada, China, Egypt, Europe, India, Indonesia, Israel, Japan, Korea, Mexico, Philippines, Singapore, South Africa, and the United States. The issued U.S. patents covering bezuclastinib and its therapeutic uses are expected to expire in 2033 and 2034, and the issued foreign patents covering bezuclastinib and its therapeutic uses are expected to expire in 2033, without consideration of potential patent term extensions. Patent applications covering methods of making bezuclastinib and intermediates could potentially provide exclusivity through at least 2041. In 2022, we filed a provisional patent application seeking to protect our new formulation of bezuclastinib, which could potentially provide exclusivity through at least 2043.We may seek to obtain rights under additional patent applications relating to bezuclastinib and its use to treat SM and GIST in the United States and in other countries as we proceed with this development program.

We are not currently a party to and have not been a party to any legal proceedings involving patent rights.

In addition to the protection afforded by patents, we seek to protect our technology and product candidates, in part, by trade secret and confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators, and advisors. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. Furthermore, the laws of some foreign countries may not protect proprietary rights to the same extent or in the same manner as the laws of the United States.

In addition, our trade secrets may otherwise become known or may be independently discovered by competitors. To the extent that our employees, contractors, consultants, collaborators, and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Moreover, we may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. Disputes regarding ownership or inventorship of our patents or other intellectual property can arise in various contexts, including collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we are unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

For more comprehensive risks related to our proprietary technology, inventions, improvements and products, please see the section on "Risk Factors—Risks Related to Intellectual Property."

Licenses and Third-Party Research Collaborations

License Agreement with Plexxikon Inc.

In July 2020, we obtained an exclusive, sublicensable, worldwide license to certain patents and other intellectual property rights to research, develop, and commercialize bezuclastinib. Under the terms of the License Agreement, we are required to pay Plexxikon aggregate payments of up to $7.5 million upon the satisfaction of certain clinical milestones and up to $25.0 million upon the satisfaction of certain regulatory milestones. During the second quarter of 2022, as a result of the progression of the PEAK study, the first clinical milestone was achieved, resulting in payment of $2.5 million to Plexxikon in June 2022. As of December 31, 2022, no other milestone payments have been made or are considered probable of occurring.

We are also required to pay Plexxikon tiered royalties ranging from a low-single digit percentage to a high-single digit percentage on annual net sales of products. These royalty obligations last on a product-by-product basis and country-by-country basis until the latest of (i) the date on which there is no valid claim of a licensed Plexxikon patent covering a subject product in such country or (ii) the 10th anniversary of the date of the first commercial sale of the product in such country. In addition, if we sublicense the rights under the License Agreement, we are 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 development and regulatory milestones.

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. Plexxikon may terminate the License Agreement within 30 days after written notice in the event of a breach of contract that remains uncured. Plexxikon may also terminate the agreement upon written notice in the event of our bankruptcy, liquidation, or insolvency. In addition, we have the right to terminate the License Agreement in its entirety at will upon 90 days' advance written notice to Plexxikon.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our technology, development experience, and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions governmental agencies, and public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology, and other related markets that address precision medicines for patients with genetically defined diseases. There are several other companies working to develop therapies in this field using a similar strategy. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes.

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 regulatory approvals, and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

Bezuclastinib, if approved for the indications for which we are currently enrolling clinical trials, will compete with the drugs discussed below and will likely compete with other drugs that are currently in development.

In SM, the only approved drugs for the treatment of AdvSM are Blueprint Medicines Corporation's ("Blueprint") avapritinib and Novartis AG's midostaurin. Additionally, Novartis AG's imatinib is approved for AdvSM patients without the KIT D816V mutation or mutational status unknown. There are currently no approved drugs for the treatment of Non-AdvSM. The most advanced drug candidate for the treatment of Non-AdvSM is Blueprint's avapritinib, for which Blueprint has submitted a supplement new drug application to the FDA and has a PDUFA date of May 22, 2023. We may also face competition from other drug candidates in pre-clinical or clinical development for SM.

In GIST, the current approved standards of care for unresectable or metastatic patients are first-line imatinib, followed by second-line sunitinib upon imatinib progression, followed by third-line regorafenib upon sunitinib progression, followed by fourth-line ripretinib for patients who have received three or more prior kinase inhibitors. In addition, avapritinib was approved by the FDA in January 2020 for patients with GIST harboring a PDGFRα exon 18 mutation, including PDGFRA D842V mutations only. We may face competition from other drug candidates in pre-clinical or clinical development including, Celldex Therapeutics, Inc., Deciphera Pharmaceuticals, Inc., Taiho Pharmaceutical Co. Ltd, Xencor, Inc., Theseus Pharmaceuticals, Inc. and IDRx.

Manufacturing and Supply

We do not own or operate, and have no current plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties to manufacture our drug candidates for preclinical and clinical testing, as well as for future commercial supply of any drugs that we may commercialize. To date, we have obtained API and drug product from third-party manufacturers for bezuclastinib to support preclinical and clinical testing. We obtain our supplies from these manufacturers on a purchase-order basis and do not have any long-term supply arrangements. We do not currently have a validated manufacturing process in place for any product candidate which would be required to support commercialization of any of our drug candidates, if approved.

Our drug candidates are compounds of low molecular weight, generally called small molecules. They can be manufactured from readily available starting materials in reliable and reproducible synthetic processes. The manufacturing process is amenable to scale-up. As we continue our clinical development of bezuclastinib, we expect to continue to enhance our manufacturing process to allow for drug candidates that are safer, more effective, have superior dosing regimens and are cost-effective.

Government Regulation

Government authorities in the United States, at the federal, state and local levels, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, product approval, manufacture, quality control, manufacturing changes, packaging, storage, recordkeeping, labeling, promotion, advertising, sales, distribution, marketing, and import and export of drugs and biologic products. Our current product candidates are expected to be regulated as drugs. The processes for obtaining regulatory approval in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities both pre- and post-commercialization, are a significant factor in the production and marketing of our products and our research and development activities and require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA and other government entities regulate drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA and the regulations promulgated thereunder, as well as other federal and state statutes and regulations. Failure to comply with applicable legal and regulatory requirements in the United States at any time during the product development process, approval process, or after approval, may subject us to a variety of administrative or judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, withdrawal of approvals, delay or suspension of clinical trials, issuance of warning letters and other types of regulatory letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil monetary penalties, refusals of or debarment from government contracts, exclusion from the federal healthcare programs, restitution, disgorgement of profits, civil or criminal investigations by the FDA, U.S. Department of Justice, State Attorneys General, and/or other agencies, False Claims Act suits and/or other litigation, and/or criminal prosecutions.

An applicant seeking approval to market and distribute a new drug in the United States must typically undertake the following:

- completion of pre-clinical laboratory tests, animal studies, and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective without FDA objection before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with the FDA's good clinical practice, or GCP, regulations, to establish the safety and effectiveness of the proposed drug product for each indication for which approval is sought;
- preparation and submission to the FDA of a New Drug Application, or NDA;
- satisfactory review of the NDA by an FDA advisory committee, where applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the drug product, and the active pharmaceutical ingredient or ingredients thereof, are produced to assess compliance with current good manufacturing practice, or GMP, regulations and to assure that the facilities, methods, and controls are adequate to ensure the product's identity, strength, quality, and purity;
- payment of user fees, as applicable, and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, such as any Risk Evaluation and Mitigation Strategies, or REMS, or post-approval studies required by the FDA.

Preclinical Studies and an IND

Preclinical studies can include in vitro and animal studies to assess the potential for adverse events and, in some cases, to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. Other studies include laboratory evaluation of the purity, stability and physical form of the manufactured drug substance or active pharmaceutical ingredient and the physical properties, stability and reproducibility of the formulated drug or drug product. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Some preclinical testing, such as longer-term toxicity testing, animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Following commencement of a clinical trial under an IND, the FDA may place a clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

Human Clinical Studies in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations.

Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

Phase 2: The product candidate is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites in late-stage clinical trials to assure compliance with GCP and the integrity of the clinical data submitted.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, currently $2.876 million for fiscal year 2021, for applications requiring clinical data, and the sponsor of an approved NDA is also subject to an annual program fee, currently $336,432 for fiscal year 2021. These fees are adjusted annually.

Under certain circumstances, the FDA will waive the application fee for the first human drug application that a small business, defined as a company with less than 500 employees, including employees of affiliates, submits for review. An affiliate is defined as a business entity that has a relationship with a second business entity if one business entity controls, or has the power to control, the other business entity, or a third-party controls, or has the power to control, both entities. In addition, an application to market a prescription drug product that has received orphan designation is not subject to a prescription drug user fee unless the application includes an indication for other than the rare disease or condition for which the drug was designated. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a disease or condition that affects fewer than 200,000 individuals in the U.S., or for which there is no reasonable expectation that U.S. sales will be sufficient to recoup the development and production costs.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP.

The FDA also may require submission of a REMS plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. After approval, the FDA may seek to prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. Some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Expedited Review and Accelerated Approval Programs

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of NDAs. For example, Fast Track Designation may be granted to a drug intended for treatment of a serious or life-threatening disease or condition and data demonstrate its potential to address unmet medical needs for the disease or condition. The key benefits of Fast Track Designation are the eligibility for priority review, rolling review (submission of portions of an application before the complete marketing application is submitted), and accelerated approval, if relevant criteria are met. The FDA may grant the NDA a priority review designation, which sets the target date for FDA action on the application at six months after the FDA accepts the application for filing. Priority review is granted where there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

The FDA may approve an NDA under the accelerated approval program if the drug treats a serious condition, provides a meaningful advantage over available therapies, and demonstrates an effect on either (1) a surrogate endpoint that is reasonably likely to predict clinical benefit, or (2) on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the drug's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit.

In addition, the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, established the Breakthrough Therapy designation. A sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug is designated as breakthrough therapy, FDA will provide more intensive guidance on the drug development program and expedite its review.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented.

FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events or problems with manufacturing processes of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant criminal and civil liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Hatch-Waxman Patent Certification and the 30 Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

To the extent that a Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Legislative Developments

The 21st Century Cures Act, or the Cures Act, which was signed into law in December 2016, includes provisions to accelerate the development and delivery of new treatments. For example, the Cures Act requires the FDA to establish a program to evaluate the potential use of real world evidence to help to support the approval of a new indication for an approved drug and to help to support or satisfy post-approval study requirements, to issue guidance on adaptive and novel clinical trial designs for new drugs, and to establish a process for qualifying drug development tools used to support FDA approval for marketing or investigational use of a drug. The Cures Act also permits the FDA to rely on qualified data summaries to support the approval of a supplemental application for an already approved drug. The FDA is in the process of implementing the Cures Act requirements.

Review and Approval of Drug Products in the European Union

In order to market any pharmaceutical product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions governing, among other things, research and development, testing, manufacturing, quality control, safety, efficacy, labeling, clinical trials, marketing authorization, packaging, storage, record keeping, reporting, export and import, advertising, marketing and other promotional practices involving pharmaceutical products, as well as commercial sales, distribution, authorization, approval and post-approval monitoring and reporting of our products. Whether or not it obtains FDA approval for a pharmaceutical product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the pharmaceutical product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Drug Development Process

The conduct of clinical trials is currently governed by the EU Clinical Trials Directive 2001/20/EC, or Clinical Trials Directive, and will be replaced by the EU Clinical Trials Regulation (EU) No. 536/2014 ("CTR") once the latter comes into effect. The CTR introduces a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU. It entered into force on January 31, 2022. Under the current regime, which will expire after a transition period of one or three years, respectively, as outlined below in more detail, before a clinical trial can be initiated it must be approved in each EU Member State where there is a site at which the trial is to be conducted. The approval must be obtained from two separate entities: the National Competent Authority ("NCA") and one or more Ethics Committees. The NCA of the EU Member States in which the clinical trial will be conducted must authorize the conduct of the trial, and the independent Ethics Committee must grant a positive opinion in relation to the conduct of the clinical trial in the relevant EU Member State before the commencement of the trial. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be submitted to or approved by the relevant NCA and Ethics Committees. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the NCA and to the Ethics Committees of the EU Member State where they occur.

A more unified procedure will apply under the new CTR. A sponsor will be able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal. One national regulatory authority (the reporting EU Member State proposed by the applicant) will take the lead in validating and evaluating the application consult and coordinate with the other concerned Member States. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned Member States. However, a concerned EU Member State may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in such Member State. The CTR also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database. The CTR foresees a three-year transition period. Member States will work in CTIS immediately after the system has gone live. For one year, until 31 January 2023, clinical trial sponsors can still choose whether to submit an initial clinical trial application in line with the current system (Clinical Trials Directive) or via CTIS. From 31 January 2023, submission of initial clinical trial applications via CTIS becomes mandatory, and by 31 January 2025, all ongoing trials approved under the current Clinical Trials Directive will be governed by the new Regulation and have to be transitioned to CTIS.

Under both the current regime and the new CTR, national laws, regulations, and the applicable Good Clinical Practice and Good Laboratory Practice standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines on Good Clinical Practice ("GCP)" and the ethical principles that have their origin in the Declaration of Helsinki.

During the development of a medicinal product, the European Medical Agency ("EMA") and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use ("CHMP") on the recommendation of the Scientific Advice Working Party ("SAWP"). A fee is incurred with each scientific advice procedure, but is significantly reduced for designated orphan medicines. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future Marketing Authorization Application ("MAA") of the product concerned.

Marketing Authorization Procedures

In the EU and in Iceland, Norway and Liechtenstein (together the European Economic Area or "EEA"), after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining a Marketing Authorization ("MA"). To obtain an MA of a drug under European Union regulatory systems, an applicant can submit an MAA through, amongst others, a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single MA by the European Commission (EC) that is valid for all EU Member States and, after respective national implementing decisions, in the three additional EEA Member States. The centralized procedure is compulsory for specific medicinal products, including for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products ("ATMP") and medicinal products with a new active substance indicated for the treatment of certain diseases (AIDS, cancer, neurodegenerative disorders, diabetes, auto- immune and viral diseases). For medicinal products containing a new active substance not yet authorized in the EEA before May 20, 2004 and indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations or for which the grant of a MA through the centralized procedure would be in the interest of public health at EU level, an applicant may voluntarily submit an application for a marketing authorization through the centralized procedure.

Under the centralized procedure, the Committee for Medicinal Products for Human Use ("CHMP"), established at the EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure, the timeframe for the evaluation of an MAA by the EMA's CHMP is, in principle, 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more, unless the application is eligible for an accelerated assessment. Accelerated assessment might be granted by the CHMP in exceptional cases when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. On request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. However, the EC has final authority for granting the MA within 67 days after receipt of the CHMP opinion.

The decentralized procedure permits companies to file identical MA applications for a medicinal product to the competent authorities in various EU Member States simultaneously if such medicinal product has not received marketing approval in any EU Member State before. This procedure is available for pharmaceutical products not falling within the mandatory scope of the centralized procedure. The competent authority of a single EU Member State, known as the reference EU Member State, is appointed to review the application and provide an assessment report. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference EU Member State and concerned EU Member States. The reference EU Member State prepares a draft assessment report and drafts of the related materials within 120 days after receipt of a valid application. Subsequently each concerned EU Member State must decide whether to approve the assessment report and related materials.

If an EU Member State cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the EC, whose decision is binding for all EU Member States.

All new MAAs must include a Risk Management Plan ("RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. RMPs and Periodic Safety Update Reports ("PSURs") are routinely available to third parties requesting access, subject to limited redactions.

Marketing Authorizations have an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Data and Market Exclusivity in the European Union

As in the United States, it may be possible to obtain a period of market and/or data exclusivity in the EU that would have the effect of postponing the entry into the marketplace of a competitor's generic, hybrid or biosimilar product (even if the pharmaceutical product has already received a MA) and prohibiting another applicant from relying on the MA holder's pharmacological, toxicological and clinical data in support of another MA for the purposes of submitting an application, obtaining MA or placing the product on the market. New Chemical Entities ("NCE") approved in the EU qualify for eight years of data exclusivity and 10 years of marketing exclusivity.

An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

The data exclusivity period begins on the date of the product's first MA in the EU. After eight years, a generic product application may be submitted and generic companies may rely on the MA holder's data. However, a generic product cannot launch until two years later (or a total of 10 years after the first MA in the EU of the innovator product), or three years later (or a total of 11 years after the first MA in the EU of the innovator product) if the MA holder obtains MA for a new indication with significant clinical benefit within the eight-year data exclusivity period. Additionally, another noncumulative one -year period of data exclusivity can be added to the eight years of data exclusivity where an application is made for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication. Another year of data exclusivity may be added to the eight years, where a change of classification of a pharmaceutical product has been authorized on the basis of significant pre-trial tests or clinical trials (when examining an application by another applicant for or holder of market authorization for a change of classification of the same substance the competent authority will not refer to the results of those tests or trials for one year after the initial chance was authorized).

Products may not be granted data exclusivity since there is no guarantee that a product will be considered by the European Union's regulatory authorities to include a NCE. Even if a compound is considered to be a NCE and the MA applicant is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the medicinal product if such company can complete a full MAA with their own complete database of pharmaceutical tests, preclinical studies and clinical trials and obtain MA of its product.

Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the European Union are similar in principle to those in the United States. The EMA grants orphan drug designation if the medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union (prevalence criterion). In addition, Orphan Drug Designation can be granted if, for economic reasons, the medicinal product would be unlikely to be developed without incentives and if there is no other satisfactory method approved in the European Union of diagnosing, preventing, or treating the condition, or if such a method exists, the proposed medicinal product is a significant benefit to patients affected by the condition. An application for orphan drug designation (which is not a marketing authorization, as not all orphan-designated medicines reach the authorization application stage) must be submitted first before an application for marketing authorization of the medicinal product is submitted. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted, and sponsors must submit an annual report to EMA summarizing the status of development of the medicine. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Designated orphan medicines are eligible for conditional marketing authorization.

The EMA's Committee for Orphan Medicinal Products reassesses the orphan drug designation of a product in parallel with the review for a marketing authorization; for a product to benefit from market exclusivity it must maintain its orphan drug designation at the time of marketing authorization review by the EMA and approval by the EC. Additionally, any marketing authorization granted for an orphan medicinal product must only cover the therapeutic indication(s) that are covered by the orphan drug designation. Upon the grant of a marketing authorization, orphan drug designation provides up to ten years of market exclusivity in the orphan indication.

During the 10-year period of market exclusivity, with a limited number of exceptions, the regulatory authorities of the EU Member States and the EMA may not accept applications for marketing authorization, accept an application to extend an existing marketing authorization or grant marketing authorization for other similar medicinal products for the same therapeutic indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan medicinal product can also obtain an additional two years of market exclusivity for an orphan-designated condition when the results of specific studies are reflected in the Summary of Product Characteristics ("SmPC"), addressing the pediatric population and completed in accordance with a fully compliant Pediatric Investigation Plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, i.e. the condition prevalence or financial returns criteria under Article 3 of Regulation (EC) No. 141/2000 on orphan medicinal products. When the period of orphan market exclusivity for an indication ends, the orphan drug designation for that indication expires as well. Orphan exclusivity runs in parallel with normal rules on data exclusivity and market protection. Additionally, a marketing authorization may be granted to a similar medicinal product (orphan or not) for the same or overlapping indication subject to certain requirements.

Pediatric Development

In the European Union, companies developing a new medicinal product are obligated to study their product in children and must therefore submit a PIP together with a request for agreement to the EMA. The EMA issues a decision on the PIP based on an opinion of the EMA's Pediatric Committee, or PDCO. Companies must conduct pediatric clinical trials in accordance with the PIP approved by the EMA, unless a deferral (e.g., until enough information to demonstrate its effectiveness and safety in adults is available) or waiver (e.g., because the relevant disease or condition occurs only in adults) has been granted by the EMA. The marketing authorization application for the product must include the results of all pediatric clinical trials performed and details of all information collected in compliance with the approved PIP, unless a waiver or a deferral has been granted, in which case the pediatric clinical trials may be completed at a later date. Medical products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the approved PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the approved PIP are developed and submitted. An approved PIP is also required when a marketing-authorization holder wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized and covered by intellectual property rights.

Post-Approval Regulation

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the EU Member States. This oversight applies both before and after grant of manufacturing licenses and marketing authorizations. It includes control of compliance with EU good manufacturing practices rules, manufacturing authorizations, pharmacovigilance rules and requirements governing advertising, promotion, sale, and distribution, recordkeeping, importing and exporting of medicinal products.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU laws and the related national laws of the individual EU Member States governing the conduct of clinical trials, manufacturing approval, MA of pharmaceutical products and marketing of such products, both before and after grant of MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of a MA for a medicinal product must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products.

These pharmacovigilance rules can impose on holders of MAs the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed medicinal products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk-management measures, which may be time consuming and expensive and could impact our profitability. MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of PSURs in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA has concerns that the riskbenefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase IV safety studies. If the EC agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the MA holder to fulfill the obligations for which the EC's decision provides can undermine the ongoing validity of the MA.

More generally, non-compliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the MA for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for pharmaceutical products in the European Union is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice ("GMP"). These requirements include compliance with EU GMP standards when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union.

Similarly, the distribution of pharmaceutical products into and within the European Union is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with GMP, before releasing the product for commercial distribution in the European Union or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Advertising and Promotion

The advertising and promotion of our products is also subject to EU laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual EU Member States may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's SmPC as approved by the competent regulatory authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription-only medicines is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the European Union could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on its promotional activities with healthcare professionals.

Pricing and Reimbursement Environment

Even if a pharmaceutical product obtains a marketing authorization in the European Union, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. The EU Member States are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. An EU Member State may approve a specific price or level of reimbursement for the pharmaceutical product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the pharmaceutical product on the market, including volume-based arrangements, caps and reference pricing mechanisms.

Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our product candidates, if any, to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, pharmaceutical products launched in the European Union do not follow price structures of the United States and generally published and actual prices tend to be significantly lower. Publication of discounts by third party payers or authorities and public tenders may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries.

The so-called health technology assessment ("HTA"), of pharmaceutical products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including France, Germany, Ireland, Italy and Sweden. The HTA process, which is governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact, and the economic and societal impact of use of a given pharmaceutical product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost- effectiveness of individual pharmaceutical products as well as their potential implications for the healthcare system. Those elements of pharmaceutical products are compared with other treatment options available on the market. The outcome of HTA regarding specific pharmaceutical products will often influence the pricing and reimbursement status granted to pharmaceutical products by the regulatory authorities of individual EU Member States. A negative HTA of one of our products by a leading and recognized HTA body could not only undermine our ability to obtain reimbursement for such product in the EU Member State in which such negative assessment was issued, but also in other EU Member States. For example, EU Member States that have not yet developed HTA mechanisms could rely to some extent on the HTA performed in other countries with a developed HTA framework, when adopting decisions concerning the pricing and reimbursement of a specific pharmaceutical product.

On January 31, 2018, the European Commission adopted a proposal for a regulation on health technology assessment. This legislative proposal is intended to boost EU level cooperation among EU Member States in assessing health technologies, including new pharmaceutical products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The proposal provides that EU Member States will be able to use common HTA tools, methodologies and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. While EU Member States could choose to delay participation in the joint work until three years after the rules enter into force, it will become mandatory after six years. The European Commission has stated that the role of the HTA regulation is not to influence pricing and reimbursement decisions in the individual EU Member States, but there can be no assurance that the HTA regulation will not have effects on pricing and reimbursement decisions. The HTA entered into force on January 11, 2022 and applies as of January 2025 followed by a further three-year transitional period during which EU member states must fully adapt to the new system.

To obtain reimbursement or pricing approval in some countries, including the EU Member States, we may be required to conduct studies that compare the cost-effectiveness of our product candidates to other therapies that are considered the local standard of care. There can be no assurance that any country will allow favorable pricing, reimbursement and market access conditions for any of our products, or that we will be feasible to conduct additional cost-effectiveness studies, if required.

In certain of the EU Member States, pharmaceutical products that are designated as orphan pharmaceutical products may be exempted or waived from having to provide certain clinical, cost-effectiveness and other economic data in connection with their filings for pricing/reimbursement approval.

European Data Laws

The collection and use of personal health data and other personal information in the European Union is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679) ("GDPR"), which came into force in May 2018 and related implementing laws in individual EU Member States.

The GDPR imposes a number of strict obligations and restrictions on the ability to process (processing includes collection, analysis and transfer of) personal data of individuals within the European Union and in the EEA, including health data from clinical trials and adverse event reporting. The GDPR also includes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data or personal health data, notification of certain data processing activities to the national data protection authorities and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national implementing legislation.

Under the GDPR, personal data can only be transferred within the EU Member States and the three additional European Economic Area countries (Norway, Iceland and Liechtenstein) that have adopted a national law implementing the GDPR. Appropriate safeguards are required to enable cross-border transfers of personal data from the EU and EEA Member States to a "third country" (a country outside the EU or EEA). This status has a number of significant practical consequences, in particular for international data transfers, competent supervisory authorities and enforcement of the GDPR.

In conclusion, the GDPR prohibits the transfer of personal data to countries outside of the European Union/EEA (including the United States) that are not considered by the European Commission to provide an adequate level of data protection, except if the data importer meets very specific requirements such as the use of standard contractual clauses ("SCCs"), issued by the European Commission. In this respect recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of personal data from the EU/EEA. For example, on June 4, 2021 the EU Commission issued a new set of SCCs for data transfers from controllers or processors in the EU/EEA to controllers or processors established outside the EU/EEA. These SCCs replace the old sets of SCCs that were adopted under the previous European Data Protection Directive 95/46. There were various implementation deadlines linked to the use of these new SCCs, and all contracts incorporating SCCs had to be updated to include the new SCCs by December 27, 2022. On November 11, 2021, the European Data Protection Board has adopted recommendations on such appropriate safeguards that supplement transfer mechanisms (like the SCCs). These recommendations aim to assist data exporters with their duty to identify and implement appropriate supplementary measures where they are needed to ensure an essentially equivalent level of protection to the personal data they transfer to third countries. However, the European Commission published a set of Questions and Answers on May 25, 2022 which provides that the new 2021 SCCs do not work for data importers whose processing operations are subject to the GDPR as they would duplicate, and in part deviate from, obligations that already follow directly from the GDPR. The Commission indicated that it is in the processing of developing an additional set of SCCs for this scenario. This has created a situation where very limited transfer mechanisms exist for use by data importers in third countries such as the United States.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses (punishable by uncapped fines) for organizations and in certain cases their directors and officers as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the European Union. Guidance developed at both EU level and at the national level in individual EU Member States concerning implementation and compliance practices are often updated or otherwise revised.

There is, moreover, a growing trend towards required public disclosure of clinical trial data in the European Union which adds to the complexity of obligations relating to processing health data from clinical trials. Such public disclosure obligations are provided in the new EU CTR, EMA disclosure initiatives and voluntary commitments by industry. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the interplay between different regulatory frameworks, such as the Clinical Trials Regulation and the GDPR, further adds to the complexity that we face with regard to data protection regulation.

On June 28, 2021 the European Commission adopted two adequacy decisions for the United Kingdom – one under the GDPR and the other for the Law Enforcement Directive. Personal data may now freely flow from the European Union to the United Kingdom since the United Kingdom is deemed to have an adequate data protection level. Additionally, following the UK's withdrawal from the European Union and the EEA, companies also have to comply with the UK's data protection laws (including the UK GDPR, which is based on the EU GDPR), which has the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The adequacy decisions include a 'sunset clause' which entails that the decisions will automatically expire four years after their entry into force.

Promotional Activities

In the European Union, interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU Member States (at a national or regional level). The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of pharmaceutical products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her regulatory professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual EU Member States (at a national or regional level). Failure to comply with these requirements could result in reputational risk, public reprimands, exclusion from public tenders, administrative penalties, fines or imprisonment.

While the UK has left the EU, as mentioned above, it should be noted that the UK still has the strictest anti-bribery regime in Europe, the UK Bribery Act 2010. The Act is applicable English law and continues to apply to any company incorporated in or "carrying on business" in the United Kingdom, irrespective of where in the world the alleged bribery activity occurs.

Other Legislation Regarding Marketing, Authorization and Pricing of Pharmaceutical Products in the European Union

Other core legislation relating to the marketing, authorization and pricing of pharmaceutical products in the European Union includes the following:

- Directive 2001/83/EC, establishing the requirements and procedures governing the marketing authorization for medicinal products for human use, as well as the rules for the constant supervision of products following authorization. This Directive has been amended several times, most recently by Directive 2012/26/EU regarding pharmacovigilance, and the Falsified Medicines Directive 2011/62/EU.
- Regulation (EC) 726/2004, as amended, establishing procedures for the authorization, supervision and pharmacovigilance of medicinal products for human and veterinary use and establishing the EMA.
- Regulation (EC) 469/2009, establishing the requirements necessary to obtain a Supplementary Protection Certificate, which extends the period of patent protection applicable to medicinal products at the EU-level.
- Directive 89/105/EEC, ensuring the transparency of measures taken by the European Union member states to set the prices and reimbursements of medicinal products. Specifically, while each member state has competence over the pricing and reimbursement of medicines for human use, they must also comply with this Directive, which establishes procedures to ensure that member state decisions and policies do not obstruct trade in medicinal products. The European Commission proposed to repeal and replace Directive 89/105/EEC, but this proposal was withdrawn in 2015.
- Directive 2003/94/EC, laying down the principles of good manufacturing practice in respect of medicinal products and investigational medicinal products for human use (the GMP Directive).
- Directive 2005/28/EC of April 8 2005, laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products (the GCP Directive).

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in the European Union, its member states and other states of Europe that could significantly change the statutory provisions governing the testing, approval, manufacturing, marketing, coverage and reimbursement of pharmaceutical products. In addition to new legislation, pharmaceutical regulations and policies are often revised or interpreted by the EMA and national agencies in ways that may significantly affect our business and our products.

The United Kingdom ("UK") formally left the EU on January 31, 2020 and the transition period, during which EU laws continued to apply to the UK, expired on December 31, 2020. This means EU laws now only apply to the UK in respect of Northern Ireland as laid out in the Protocol on Ireland and Northern Ireland. Following the end of the transition period, the EU and the UK concluded a trade and cooperation agreement ("TCA"), which applied provisionally from January 1, 2021 and entered into force on May 1, 2021.

The TCA includes provisions affecting the life sciences sector (including on customs and tariffs) but areas for further discussion between the EU and the UK remain. In addition, there are some specific provisions concerning pharmaceuticals. These include the mutual recognition of Good Manufacturing Practice ("GMP") and issued GMP documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

Since January 1, 2021, the EU laws which have been transposed into UK law through secondary legislation continue to be applicable in the UK as "retained EU law". As there is no general power to amend these regulations, the UK government has enacted the Medicines and Medical Devices Act 2021. The purpose of the act is to enable the existing regulatory frameworks in relation to human medicines, clinical trials of human medicines, veterinary medicines and medical devices to be updated. The powers under the act may only be exercised in relation to specified matters and must safeguard public health.

Specified provisions of the Medicines and Medical Devices Act 2021 entered into force on February 11, 2021. The remaining provisions came into effect within two months of February 11, 2021 or will otherwise come into effect as stipulated in subsequent statutory instruments. The Medicines and Medical Devices Act 2021 supplements the UK Medical Devices Regulations 2002 ("UK Regulations"), which are based on the EU Medical Devices Directive as amended to reflect the UK's post-Brexit regulatory regime. Notably, the UK Regulations do not include any of the revisions that have been made by the EU Medical Devices Regulation (EU) 2017/745, which, since May 26, 2021, now applies in all EU Member States.

The UK's Medicines and Healthcare products Regulatory Agency ("MHRA") conducted a comprehensive consultation between September and November 2021 on proposals to develop a new UK regime for medical devices in the UK. The proposals include more closely aligning definitions for medical devices and in vitro medical devices with internationally recognised definitions and changing the classification of medical devices according to levels or risk. The proposals are intended to improve patient and public safety and increase the appeal of the UK market. The new regime is planned to come into force on July 1, 2023, which will align with the date from which the UK is due to stop accepting CE marked medical devices and require UKCA ("UK Conformity Assessed") marking. It is envisaged that, in Northern Ireland, the amended regime could run in parallel with any existing or future EU rules in accordance with the Protocol on Ireland and Northern Ireland.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as, in the United States, Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a drug product does not necessarily imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on our investment in product development. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs, which may impact physician utilization.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider a product to be cost effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, risk sharing, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals. As a result, the marketability of any product which receives regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement.

In addition, an increasing emphasis on managed care in the United States has increased and will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the ACA, contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

Since its enactment, there have been continual judicial and Congressional challenges to certain aspects of the ACA. It is unclear how these efforts to repeal, replace or otherwise modify the ACA will impact the law on reimbursement. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, particularly as a result of the recent presidential election, or how any future legislation or regulation may affect us. Even if favorable coverage and reimbursement status is attained for one or more products that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert

competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements for any of our products.

Healthcare Laws and Regulations

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with healthcare providers, physicians, third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons from soliciting, offering, receiving or providing any remuneration (in cash or in kind), directly or indirectly, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any item, facility or service for which payment may be made in whole or in part under a federal healthcare program such as Medicare and Medicaid. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate the statute in order to have committed a violation;
- the federal Foreign Corrupt Practices Act, or FCPA, prohibits, among other things, U.S. corporations and persons acting on their behalf from offering, promising, authorizing or making payments to any foreign government official (including certain healthcare professionals in many countries), political party, or political candidate in an attempt to obtain or retain business or otherwise seek preferential treatment abroad;
- the federal False Claims Act, which may be enforced by the U.S. Department of Justice or private whistleblowers to bring civil actions (qui tam actions) on behalf of the federal government, imposes civil penalties, as well as liability for treble damages and for attorneys' fees and costs, on individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, making a false statement material to a false or fraudulent claim, or improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the Department of Health and Human Services' Civil Monetary Penalties authorities, which imposes administrative sanctions for, among other things, presenting or causing to be presented false claims for government payment and providing remuneration to government health program beneficiaries to influence them to order or receive healthcare items or services;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other conduct, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes criminal and civil liability and penalties on those who violate requirements, including mandatory contractual terms, intended to safeguard the privacy, security, transmission and use of individually identifiable health information;
- the federal false statements statute relating to healthcare matters prohibits falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal Physician Payment Sunshine Act requires manufacturers of drugs (among other products) to report to the Centers for Medicare and Medicaid Services within the U.S. Department of Health and Human Services, or HHS, information related to payments and other transfers of value to physicians (as defined by statute) and teaching hospitals, as well as physician ownership and investment interests in the reporting manufacturers. Beginning in 2022, applicable manufacturers also will be required to report payments and other transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;

- similar state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third-party payors, including private insurers; and
- certain state laws require pharmaceutical companies to comply with voluntary compliance guidelines promulgated by a pharmaceutical industry association and relevant compliance guidance issues by HHS Office of Inspector General; bar drug manufacturers from offering or providing certain types of payments or gifts to physicians and other health care providers; and/or require disclosure of gifts or payments to physicians and other healthcare providers.

Various state and foreign laws also govern the privacy and security of health information in some circumstances; many of these laws differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Violation of any of these laws or any other current or future governmental laws and regulations that may apply to drug manufacturers include significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if the manufacturer becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of its operations, any of which could substantially disrupt its operations. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Additional Regulation

In addition to the foregoing, state, and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act, and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling, and disposal of various biologic, chemical, and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in third countries that impose similar obligations.

Human Capital

As of December 31, 2022, we had 138 employees, approximately 62% of whom have an M.D., Ph.D., or other advanced degree. We believe that our future success largely depends upon our continued ability to attract and retain a diverse group of highly skilled employees. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our employee relations to be good.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are not currently a party to any material legal proceedings.

Corporate Information

We were incorporated under the laws of the State of Delaware in March 2014 under the name Unum Therapeutics Inc. On April 3, 2018, we completed our initial public offering (IPO) of our common stock under the ticker "UMRX." On October 2, 2020, we filed an amendment to our certificate of incorporation to change our name to Cogent Biosciences, Inc. The name change became effective on October 6, 2020. In connection with the name change, our common stock began trading under the ticker symbol "COGT."

As of December 31, 2022, we had 90,761,994 shares outstanding on a fully diluted and as-converted basis, including the 69,893,434 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.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission (SEC). We may choose to take advantage of some but not all of these exemptions. We have taken advantage of the reduced reporting requirements in this Annual Report on Form 10-K. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

We have irrevocably elected to "opt out" of the exemption for the delayed adoption of certain accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Available Information

Our Internet address is www.cogentbio.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at *http://www.sec.gov*. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

ITEM 1A. RISK FACTORS

The following risk factors and other information included in this Annual Report on Form 10-K 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 Annual Report on Form 10-K, 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 may later be found to cause side effects that prevent further development of the drug. Currently marketed therapies for the treatment of AdvSM and cancer are generally limited to some extent by their toxicity. In addition, some of our drug candidates would be chronic therapies, 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, when used in combination with other therapies, our drug candidates could exacerbate adverse events associated with the other 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. For further information, see "Business-Competition," which discusses the pharmaceutical and biotechnology companies developing or marketing treatments for cancer and hematologic diseases that are competitive with bezuclastinib and the drug candidates we are developing.

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.

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.

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 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.

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 publicly disclose preliminary or "top-line" data from our clinical trials, which is 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 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.

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. The formulation is unproven to date, and there is no guarantee that it will be successful.

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.

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 COVID-19 pandemic, 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 ongoing 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, 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, discovery, manufacturing and supply 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"), contract 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 Non-AdvSM. 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.

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.

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.

Risks Related to Our Intellectual Property

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, Brazil, 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 Australia, Brazil, Canada, China, Egypt, Europe, India, Indonesia, Israel, Japan, Korea, Mexico, Philippines, Singapore, South Africa, 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.

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.

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 year ended December 31, 2022, we increased our headcount from 77 to 138 full time employees through the expansion of our research, development, manufacturing and G&A infrastructure, and we moved into new offices and labs in Massachusetts and Colorado, respectively. 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 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.

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.

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 the deferred tax assets related to these attributes, which were previously fully reserved for, in 2020. As of December 31, 2022, approximately $66.4 million and $2.8 million of federal and state net operating losses, respectively, as well as $7.1 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 2020 to December 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. The Company has not performed a Section 382 analysis since December 2020.

Risks Related to Ownership of our Common Stock

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, 2022. 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.

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

Given the low trading 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.

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 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Waltham, Massachusetts

Our corporate headquarters are located in Waltham, Massachusetts, where we sublease approximately 17,749 square feet of office space pursuant to a sublease agreement that commenced in June 2022 and expires in September 2026. This facility primarily houses our clinical, regulatory, and administrative personnel.

Boulder, Colorado

We lease approximately 44,657 square feet of office and laboratory space in Boulder, Colorado. The Boulder Lease has an initial term of 12 years with the option to extend for three successive five-year terms. This facility primarily houses our research and other administrative personnel.

Cambridge, Massachusetts

We also lease approximately 33,500 square feet of office and laboratory space in Cambridge, Massachusetts pursuant to a lease agreement that commenced in July 2015 and expires in April 2023. This served as our corporate headquarters before moving to our new location in Waltham, Massachusetts. We sublease approximately 70% of this space under the terms of a sublease agreement.

We believe that our current facilities are adequate to meet our immediate needs.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party 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 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "COGT" on the Nasdaq Global Select Market and has been publicly traded since March 29, 2018. On October 2, 2020, we filed an amendment to our certificate of incorporation to change our name from Unum Therapeutics Inc. to Cogent Biosciences, Inc. The name change became effective on October 6, 2020. In connection with the name change, our common stock began trading under the ticker symbol "COGT." Our common stock previously traded under the ticker symbol "UMRX." Prior to March 29, 2018, there was no public market for our common stock.

Holders of Our Common Stock

As of March 12, 2023, there were approximately 4 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Securities authorized for issuance under equity compensation plans

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Recent Sales of Unregistered Equity Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. Reserved

ITEM 7. 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 financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

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 in mast cells, a type of white blood cell, it causes them 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 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 and is initially targeting FGFR2 and ErbB2.

Bezuclastinib

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. We also presented data supporting that bezuclastinib inhibits KIT downstream signaling and may drive tumor regressions at clinically achievable doses.

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 and we presented updated positive clinical data in an oral presentation at the American Society of Hematology Annual Meeting in December 2022. We expect to provide an update on the planned initiation of APEX Part 2 based on clinical data from approximately 25-30 patients in APEX Part 1 in mid-2023.

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 was amended in 2022 to allow for the new formulation to be introduced during the dose exploration phase. We expect to report initial clinical data in patients with Non-AdvSM in the second half of 2023. In March 2023, Cogent received approvals from European regulatory authorities to initiate the SUMMIT trial in patients with Non-AdvSM. Beginning in April 2023, we expect to start activating clinical trial sites across major countries in the European Union.

We are also 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 the Phase 1/2 clinical trial were published in the Journal of American Medical Association and were 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., a member of the Daiichi Sankyo Group ("Plexxikon"), 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.

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 was presented at the CTOS annual meeting in November 2022. We expect to present updated clinical data from refractory GIST patients in the lead-in cohort of the Phase 3 PEAK trial of bezuclastinib plus sunitinib during the first 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. During the second quarter of 2022, as a result of the progression of the Peak study, the first clinical milestone was achieved, resulting in payment of $2.5 million to Plexxikon in June 2022.

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. In October 2022, we reported preclinical data at EORTC-NCI-AACR (ENA) annual meeting on a next-generation fibroblast growth factor receptor 2 ("FGFR2") program, which retains potency across all primary, gatekeeper and molecular brake resistance mutations, including N549K and V564I, while sparing FGFR1 inhibition.

Our research team is also advancing a novel, ErbB2 mutant program, which is focused on actionable and underserved mutations in a variety of solid tumor indications. Currently available oral ErbB2 inhibitors struggle to provide broad mutant coverage while sparing EGFR activity. In October 2022, presented preclinical data at ENA on a novel ErbB2 mutant selective program which demonstrates robust cellular inhibition of all key resistance and primary driver mutations, including L755S, V842I and S310F/Y, while sparing wild type EGFR target engagement.

For both FGFR and ErBB2, we see an opportunity to provide a more robust molecular response compared to existing therapies. We expect to initiate clinical trials for both of these programs in 2024.

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 $140.2 million for the year ended December 31, 2022 compared to net losses of $72.3 million for the year ended December 31, 2021. As of December 31, 2022, we had an accumulated deficit of $411.2 million. We expect to continue to incur significant expenses and operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

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

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

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

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

As of December 31, 2022, we had cash, cash equivalents and marketable securities of $259.3 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.

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.

Sublease Income

Sublease income consists of income from subleasing a portion of our former headquarters facilities in Cambridge, Massachusetts.

Other Income, Net

Other income consists of miscellaneous income and expense unrelated to our core operations.

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, 2022. We reevaluate the utilization of net operating loss carryforwards and tax credits at each reporting period. As of December 31, 2022, we had U.S. federal and state net operating loss carryforwards of $151.9 million and $65.1 million, respectively, which may be available to offset future taxable income and begin to expire in 2035. Of the federal net operating loss carryforwards at December 31, 2022, $148.7 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, 2022, we also had U.S. federal and state research and development tax credit carryforwards of $10.7 million and $1.9 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 Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	Year Ended December 31,		
	2022	2021	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 121,627	$ 55,913	$ 65,714
General and administrative	26,212	19,638	6,574
Total operating expenses	147,839	75,551	72,288
Loss from operations	(147,839)	(75,551)	(72,288)
Other income:			
Interest income	3,989	467	3,522
Other income, net	2,249	2,468	(219)
Change in fair value of CVR liability	1,360	343	1,017
Total other income, net	7,598	3,278	4,320
Net loss	$ (140,241)	$ (72,273)	$ (67,968)

Research and Development Expenses

The following table summarizes our research and development expenses for the year ended December 31, 2022 and 2021:

	Year Ended December 31,		
	2022	2021	Change
	(in thousands)		
Direct external research and development expenses:			
Bezuclastinib	$ 61,270	$ 29,526	$ 31,744
Preclinical research and discovery	12,957	4,121	8,836
Unallocated expenses:			
Personnel related (including stock-based compensation)	35,506	16,809	18,697
Laboratory supplies, facility related and other	11,894	5,457	6,437
Total research and development expenses	$ 121,627	$ 55,913	$ 65,714

Total research and development expense increased by $65.7 million for the year ended December 31, 2022 compared to the year ended December 31, 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 $4.1 million for the year ended December 31, 2022 compared to the year ended December 31, 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 year ended December 31, 2022 were $26.2 million, compared to $19.6 million for the year ended December 31, 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 $2.6 million for the year ended December 31, 2022 compared to the year ended December 31, 2021.

Interest Income

Interest income for the year ended December 31, 2022 was $4.0 million, compared to $0.5 million for the year ended December 31, 2021. The increase in interest income was primarily due to higher average invested balances and higher interest rates in the current year compared to the prior period.

Other Income, Net

Other income, net was $2.2 million in the year ended December 31, 2022, compared to $2.5 million for the year ended December 31, 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 of $0.4 million recorded for this space in 2022.

Change in fair value of CVR liability

The change in fair value of CVR liability for year ended December 31, 2022 was $1.4 million, compared to $0.3 million for the year ended December 31, 2021. The increase in the change in fair value of CVR liability was a result of a decrease in the probability of receiving the milestone payments from Sotio prior to the expiration of the CVR.

Liquidity and Capital Resources

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

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

Additionally, on May 6, 2022, pursuant to the Form S-3, we entered into a Sales Agreement (the "Sales Agreement") with Guggenheim Securities, LLC ("Guggenheim Securities"), pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $75.0 million through Guggenheim Securities, as the sales agent. As of December 31, 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.

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

As of December 31, 2022, we had 90,761,994 shares outstanding on a fully diluted and as-converted basis, including the 69,893,434 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 December 31, 2022, we had cash, cash equivalents and marketable securities of $259.3 million, which we believe will be sufficient to fund our operating expenses and capital expenditure requirements into 2025. Cogent holds a de minimis amount of cash related balances at Silicon Valley Bank.

Cash Flows

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

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (118,638)	$ (58,763)
Net cash used in investing activities	(124,718)	(1,719)
Net cash provided by financing activities	163,558	37,976
Net decrease in cash, cash equivalents and restricted cash	$ (79,798)	$ (22,506)

Operating Activities

During the year ended December 31, 2022, operating activities used $118.6 million of cash, primarily resulting from our net loss of $140.2 million, partially offset by changes in our operating assets and liabilities of $0.8 million and net non-cash charges of $20.9 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2022 consisted primarily of a $12.0 million increase in accounts payable and accrued expenses and other current liabilities, partially offset by a $8.7 million decrease in operating lease liabilities, a $1.5 million increase in prepaid expenses and other current assets and a $1.0 million decrease in other assets.

During the year ended December 31, 2021, operating activities used $58.8 million of cash, primarily resulting from our net loss of $72.3 million, partially offset by changes in our operating assets and liabilities of $0.2 million and net non-cash charges of $13.3 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2021 consisted primarily of a $0.2 million decrease in prepaid expenses and other current assets, a $2.1 million decrease in operating lease liabilities and a $3.7 million decrease in other assets, partially offset by $6.2 million increase in accounts payable and accrued expenses and other current liabilities.

Changes in accounts payable, accrued expenses, and prepaid expenses and other current assets and other assets in all periods were generally due to changes in our business, the advancement of our product candidates, and the timing of vendor invoicing and payments.

Investing Activities

During the year ended December 31, 2022, net cash used in investing activities was $124.7 million, consisting of purchases of marketable securities and property and equipment, partially offset by maturities and sales of marketable securities.

During the year ended December 31, 2021, net cash used in investing activities was $1.7 million, consisting of purchases of property and lab equipment.

Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $163.6 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, $1.6 million from the issuance of common stock upon stock option exercises, from the issuance of common stock under the Employee Stock Purchase Plan and from pre-funded warrant exercises.

During the year ended December 31, 2021, net cash provided by financing activities was $38.0 million which consisted of $38.0 million in net proceeds from the issuance of common stock under the ATM, $0.1 million from the issuance of common stock upon stock option exercises and from the issuance of common stock under the Employee Stock Purchase Plan. This is offset by $0.1 million in payments to CVR holders.

Funding Requirements

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

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

Based on our current plans, we believe that our existing cash, cash equivalents and marketable securities of $259.3 million as of December 31, 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. We will require additional funding to complete the critical activities planned to support ongoing research and development programs.

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

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. Actual results may differ from these estimates under different assumptions or conditions and could have a material impact on our reported results. While our significant accounting policies are more fully described in the Notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be the most critical in understanding the judgments and estimates we use in preparing our consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with the preclinical development activities;
- CMOs in connection with the production of preclinical and clinical trial materials;
- CROs in connection with preclinical studies and clinical trials; and
- investigative sites in connection with clinical trials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct, and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation

We measure stock options and other stock-based awards granted to employees, non-employees and directors based on their fair value on the date of the grant and recognize compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We apply the straight-line method of expense recognition to all awards with only service-based vesting conditions and apply the graded-vesting method to all awards with performance-based vesting conditions or to awards with both service-based and performance-based vesting conditions.

For performance-based stock options, we begin to recognize expense when we determine that the achievement of such performance conditions is deemed probable. This determination requires significant judgment by management. At the date achievement becomes probable, we record a cumulative expense catch-up, with remaining expense amortized over the remaining service period.

We estimate the fair value of our stock-based awards to employees and non-employees using the Black-Scholes option-pricing model, which requires the input of highly subjective assumptions, including (a) the expected volatility of our stock, (b) the expected term of the award, (c) the risk-free interest rate, and (d) expected dividends. Due to the lack of a sufficient history of public trading of our common stock and a lack of sufficient company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of companies in the pharmaceutical and biotechnology industries in a similar stage of development as us and that are publicly traded. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We have estimated the expected term of our employee stock options using the "simplified" method, whereby, the expected term equals the average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period the options were granted. The expected dividend yield of zero is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future. We account for forfeitures as they occur.

Off-Balance Sheet Arrangements

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

Recently Issued Accounting 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 consolidated financial statements appearing elsewhere in this Annual Report.

ITEM 7A. 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

COGENT BIOSCIENCES, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Cogent Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cogent Biosciences, Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity, and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 14, 2023

We have served as the Company's auditor since 2015.

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 139,886	$ 219,684
Marketable securities	119,390	—
Prepaid expenses and other current assets	4,435	2,949
Restricted cash	1,255	—
Total current assets	264,966	222,633
Operating lease, right-of-use asset	23,316	2,771
Property and equipment, net	7,783	1,706
Restricted cash	—	1,255
Other assets	4,745	3,727
Total assets	$ 300,810	$ 232,092
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,842	$ 3,483
Accrued expenses and other current liabilities	17,884	8,210
CVR liability (Note 3)	1,700	3,060
Operating lease liability	1,423	2,324
Total current liabilities	26,849	17,077
Operating lease liability, net of current portion	18,226	831
Total liabilities	45,075	17,908
Commitments and contingencies (Note 9)		
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 December 31, 2022 and December 31, 2021, respectively	65,830	85,400
Common stock, $0.001 par value; 150,000,000 shares authorized; 69,893,434 shares and 43,805,922 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	70	44
Additional paid-in capital	601,153	399,713
Accumulated other comprehensive loss	(104)	—
Accumulated deficit	(411,214)	(270,973)
Total stockholders' equity	255,735	214,184
Total liabilities and stockholders' equity	$ 300,810	$ 232,092

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

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

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 121,627	$ 55,913
General and administrative	26,212	19,638
Total operating expenses	147,839	75,551
Loss from operations	(147,839)	(75,551)
Other income:		
Interest income	3,989	467
Other income, net	2,249	2,468
Change in fair value of CVR liability	1,360	343
Total other income, net	7,598	3,278
Net loss	$ (140,241)	$ (72,273)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.39)	$ (1.87)
Weighted average common shares outstanding, basic and diluted	58,739,713	38,730,813
Comprehensive loss:		
Net loss	$ (140,241)	$ (72,273)
Other comprehensive loss		
Net unrealized losses on marketable securities	(104)	—
Total other comprehensive loss	(104)	—
Comprehensive loss	$ (140,345)	$ (72,273)

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

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

	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				
Balance 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	(28,955)	(25,481)	7,238,750	8	25,473	—	—	—
Issuance of common stock for services	—	—	31,683	—	260	—	—	260
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
Issuance of common stock under ATM, net of issuance costs of $1.2 million	—	—	3,954,900	4	38,002	—	—	38,006
Issuance of common stock to settle CVR liability	—	—	212,429	—	2,043	—	—	2,043
Stock-based compensation expense	—	—	—	—	11,426	—	—	11,426
Net loss	—	—	—	—	—	—	(72,273)	(72,273)
Balances at December 31, 2021	103,289	$ 85,400	43,805,922	$ 44	$ 399,713	$ —	$ (270,973)	$ 214,184
Issuance of common stock in underwritten public offering, net of offering costs of $10.8 million	—	—	17,899,698	18	161,897	—	—	161,915
Pre-funded warrant exercise	—	—	2,424,242	2	22	—	—	24
Conversion of Series A non-voting preferred stock into common stock	(22,239)	(19,570)	5,559,750	6	19,564	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	49,000	—	351	—	—	351
Unrealized losses on marketable securities	—	—	—	—	—	(104)	—	(104)
Issuance of common stock from exercises	—	—	154,822	—	1,238	—	—	1,238
Stock-based compensation expense	—	—	—	—	18,368	—	—	18,368
Net loss	—	—	—	—	—	—	(140,241)	(140,241)
Balances at December 31, 2022	81,050	$ 65,830	69,893,434	$ 70	$ 601,153	$ (104)	$ (411,214)	$ 255,735

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

COGENT BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (140,241)	$ (72,273)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	842	147
Stock-based compensation expense	18,368	11,686
Amortization of right-of-use operating lease assets	5,036	1,844
Change in fair value of CVR liability	(1,360)	(343)
Net amortization (accretion) of premiums (discounts) on marketable securities	(1,638)	—
Right-of-use asset impairment	(396)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,486)	(227)
Other assets	(1,018)	(3,727)
Accounts payable	2,359	2,751
Accrued expenses and other current liabilities	9,586	3,431
Operating lease liability	(8,690)	(2,052)
Net cash used in operating activities	(118,638)	(58,763)
Cash flows from investing activities:		
Purchases of property and equipment	(6,863)	(1,719)
Purchases of marketable securities	(177,855)	—
Maturities and sales of marketable securities	60,000	—
Net cash used in investing activities	(124,718)	(1,719)
Cash flows from financing activities:		
Proceeds from issuance of common stock under ATM, net of issuance costs of $1.2 million	—	38,006
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 common stock upon stock option exercises	1,238	24
Proceeds from pre-funded warrant exercises	24	—
Proceeds from issuance of stock from employee stock purchase plan	351	31
Payments to CVR Holders	—	(85)
Net cash provided by financing activities	163,558	37,976
Net decrease in cash, cash equivalents and restricted cash	(79,798)	(22,506)
Cash, cash equivalents and restricted cash at beginning of period	220,939	243,445
Cash, cash equivalents and restricted cash at end of period	$ 141,141	$ 220,939
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:		
Conversion of Series A non-voting convertible preferred stock into common stock	19,570	25,481
Offering costs included in accounts payable and accrued expenses	30	—
Property & equipment included in accounts payable and accrued expenses	58	—
Issuance of common shares in partial settlement of CVR liability	—	2,043

The accompanying notes are an integral part of these 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, and is initially targeting FGFR2 and ErbB2.

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

The accompanying 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 $140.2 million for the year ended December 31, 2022. As of December 31, 2022, the Company had an accumulated deficit of $411.2 million. The Company expects to continue to generate operating losses in the foreseeable future. As of the issuance date of the 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 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 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

Principles of Consolidation

The accompanying 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 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 consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these 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.

Concentrations of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company maintains most of its cash and cash equivalents at two accredited financial institutions. The Company has not experienced any losses on such accounts and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Such deposits have and will continue to exceed federally insured limits.

The Company is dependent on third-party vendors for its product candidates. In particular, the Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and process its product candidates for its development programs. These programs could be adversely affected by a significant interruption in the manufacturing process.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

Restricted Cash

Restricted cash consists of security deposits in separate restricted bank accounts as required under the terms of the Company's lease agreement for its former corporate headquarters in Cambridge, Massachusetts, which expires in April 2023.

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).

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Laboratory equipment	5 years
Computer equipment and software	3 years
Furniture and fixtures	5 years
Leasehold improvements	Shorter of life of lease or 10 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated in accordance with the above guidelines once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company’s cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company’s accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company’s singular focus is the development and commercialization of precision therapies for genetically defined diseases. All of the Company’s tangible assets are held in the United States.

Leases

The Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the assets' economic benefits. The Company determines the initial classification and measurement of its operating right-of-use assets and operating lease liabilities at the lease commencement date, and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The Company's policy is to not record leases with an original term of twelve months or less on its consolidated balance sheets. The Company's only existing leases are for office and laboratory space.

The right-of-use asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term.

Lease payments included in the measurement of the lease liability consist of the following: the fixed noncancelable lease payments, payments for optional renewal periods where it is reasonably certain the renewal period will be exercised, and payments for early termination options unless it is reasonably certain the lease will not be terminated early.

Leases may contain rent escalation clauses and variable lease payments that require additional rental payments in later years of the term, including payments based on an index or inflation rate. Payments based on the change in an index or inflation rate, or payments based on a change in the Company's portion of the operating expenses, including real estate taxes and insurance, are not included in the initial lease liability and are recorded as a period expense when incurred. The operating leases may include an option to renew the lease term for various renewal periods and/or to terminate the leases early. These options to exercise the renewal or early termination clauses in the Company's operating leases were not reasonably certain of exercise as of the date of adoption and these have not been included in the determination of the initial lease liability or operating lease expense.

Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the consolidated statements of operations and comprehensive loss. For finance leases, any interest expense is recognized using the effective interest method and is included within interest expense. The Company has no financing leases.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs and laboratory supplies, depreciation, manufacturing expenses and external costs of outside vendors engaged to conduct preclinical development activities and clinical trials as well as the cost of licensing technology.

Upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred. Nonrefundable advance payments 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.

Research Contract Costs and Accruals

The Company has entered into various research and development contracts with companies both inside and outside of the United States. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock-Based Compensation

The Company measures stock options and other stock-based awards granted to employees, non-employees and directors based on their fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. The Company applies the straight-line method of expense recognition to all awards with only service-based vesting conditions and applies the graded-vesting method to all awards with performance-based vesting conditions or to awards with both service-based and performance-based vesting conditions.

For performance-based stock options, the Company begins to recognize expense when it determines that the achievement of such performance conditions is deemed probable. This determination requires significant judgment by management. At the date achievement becomes probable, the Company records a cumulative expense catch-up, with remaining expense amortized over the remaining service period.

The Company estimates the fair value of stock-based awards to employees and non-employees using the Black-Scholes option-pricing model, which requires the input of highly subjective assumptions, including (a) the expected volatility of its stock, (b) the expected term of the award, (c) the risk-free interest rate, and (d) expected dividends. Due to the lack of a sufficient history of public trading of the Company's common stock and a lack of sufficient company-specific historical and implied volatility data, the Company has based the estimate of expected volatility on the historical volatility of a group of companies in the pharmaceutical and biotechnology industries in a similar stage of development and that are publicly traded. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. The Company estimates the expected life of employee stock options using the "simplified" method, whereby, the expected life equals the average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period the options were granted. The expected dividend yield of zero is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The Company accounts for forfeitures as they occur.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the year ended December 31, 2022, the Company's only element of other comprehensive loss was unrealized gains (losses) on marketable securities. For the year ended December 31, 2021, there were no elements of other comprehensive loss.

Net Income (Loss) per Share

Basic net income (loss) per common share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period.

Diluted net income (loss) per common share attributable to common stockholders is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options. Accordingly, in periods in which the Company reported a net loss, dilutive common shares were not assumed to have been issued as their affect was anti-dilutive, and as a result, diluted net loss per common share was the same as basic net loss per common share.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

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 consolidated financial statements.

3. Fair Value Measurements of Financial Assets and Liabilities

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

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury bills and notes (due within one year)	$ 119,494	$ —	$ (104)	$ 119,390
	$ 119,494	$ —	$ (104)	$ 119,390

As of December 31, 2022, the Company held seven securities that were in an unrealized loss position. The aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months as of December 31, 2022 was $99.5 million and there were no securities held by the Company in an unrealized loss position for more than twelve months. The Company has the intent and ability to hold such securities until recovery. As a result, the Company did not record any charges for credit-related impairments for its marketable debt securities for the year ended December 31, 2022. 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 December 31, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 108,829	$ —	$ —	$ 108,829
Marketable securities:				
U.S. Treasury bills and notes	$ —	$ 119,390	$ —	$ 119,390
Total Assets	$ 108,829	$ 119,390	$ —	$ 228,219
Liabilities:				
CVR Liability	$ —	$ —	$ 1,700	$ 1,700
Total Liabilities	$ —	$ —	$ 1,700	$ 1,700

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

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 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 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 its assets, rights and interests relating to its BOXR Platform, to Sotio. Pursuant to the BOXR Platform Purchase Agreement, Sotio has agreed to pay the Company total cash consideration of up to $11.5 million, consisting of an upfront payment of $8.1 million and potential milestone payments of up to $3.4 million in the aggregate upon the achievement of certain milestones related to the issuance of Specified Claims (as described in the BOXR Platform Purchase Agreement) by the U.S. Patent and Trademark Office and the European Patent Office. The upfront payment was received in 2020. In 2020, the Company also sold additional fixed assets used in the legacy business. Both transactions triggered payment to the 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.

In the fourth quarter of 2022, the Company updated the probability weighted discounted cash flow assumptions to reflect the current probability of receiving the milestone payments from Sotio prior to the expiration of the CVR. Based on the Company's assessment of the available information, this update resulted in a decrease in the probability of receiving the milestone payment prior to the expiration of the CVR and a corresponding decrease in the CVR liability. The change in fair value of the liability of $1.4 million was recognized as a component of other income (expense) in 2022.

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		(1,360)
Balance at December 31, 2022	$	1,700

During the years ended December 31, 2022 and 2021, there were no transfers between Level 1, Level 2 and Level 3.

4. Property and Equipment, Net

Property and equipment, net consisted of the following *(in thousands)*:

	December 31,	
	2022	2021
Laboratory equipment	$ 5,507	$ 1,073
Computer equipment and software	546	53
Furniture and fixtures	873	85
Leasehold improvements	1,776	408
Construction-in-progress	482	646
Total property and equipment	9,184	2,265
Accumulated depreciation and amortization	(1,401)	(559)
Property and equipment, net	$ 7,783	$ 1,706

Depreciation and amortization expense was $0.8 million and $0.1 million for the years ended December 31, 2022 and 2021, respectively.

5. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2022	2021
Accrued employee compensation and benefits	$ 6,063	$ 3,389
Accrued external research and development expense	5,898	1,953
Accrued external manufacturing costs	3,741	1,556
Accrued professional and consulting services	1,778	1,077
Other	404	235
	$ 17,884	$ 8,210

6. 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 2020 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 December 31, 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 December 31, 2022 are convertible into 20,262,500 shares of common stock. Subsequent to December 31, 2022, an additional 4,000 shares of Series A Preferred Stock were converted into 1,000,000 shares of common stock.

No other classes of preferred stock have been designated and no other preferred shares have been issued or are outstanding as of December 31, 2022 or 2021.

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 Form 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.

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 December 31, 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. In accordance with 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 December 31, 2022, 2,424,242 pre-funded warrants have been exercised and 606,060 pre-funded warrants remain outstanding.

7. 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. As of December 31, 2022, 686,585 shares of common stock remain available for issuance under the 2018 Plan.

The number of authorized shares reserved for issuance under the 2018 Plan was increased by 2,795,737 shares effective as of January 1, 2023. 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.

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 the Company'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 December 31, 2022, 677,995 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. As of December 31, 2022, 404,268 shares remain available for issuance under the ESPP. The number of authorized shares reserved for issuance under the ESPP was increased by 125,000 shares effective as of January 1, 2023. In January 2023, 39,228 shares were issued to employees under the ESPP.

Stock Option Valuation

The following table presents, on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model to determine the fair value of stock options granted to employees and directors:

	Year Ended December 31,	
	2022	2021
Risk-free interest rate	2.2%	1.3%
Expected volatility	72.4%	75.3%
Expected dividend yield	—	—
Expected life (in years)	6.22	6.21

Stock Option Activity

The following table summarizes the activity of our 2018 Stock Option and Incentive Plan and the Inducement Plan, excluding performance-based stock options:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	8,793,626	$ 9.57		
Granted	4,724,584	8.36		
Exercised	(154,822)	7.99		
Forfeited	(531,617)	8.55		
Outstanding as of December 31, 2022	12,831,771	$ 9.19	8.49	$ 32,864
Vested and expected to vest as of December 31, 2022	12,831,771	$ 9.19	8.49	$ 32,864
Options exercisable as of December 31, 2022	4,639,104	$ 9.31	8.15	$ 11,134

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had strike prices lower than the fair value of the Company's common stock.

The aggregate intrinsic value of options exercised during the years ended December 31, 2022 and 2021 was $1.0 million and $0.1 million, respectively. The weighted average grant-date fair value of awards granted during the years ended December 31, 2022 and 2021 was $5.52 per share and $5.93 per share, respectively.

Employee Stock Purchase Plan

The Company estimates the fair value of shares to be issued under the 2018 Employee Stock Purchase Plan using the Black-Scholes option-pricing model on the date of grant, or first day of the offering period. The following table summarizes information pertaining to stock purchase rights granted under the employee stock purchase plan, during the years indicated:

	Year Ended December 31,	
	2022	2021
Risk-free interest rate	1.3%	0.1%
Expected volatility	64.1%	66.9%
Expected dividend yield	—	—
Expected life (in years)	0.50	0.50

Stock-Based Compensation

The following table summarizes stock-based compensation expense during the years ended December 31, 2022, in thousands:

	Year Ended December 31,	
	2022	2021
Stock-based compensation expense by type of award:		
Time-based stock options	$ 18,144	$ 11,361
Employee stock purchase plan	224	65
Non-employee stock options	—	260
Total	$ 18,368	$ 11,686

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

	Year Ended December 31,	
	2022	2021
Research and development expenses	$ 8,510	$ 4,392
General and administrative expenses	9,858	7,294
Total	$ 18,368	$ 11,686

As of December 31, 2022, total unrecognized compensation cost related to the unvested stock-based options was $47.5 million, which is expected to be recognized over a weighted average period of 2.57 years.

8. Income Taxes

During the years ended December 31, 2022 and 2021, the Company recorded no current or deferred income tax benefits due to its full valuation allowance. Also, the Company had no foreign operations.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2022	2021
Federal statutory income tax rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(4.4)	(2.9)
Federal and state research and development tax credits	(6.1)	(4.0)
Nondeductible stock compensation	1.1	1.4
Other items	(0.2)	0.4
Change in valuation allowance	30.6	26.1
Effective income tax rate	0.0%	0.0%

The Company's net deferred tax assets as of December 31, 2022 and 2021 consisted of the following *(in thousands)*:

	December 31,	
	2022	2021
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 36,161	$ 30,147
Research and development and investment tax credits	12,202	3,719
Accrued expenses	1,676	734
Capitalized research and development expense	33,155	8,529
Operating lease right-of-use assets	(5,922)	(703)
Operating lease liabilities	4,991	800
Contingent consideration	864	862
Stock compensation	4,758	2,257
Other	1,659	342
Total deferred tax assets	89,544	46,687
Valuation allowance	(89,544)	(46,687)
Net deferred tax assets	$ —	$ —

As of December 31, 2022, the Company had U.S. federal and state net operating loss carryforwards of $151.9 million and $65.1 million, respectively, which may be available to offset future taxable income and begin to expire in 2035. Of the federal net operating loss carryforwards at December 31, 2022, $148.7 million is available to be carried forward indefinitely but can only offset 80% of taxable income per year. As of December 31, 2022, the Company also had U.S. federal and state research and development tax credit carryforwards of $10.7 million and $1.9 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2040 and 2035, respectively.

On December 22, 2017, the Tax Cuts and Jobs Act (the "TCJA") was signed into law. Under the TCJA provisions, effective with tax years beginning on or after January 1, 2022, taxpayers can no longer immediately expense research and development expenditures. Taxpayers are now required to capitalize and amortize these costs over 5 years for research conducted within the United States or 15 years for research conducted abroad. As a result, the Company capitalized $111.2 million of research and development expenses for the year ended December 31, 2022.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial 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.

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 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. The Company has written off the deferred tax assets related to these attributes, which were previously fully reserved for, in 2020. As of December 31, 2022, approximately $66.4 million and $2.8 million of federal and state net operating losses, respectively, as well as $7.1 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 2020 to December 2020. The December 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. The Company has not performed a Section 382 analysis since December 2020.

The Company has not performed a research and development tax credit study. Any change to the Company's credits as a result of a study would be offset by a change in the valuation allowance.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its net deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of its net deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2022 and 2021. Management reevaluates the positive and negative evidence at each reporting period.

The changes in the valuation allowance during the year ended December 31, 2022 primarily related to net operating loss carryforwards and capitalized research and development expenses and the change in the valuation allowance during the year ended December 31, 2021 primarily related to the operating loss carryforwards and were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Valuation allowance as of beginning of year	$ 46,687	$ 27,799
Decreases recorded to income tax provision	—	—
Increases recorded to income tax provision	42,857	18,888
Valuation allowance as of end of year	$ 89,544	$ 46,687

As of December 31, 2022 and 2021, the Company had not recorded any amounts for unrecognized tax benefits. The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The statute of limitations for assessment by the Internal Revenue Service remains open for all years since 2019, with certain states open since 2018. 'The Company's tax attributes related to years prior to 2019 can still be adjusted under audit. No federal or state tax audits are currently in process.

9. 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, Massachusetts, 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 is 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 consolidated balance sheet as of December 31, 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 recorded a right-of-use asset and lease liability for this lease 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, Colorado, which includes 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").

In accordance with 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 consolidated balance sheet as of December 31, 2022.

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

Former Corporate Headquarters- Cambridge, MA

The Company leases office and laboratory space in Cambridge, Massachusetts 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 year ended December 31, 2022, following the move of the Corporate Headquarters from Cambridge, Massachusetts to Waltham, Massachusetts.

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

	Year Ended December 31, 2022	Year Ended December 31, 2021
Lease cost		
Operating lease cost	$ 4,052	$ 2,424
Variable lease cost (1)	991	825
Sublease income	(2,621)	(2,468)
Total lease cost	$ 2,422	$ 781
Other information		
Cash paid for amounts included in the measurement of lease liabilities	$ 8,413	$ 3,250
Weighted average remaining lease term	10.84	1.33
Weighted average discount rate	8.04%	9.50%

(1) The variable lease costs for the year ended December 31, 2022 include common area maintenance and other operating charges.

Future minimum lease payments under the Company's operating leases as of December 31, 2022 are as follows *(in thousands)*:

Year Ending December 31,	
2023	$ 2,544
2024	2,780
2025	2,841
2026	2,697
2027	2,132
Thereafter	17,546
Total future minimum lease payments	30,540
Less: imputed interest	10,628
Less: tenant improvement allowance receivable	263
Total operating lease liability	$ 19,649
Included in the consolidated balance sheet:	
Current operating lease liability	$ 1,423
Operating lease liability, net of current portion	18,226
Total operating lease liability	$ 19,649

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 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 progression of the PEAK study, the first clinical milestone was achieved, resulting in payment of $2.5 million to Plexxikon in June 2022. As of December 31, 2022, no other milestone payments have been made or are considered probable of occurring.

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

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

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2022 or 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.

10. Net Loss per Share

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

	Year Ended December 31,	
	2022	2021
Numerator:		
Net loss	$ (140,241)	$ (72,273)
Net loss attributable to common stockholders	$ (140,241)	$ (72,273)
Denominator:		
Weighted average common shares outstanding, basic and diluted	58,739,713	38,730,813
Net loss per common share, basic and diluted	$ (2.39)	$ (1.87)

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:

	December 31,	
	2022	2021
Stock options to purchase common stock	12,831,771	8,793,626
Series A Preferred Stock	20,262,500	25,822,250
	33,094,271	34,615,876

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.

11. 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 $0.8 million and $0.4 million for the years ended December 31, 2022 and December 31, 2021, respectively.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. 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 December 31, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under 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 December 31, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of Cogent's internal control over financial reporting as of December 31, 2022. In making this assessment, it used the criteria established in Internal Control—Integrated Framework (2013) issued by the *Committee of Sponsoring Organizations of the Treadway Commission (COSO)*. Based on such assessment, our management has concluded that Cogent's internal control over financial reporting was effective, as of December 31, 2022.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption established by the Jumpstart Our Business Startups Act of 2012 for "emerging growth companies."

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 December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) 1. *Financial Statements*

For a list of the financial statements included herein, see Index to the Financial Statements on page 64 of this Annual Report on Form 10-K, incorporated into this Item by reference.

2. *Financial Statement Schedules*

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the financial statements or the notes thereto.

3. *Exhibits*

See the Exhibit Index in Item 15(b) below.

(b) Exhibit Index.

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-223414) filed on March 19, 2018)
3.2	Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K (File No. 001-38443) filed on October 5, 2020)
3.3	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's on Form 8-K (File No. 001-38443) filed on October 5, 2020)
3.4	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's on Form 8-K (File No. 001-38443) filed on November 9, 2020)
3.5	Certificate of Designations of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's on Form 8-K (File No. 001-38443) filed on July 6, 2020)
4.1	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-K (File No. 001-38443) filed on March 15, 2022)
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K (File No. 001-38443) filed on June 16, 2022)
10.1	Form of Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-K (File No. 001-38443) filed on March 15, 2022)
10.2#	Cogent Biosciences, Inc. Amended and Restated 2018 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38443) filed on June 17, 2021)
10.3#	Cogent Biosciences, Inc. 2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Form 10-K (File No. 001-38443) filed on March 16, 2021)
10.4#	Amended and Restated Cogent Biosciences, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-K (File No. 001-38443) filed on March 15, 2022)
10.5(1)	Securities Purchase Agreement among the Registrant and the purchasers party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's on Form 8-K (File No. 001-38443) filed on July 6, 2020)
10.6	Registration Rights Agreement between the Registrant and the purchasers party thereto (incorporated by reference to Exhibit 10.2 to the Registrant's on Form 8-K (File No. 001-38443) filed on July 6, 2020)

10.7	Contingent Value Rights Agreement dated as of August 6, 2020 among the Registrant, Computershare Inc. and Computershare Trust Company, N.A., (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38443) filed on August 10, 2020)
10.8	License Agreement between KIQ LLC and Plexxikon Inc. dated as of May 27, 2020 (incorporated by reference to Exhibit 10.6 to the Registrant's Form 10-Q/A (File No. 001-38443) filed on October 6, 2020)
10.9	Asset Purchase Agreement dated as of August 28, 2020 among the Registrant, Sotio, LLC and Sotio N.V. (incorporated by reference to Exhibit 10.5 to the Registrant's Form 10-Q (File No. 001-38443) filed on November 9, 2020)
10.10	Sales Agreement, by and between the Company and Guggenheim Securities LLC, dated May 6, 2022 (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3 (File No. 333-264773) filed on May 6, 2022)
10.11	Underwriting Agreement dated as of June 13, 2022, among the Company and Jefferies LLC, Piper Sandler & Co. and Guggenheim Securities, LLC, as the representatives of the underwriters named therein (incorporated by reference to Exhibit 1.1 on Form 8-K filed on June 15, 2022)
10.12#	Employment Agreement dated as of October 23, 2020, between Cogent Biosciences, Inc. and Andrew Robbins (incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-Q (File No. 001-38443) filed on November 9, 2020)
10.13#	Cogent Biosciences, Inc. 2020 Inducement Plan and form of option award agreement thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38443) filed on October 26, 2020)
10.14#	Amended and Restated Employment Agreement entered into on December 24, 2021 by and between Cogent Biosciences, Inc. and John Green (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38443) filed on December 27, 2021)
10.15#	Amended and Restated Employment Agreement entered into on December 24, 2021 by and between Cogent Biosciences, Inc. and Jessica Sachs, MD (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38443) filed on December 27, 2021)
10.16	Lease by and between Cogent Biosciences, Inc. and BCSP Pearl East Property LLC dated July 6, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38443) filed on July 9, 2021)
10.17	Sublease by and between Cogent Biosciences, Inc. and Cimpress USA Incorporated dated March 19, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q (File No. 001-38443) filed on November 2022)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
31.1*	Certification of Chief Executive Officer of the Registrant Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer of the Registrant Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*†	Certification of Chief Executive Officer of the Registrant 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 Chief Financial Officer of the Registrant Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101INS*	Inline XBRL Instance Document.
101SCH*	Inline XBRL Taxonomy Extension Schema Document.
101CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.

101DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104*	Coverage Page Interative Data File (formatted as inline XRBL with applicable taxonomy extensive information contained in Exhibits 101.)

* Filed herewith.

# Indicates management contract or compensation plan.

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

† The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K, 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 Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: March 14, 2023

COGENT BIOSCIENCES, INC.

By: /s/ Andrew Robbins
Andrew Robbins
Chief Executive Officer and President

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities indicated on March 14, 2023:

Signature	Title(s)
/s/ Andrew Robbins Andrew Robbins	Chief Executive Officer, President and Director (Principal Executive Officer)
/s/ John Green John Green	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ Chris Cain Chris Cain	Director
/s/ Karen Ferrante Karen Ferrante, M.D.	Director
/s/ Peter Harwin Peter Harwin	Director
/s/ Arlene Morris Arlene Morris	Director
/s/ Matthew Ros Matthew Ros	Director
/s/ Todd Shegog Todd Shegog	Director

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

The following is a list of our subsidiaries:

Name	State or Other Jurisdiction of Incorporation	Name Under Which Does Business
Mono Inc.	Massachusetts	Mono Inc.
Kiq Bio LLC	Delaware	Kiq Bio LLC

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-363368, 333-258865, 333-254320, 333-249884, 333-224137, 333-237406 and 333-230559) and Form S-3 (Nos. 333-269707, 333-264773, and 333-248971) of Cogent Biosciences, Inc. of our report dated March 14, 2023 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 14, 2023

Exhibit 31.1

CERTIFICATIONS

I, Andrew Robbins, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 14, 2023

By: /s/ Andrew Robbins

Andrew Robbins

Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, John Green certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 14, 2023

By: /s/ John Green

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

Exhibit 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Cogent Biosciences, Inc. (the "Company") for the fiscal year ended December 31, 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: March 14, 2023

By: /s/ Andrew Robbins
Andrew Robbins
Chief Executive Officer
(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 Annual Report on Form 10-K of Cogent Biosciences, Inc. (the "Company") for the fiscal year ended December 31, 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: March 14, 2023

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

275 Wyman Street, 3rd Floor, Waltham, Massachusetts 02451

NOTICE OF THE 2023 ANNUAL MEETING OF STOCKHOLDERS TO BE HELD ON JUNE 7, 2023

To the Stockholders of Cogent Biosciences, Inc.:

Cogent Biosciences, Inc. (the "Company") will hold its 2023 Annual Meeting of Stockholders (the "Annual Meeting") on Wednesday, June 7, 2023, at 9:00 a.m. Eastern Time. The Annual Meeting will be a virtual meeting conducted exclusively online via live audio webcast at *www.virtualshareholdermeeting.com/COGT2023*. The Annual Meeting will be held for the following purposes, as more fully described in the accompanying proxy statement (the "Proxy Statement"):

(1) To elect the three Class II director nominees named in the Proxy Statement to serve until the 2026 Annual Meeting of Stockholders or until their successors are duly elected and qualified;

(2) To approve an increase of 6,000,000 shares reserved for issuance pursuant to our Amended and Restated 2018 Stock Option and Incentive Plan;

(3) To ratify the selection of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the year ending December 31, 2023; and

(4) To transact any other matters that may properly come before the Annual Meeting or any adjournments or postponements thereof.

The Board of Directors has fixed April 10, 2023 as the record date. Only stockholders of record at the close of business on that date will be entitled to notice of, and to vote at, the Annual Meeting or any adjournment or postponement thereof.

Instructions for accessing the virtual Annual Meeting are provided in the Proxy Statement. In the event of a technical malfunction or other situation that the meeting chair determines may affect the ability of the Annual Meeting to satisfy the requirements for a meeting of stockholders to be held by means of remote communication under the Delaware General Corporation Law, or that otherwise makes it advisable to adjourn the Annual Meeting, the meeting chair or secretary will convene the meeting at 10:00 a.m. Eastern Time on the date specified above and at the Company's address specified above solely for the purpose of adjourning the meeting to reconvene at a date, time and physical or virtual location announced by the meeting chair or secretary. Under either of the foregoing circumstances, we will post information regarding the announcement on the Investors page of the Company's website at *https://investors.cogentbio.com/*.

By Order of the Board of Directors,

/s/ Andrew Robbins

Andrew Robbins
Chief Executive Officer, President and Director

Waltham, Massachusetts
April 25, 2023

Whether or not you expect to participate in the virtual Annual Meeting, please vote as promptly as possible in order to ensure your representation at the Annual Meeting. You may vote online or, if you requested printed copies of the proxy materials, by telephone or by using the proxy card or voting instruction form provided with the printed proxy materials.

TABLE OF CONTENTS

LEGAL MATTERS

Important Notice Regarding the Availability of Proxy Materials for the 2023 Annual Meeting of Stockholders to Be Held on June 7, 2023. The Proxy Statement and Annual Report for the year ended December 31, 2022 are available at *www.proxyvote.com*.

Forward-Looking Statements. The Proxy Statement may contain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements other than statements of historical fact included in the Proxy Statement are forward-looking statements, including statements about the Company's Board of Directors, corporate governance practices, executive compensation program, equity compensation utilization and environment, social and governance ("ESG") initiatives. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in the Proxy Statement. Such risks, uncertainties and other factors include those identified in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the U.S. Securities and Exchange Commission ("SEC") and other subsequent documents we file with the SEC. The Company expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Website References. Website references throughout this document are inactive textual references and provided for convenience only, and the content on the referenced websites is not incorporated herein by reference and does not constitute a part of the Proxy Statement.

275 Wyman Street, 3rd Floor, Waltham, Massachusetts 02451

PROXY STATEMENT
FOR THE 2023 ANNUAL MEETING OF STOCKHOLDERS

QUESTIONS AND ANSWERS ABOUT THE PROXY MATERIALS AND VOTING

What Is the Purpose of These Proxy Materials?

We are making these proxy materials available to you in connection with the solicitation of proxies by the Board of Directors (the "Board") of Cogent Biosciences, Inc. ("we," "us," "our" or the "Company") for use at the 2023 Annual Meeting of Stockholders (the "Annual Meeting") to be held virtually on Wednesday, June 7, 2023 at 9:00 a.m. Eastern Time, or at any other time following adjournment or postponement thereof. You are invited to participate in the Annual Meeting and to vote on the proposals described in this Proxy Statement. The proxy materials are first being made available to our stockholders on or about April 25, 2023.

Why Did I Receive a Notice of Internet Availability?

Pursuant to U.S. Securities and Exchange Commission ("SEC") rules, we are furnishing the proxy materials to our stockholders primarily via the Internet instead of mailing printed copies. This process allows us to expedite our stockholders' receipt of proxy materials, lower the costs of printing and mailing the proxy materials and reduce the environmental impact of our Annual Meeting. If you received a Notice of Internet Availability of Proxy Materials (the "Notice"), you will not receive a printed copy of the proxy materials unless you request one. The Notice provides instructions on how to access the proxy materials for the Annual Meeting via the Internet, how to request a printed set of proxy materials and how to vote your shares.

Why Are We Holding a Virtual Annual Meeting?

We have adopted a virtual meeting format for the Annual Meeting to provide a consistent experience to all stockholders regardless of geographic location. We believe this expands stockholder access, improves communications and lowers our costs while reducing the environmental impact of the meeting. In structuring our virtual Annual Meeting, our goal is to enhance rather than constrain stockholder participation in the meeting, and we have designed the meeting to provide stockholders with the same rights and opportunities to participate as they would have at an in-person meeting.

Who Can Vote?

Only stockholders of record at the close of business on April 10, 2023 (the "Record Date") are entitled to notice of the Annual Meeting and to vote on the proposals described in this Proxy Statement. At the close of business on the Record Date, 70,946,790 shares of our common stock were issued and outstanding.

What Is the Difference between Holding Shares as a Registered Stockholder and as a Beneficial Owner?

Registered Stockholder: Shares Registered in Your Name

If your shares of common stock are registered directly in your name with our transfer agent, Computershare Trust Company, N.A., you are considered to be, with respect to those shares of common stock, the registered stockholder, and these proxy materials are being sent directly to you by us.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If your shares of common stock are held by a broker, fiduciary or custodian, you are considered the beneficial owner of shares of common stock held in "street name," and these proxy materials are being forwarded to you from that broker, fiduciary or custodian.

How Can I Participate in the Virtual Annual Meeting?

Stockholders of record as of the close of business on the Record Date are entitled to participate in and vote at the Annual Meeting. To participate in the Annual Meeting, including to vote, ask questions and view the list of registered stockholders as of the Record Date during the meeting, stockholders of record should go to the meeting website at *www.virtualshareholdermeeting.com/COGT2023*, enter the 16-digit control number found on your proxy card or Notice, and follow the instructions on the website. If your shares are held in street name and your voting instruction form or Notice indicates that you may vote those shares through *www.proxyvote.com*, then you may access, participate in and vote at the Annual Meeting with the 16-digit access code indicated on that voting instruction form or Notice. Otherwise, stockholders who hold their shares in street name should contact their bank, broker or other nominee (preferably at least five days before the Annual Meeting) and obtain a "legal proxy" in order to be able to attend, participate in or vote at the Annual Meeting.

We will endeavor to answer as many stockholder-submitted questions as time permits that comply with the Annual Meeting rules of conduct. We reserve the right to edit profanity or other inappropriate language and to exclude questions regarding topics that are not pertinent to meeting matters or Company business. If we receive substantially similar questions, we may group such questions together and provide a single response to avoid repetition.

The meeting webcast will begin promptly at 9:00 a.m. Eastern Time. Online check-in will begin approximately 15 minutes before then, and we encourage you to allow ample time for check-in procedures. If you experience technical difficulties during the check-in process or during the meeting, please call the number listed on the meeting website for technical support. Additional information regarding the rules and procedures for participating in the Annual Meeting will be set forth in our meeting rules of conduct, which stockholders can view during the meeting at the meeting website.

What Am I Voting on?

The proposals to be voted on at the Annual Meeting are as follows:

(1) Election of three Class II director nominees to serve until the 2026 Annual Meeting of Stockholders ("Proposal 1");

(2) Approval of an increase of 6,000,000 shares reserved for issuance pursuant to our Amended and Restated 2018 Stock Option and Incentive Plan ("Proposal 2"); and

(3) Ratification of the selection of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for 2023 ("Proposal 3").

How Does the Board Recommend That I Vote?

The Board recommends that you vote your shares "FOR" each director nominee in Proposal 1 and "FOR" Proposals 2 and 3.

What If Another Matter Is Properly Brought before the Annual Meeting?

As of the date of filing this Proxy Statement, the Board knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the Annual Meeting, it is the intention of the persons named as proxies in the proxy card to vote on such matters in accordance with their best judgment.

How Many Votes Do I Have?

Each share of common stock is entitled to one vote on each proposal to be voted on at the Annual Meeting.

What Does It Mean If I Receive More Than One Set of Proxy Materials?

If you receive more than one set of proxy materials, your shares may be registered in more than one name or held in different accounts. Please cast your vote with respect to each set of proxy materials that you receive to ensure that all of your shares are voted.

How Do I Vote?

Even if you plan to attend the Annual Meeting, we recommend that you also submit your vote as early as possible in advance so that your vote will be counted if you later decide not to, or are unable to, virtually attend the Annual Meeting.

Registered Stockholder: Shares Registered in Your Name

If you are the registered stockholder, you may vote your shares online during the virtual Annual Meeting (see "How Can I Participate in the Virtual Annual Meeting?" above) or by proxy in advance of the Annual Meeting by Internet (at *www.proxyvote.com*) or, if you requested paper copies of the proxy materials, by completing and mailing a proxy card or by telephone (at (800) 690-6903).

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner, you may vote your shares online during the virtual Annual Meeting (see "How Can I Participate in the Virtual Annual Meeting?" above) or you may direct your broker, fiduciary or custodian how to vote in advance of the Annual Meeting by following the instructions they provide.

What Happens If I Do Not Vote?

Registered Stockholder: Shares Registered in Your Name

If you are the registered stockholder and do not vote in one of the ways described above, your shares will not be voted at the Annual Meeting and will not be counted toward the quorum requirement.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner and do not direct your broker, fiduciary or custodian how to vote your shares, your broker, fiduciary or custodian will only be able to vote your shares with respect to proposals considered to be "routine." Your broker, fiduciary or custodian is not entitled to vote your shares with respect to "non-routine" proposals, which we refer to as a "broker non-vote." Whether a proposal is considered routine or non-routine is subject to stock exchange rules and final determination by the stock exchange. Even with respect to routine matters, some brokers are choosing not to exercise discretionary voting authority. As a result, we urge you to direct your broker, fiduciary or custodian how to vote your shares on all proposals to ensure that your vote is counted.

What If I Sign and Return a Proxy Card or Otherwise Vote but Do Not Indicate Specific Choices?

Registered Stockholder: Shares Registered in Your Name

The shares represented by each signed and returned proxy will be voted at the Annual Meeting by the persons named as proxies in the proxy card in accordance with the instructions indicated on the proxy card. However, if you are the registered stockholder and sign and return your proxy card without giving specific instructions, the persons named as proxies in the proxy card will vote your shares in accordance with the recommendations of the Board. Your shares will be counted toward the quorum requirement.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner and do not direct your broker, fiduciary or custodian how to vote your shares, your broker, fiduciary or custodian will only be able to vote your shares with respect to proposals considered to be "routine." Your broker, fiduciary or custodian is not entitled to vote your shares with respect to "non-routine" proposals, resulting in a broker non-vote with respect to such proposals.

Can I Change My Vote after I Submit My Proxy?

Registered Stockholder: Shares Registered in Your Name

If you are the registered stockholder, you may revoke your proxy at any time before the final vote at the Annual Meeting in any one of the following ways:

(1) You may complete and submit a new proxy card, but it must bear a later date than the original proxy card;

(2) You may submit new proxy instructions via telephone or the Internet;

(3) You may send a timely written notice that you are revoking your proxy to our Corporate Secretary at the address set forth on the first page of this Proxy Statement; or

(4) You may vote by attending the Annual Meeting virtually. However, your virtual attendance at the Annual Meeting will not, by itself, revoke your proxy.

Your last submitted vote is the one that will be counted.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner, you must follow the instructions you receive from your broker, fiduciary or custodian with respect to changing your vote.

What Is the Quorum Requirement?

The holders of a majority of the shares of common stock outstanding and entitled to vote at the Annual Meeting must be present at the Annual Meeting, either virtually or represented by proxy, to constitute a quorum. A quorum is required to transact business at the Annual Meeting.

Your shares will be counted toward the quorum only if you submit a valid proxy (or a valid proxy is submitted on your behalf by your broker, fiduciary or custodian) or if you attend the Annual Meeting virtually and vote. Abstentions and broker non-votes will be counted toward the quorum requirement. If there is no quorum, the chairman of the Annual Meeting or the holders of a majority of shares of common stock virtually present at the Annual Meeting, either personally or by proxy, may adjourn the Annual Meeting to another time or date.

How Many Votes Are Required to Approve Each Proposal and How Are Votes Counted?

Our Board has appointed our Chief Financial Officer to serve as the Inspector of Elections to count the votes cast at the Annual Meeting.

Proposal 1: Election of Directors

A nominee will be elected as a director at the Annual Meeting if the nominee receives a plurality of the votes cast "FOR" his or her election. "Plurality" means that the individuals who receive the highest number of votes cast "FOR" are elected as directors. Broker non-votes, if any, and votes that are withheld will not be counted as votes cast on the matter and will have no effect on the outcome of the election. Stockholders do not have cumulative voting rights for the election of directors.

Proposal 2: Approval of an Amendment and Restatement of the Amended and Restated 2018 Stock Option and Incentive Plan

The majority of votes cast on the proposal is required for approval of Proposal 2. Abstentions and broker non-votes, if any, will not be counted as votes cast on the matter and will have no effect on the outcome of the matter.

Proposal 3: Ratification of Independent Registered Public Accounting Firm Selection

The majority of votes cast on the proposal is required for approval of Proposal 3. Abstentions and broker non-votes, if any, will not be counted as votes cast on the matter and will have no effect on the outcome of the matter.

Who Is Paying for This Proxy Solicitation?

We will pay the costs associated with the solicitation of proxies, including the preparation, assembly, printing and mailing of the proxy materials, any solicitation by telephone or other electronic means and any in-person solicitation. We may also reimburse brokers, fiduciaries or custodians for the cost of forwarding proxy materials to beneficial owners of shares of common stock held in "street name."

Alliance Advisors, LLC has been retained to assist us in soliciting proxies for a fee of $12,500 plus distribution costs and other expenses. Our employees, officers and directors may also solicit proxies, but we will not pay additional compensation for any of these services.

How Can I Find out the Voting Results?

We expect to announce preliminary voting results at the Annual Meeting. Final voting results will be published in a Current Report on Form 8-K to be filed with the SEC within four business days after the Annual Meeting.

PROPOSAL 1: ELECTION OF DIRECTORS

In accordance with our Bylaws, the Board has fixed the number of directors constituting the Board at seven. At the Annual Meeting, the stockholders will vote to elect the three Class II director nominees named in this Proxy Statement to serve until the 2026 Annual Meeting of Stockholders or until their successors are duly elected and qualified or until their earlier resignation or removal. Our Board has nominated Dr. Chris Cain, Arlene M. Morris and Todd Shegog, each of whom is a current Class II director, for re-election to our Board.

Our director nominees have indicated that they are willing and able to serve as directors. However, if any of them becomes unable or, for good cause, unwilling to serve, proxies may be voted for the election of such other person as shall be designated by our Board, or the Board may decrease the size of the Board.

Information Regarding Director Nominees and Continuing Directors

Our Board is divided into three classes, with members of each class holding office for staggered three-year terms. There are currently two Class I directors, whose terms expire at the 2025 Annual Meeting of Stockholders; three Class II directors, who are up for election at this meeting for a term expiring at the 2026 Annual Meeting of Stockholders; and two Class III directors, whose terms expire at the 2024 Annual Meeting of Stockholders.

Biographical and other information regarding our director nominees and directors continuing in office, including the primary skills and experiences considered by our Nominating and Corporate Governance Committee (the "Nominating Committee") in determining to recommend them as nominees, is set forth below.

Name	Class	Age (as of April 25)	Position
Andrew Robbins	Class III	47	Chief Executive Officer, President and Director
Chris Cain, Ph.D.[2][4]	Class II	39	Independent Director
Karen Ferrante, M.D.[3][4]	Class I	65	Independent Director
Peter Harwin[3][4]	Class III	37	Independent Chairman and Director
Arlene M. Morris[1][2]	Class II	71	Independent Director
Matthew E. Ros[1][3]	Class I	56	Independent Director
Todd Shegog[1][2]	Class II	58	Independent Director

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating Committee
(4) Member of the Science & Technology Committee (the "Science Committee")

Class I Directors Continuing in Office

Karen Ferrante, M.D. Dr. Ferrante has served as a member of our Board since February 2018. Dr. Ferrante is a medical oncologist who served as the Chief Medical Officer and Head of Research and Development of Tokai Pharmaceuticals, Inc (Nasdaq: TKAI), a biopharmaceutical company focused on developing treatments for prostate cancer and other hormonally driven diseases, from April 2014 until August 2016. From 2007 to July 2013, Dr. Ferrante held senior positions at Millennium Pharmaceuticals, Inc. and its parent company, Takeda Pharmaceutical Company Limited (NYSE: TAK), including Chief Medical Officer and subsequently, Oncology Therapeutic Area Head and Cambridge USA Site Head from May 2013 to July 2013. Dr. Ferrante previously held positions of increasing responsibility at Pfizer Global Research and Development and Bristol-Myers Squibb Company (NYSE: BMY). Dr. Ferrante serves on the board of directors of MacroGenics, Inc. (Nasdaq: MGNX) and HUTCHMED (China) Limited (Nasdaq: HCM). Dr. Ferrante also served as a director of Progenics Pharmaceuticals, Inc. from 2014 until its acquisition by Lantheus Holdings, Inc. (Nasdaq: LNTH) in 2020 and Baxalta Inc., a previously publicly-traded global biopharmaceutical company, from 2015 until its acquisition by

Shire plc in 2016. She also served as an advisory board member for Kazia Therapeutics Limited (Nasdaq: KZIA) from 2016 until 2022 and Trillium Therapeutics Inc. (Nasdaq: TRIL) from 2020 until its acquisition by Pfizer in November 2021. Dr. Ferrante holds an M.D. from Georgetown University and a B.S. in Chemistry and Biology from Providence College.

We believe Dr. Ferrante is qualified to serve on our Board because of her extensive leadership, scientific, business and managerial experience in the biotechnology industry and her experience and expertise serving as a member of the board of directors of several biotechnology companies.

Matthew E. Ros. Mr. Ros has served as a member of our Board since July 2019. Mr. Ros has served as Chief Executive Officer and Director of Fore Biotherapeutics Inc., a clinical-stage precision oncology company, since April 2022. Mr. Ros has more than 30 years of experience in global pharmaceutical and early-stage biotechnology companies, building and leading teams across sales, marketing, franchise strategy and business operations. Prior to joining Fore, Mr. Ros previously served as Chief Strategy and Business Officer of Epizyme, Inc. (Nasdaq: EPZM), a biopharmaceutical company, from September 2018 to October 2021. He served as Chief Operating Officer of Epizyme from May 2016 to September 2018. Prior to joining Epizyme, from September 2010 to May 2016, Mr. Ros served in increasing levels of responsibility at Sanofi S.A. (Nasdaq: SNY), a multinational pharmaceutical company, most recently as Chief Operating Officer/Global Head of the Oncology business unit from December 2014 to May 2016. Prior to that role, Mr. Ros served in the rare disease business of Genzyme Corporation, a Sanofi company, where he served as Vice President and Franchise Head of its Pompe disease unit from September 2012 to December 2014, and also served as the Associate Vice President and Iniparib Global Brand Leader in Sanofi's Oncology business unit from September 2010 to September 2012. From October 2007 to June 2010, Mr. Ros served at ARIAD Pharmaceuticals, Inc., a global oncology company, most recently as Senior Vice President, Commercial Operations. He started his pharmaceutical career in Bristol-Myers Squibb's Oncology Division, serving in roles with increasing responsibility from 1990 to 2007. He received a B.S. from the State University of New York, College at Plattsburgh and completed the Executive Education Program in Finance and Accounting for the Non-Financial Manager at Wharton School of the University of Pennsylvania.

We believe Mr. Ros is qualified to serve on our Board because of his extensive leadership, executive, managerial and business experience with life sciences companies.

Class II Directors Nominees

Chris Cain, Ph.D. Dr. Cain has served as a member of our Board since July 2020 and is a designee of Fairmount Funds Management LLC ("Fairmount"), a healthcare investment firm. Dr. Cain has served as Director of Research at Fairmount since April 2020. From February 2019 to February 2020, Dr. Cain served as Vice President at Samsara BioCapital, a biotherapeutics-focused venture capital fund. Prior to that role, Dr. Cain worked at Apple Tree Partners, a life sciences-focused venture capital fund, from 2016 to January 2019, and at RA Capital Management, an investment management company, before that. Previously, Dr. Cain was a writer and editor at BioCentury Publications. He received a B.A. from the University of California, Santa Barbara and a Ph.D. in Biochemistry and Molecular Biology from the University of California, San Francisco.

We believe Dr. Cain is qualified to serve on our Board because of his extensive leadership, scientific, business and managerial experience in the biotechnology industry.

Arlene M. Morris. Ms. Morris has served as a member of our Board since July 2019. Ms. Morris has served as Chief Executive Officer of Willow Advisors, a consultancy advising biotech companies on financing, strategy and business development, since 2015. Previously, she spent over a decade leading public biotechnology companies. From 2012 to 2015, Ms. Morris served as Chief Executive Officer of Syndax Pharmaceuticals Inc. (Nasdaq: SNDX), a biopharmaceutical company focused on the development and commercialization of an epigenetic therapy for treatment-resistant cancers. Prior to this, she served as President and Chief Executive

Officer of Affymax Inc. (OTCMKTS: AFFY), a biotechnology company, where she led the company through the development of peginesatide (Omontys®). She spent 15 years at Johnson & Johnson (NYSE: JNJ), a pharmaceutical company, in marketing, sales and senior level business development positions. Ms. Morris served on the board of directors of Viveve Medical, Inc. (OTCMKTS: VIVE) from 2016 to 2022, Dimension Therapeutics, Inc. (Nasdaq: DMTX) from 2015 to 2018 and Neovacs, SA (Euronext: ALNEV) from 2011 to 2020. She was also a director of Biodel Inc., a publicly traded specialty pharmaceutical company, from 2015 until its merger with Albireo Limited in 2016. Ms. Morris is currently a member of the board of directors of Palatin Technologies, Inc. (NYSE: PTN) and Viridian Therapeutics, Inc. (Nasdaq: VRDN). She received a B.A. in Biology and Chemistry from Carlow College.

We believe Ms. Morris is qualified to serve on our Board because of her extensive leadership, executive, managerial and board experience within pharmaceutical and biotechnology industries.

Todd Shegog. Mr. Shegog has served as a member of our Board since February 2021. Mr. Shegog has more than 25 years of financial, operations, corporate strategy and compliance expertise in the biotechnology and pharmaceutical industries. He served as Senior Vice President and Chief Financial Officer of Forma Therapeutics, Inc. (Nasdaq: FMTX), a clinical-stage biopharmaceutical company, from September 2019 through its acquisition by Nova Nordisk in October 2022. Prior to Forma Therapeutics, Mr. Shegog served as Chief Financial Officer of Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage biopharmaceutical company, where he directed the company's financial strategy and management as well as facilities and information systems from September 2016 to September 2019. From April 2014 to August 2016, Mr. Shegog served as Senior Vice President and Chief Financial Officer at Forum Pharmaceuticals, Inc., an early-stage biopharmaceutical company, where he was responsible for finance, operations and information systems during their pursuit of innovative therapies for schizophrenia and Alzheimer's disease. He also served as the Chief Financial Officer of Millennium Pharmaceuticals, Inc., now Takeda Oncology, where he was responsible for management of the company's financial resources, corporate planning, financial reporting and compliance from 1998 to 2014. Mr. Shegog earned a B.S. in Electrical Engineering from Lafayette College and an M.B.A. from the Tepper School of Management at Carnegie Mellon University.

We believe Mr. Shegog is qualified to serve on our Board because of his financial expertise, extensive leadership, executive, managerial and business experience with life sciences companies.

Class III Directors Continuing in Office

Andrew Robbins. Mr. Robbins has served as our Chief Executive Officer, President, principal executive officer and a member of our Board since October 2020. Prior to joining Cogent, Mr. Robbins served as Chief Operating Officer at Array BioPharma Inc., a pharmaceutical company, from March 2015 through its acquisition by Pfizer Inc. (NYSE: PFE), a pharmaceutical company, in July 2019, after serving as its Senior Vice President, Commercial Operations from July 2012 to March 2015. From January 2007 to July 2012, Mr. Robbins held management positions at Hospira, Inc., a pharmaceutical and medical device company, including General Manager and Vice President of the U.S. Alternate Site business unit and Vice President of Corporate Development. Prior to Hospira, Mr. Robbins held commercial and leadership positions within Pfizer's oncology unit. Additionally, Mr. Robbins currently serves on the board of directors of Harpoon Therapeutics, Inc. (Nasdaq: HARP) and Turmeric Acquisition Corporation (Nasdaq: TMPMU). Mr. Robbins holds an M.B.A. from the Kellogg School of Management, Northwestern University and a bachelor's degree from Swarthmore College.

We believe Mr. Robbins is qualified to serve on our Board because of his extensive commercial, development and strategic leadership experience in the pharmaceutical industry.

Peter Harwin. Mr. Harwin has served as a member of our Board since July 2020 and is a designee of Fairmount. He is currently a managing member at Fairmount, a healthcare investment firm he co-founded in April 2016. Prior to Fairmount, Mr. Harwin served as a member of the investment team at Boxer Capital, LLC,

part of the Tavistock Group, based in San Diego. Mr. Harwin also serves on the board of directors of Viridian Therapeutics, Inc. (Nasdaq: VRDN), Paragon Therapeutics, Inc. and Apogee Therapeutics, LLC. Mr. Harwin received his B.B.A. from Emory University.

We believe Mr. Harwin is qualified to serve on our Board because of his extensive leadership, executive, managerial and board experience within pharmaceutical and biotechnology industries.

Board Recommendation

The Board recommends a vote "**FOR**" the election of each of the Class II director nominees set forth above.

PROPOSAL 2: APPROVAL OF AN AMENDMENT AND RESTATEMENT OF OUR AMENDED AND RESTATED 2018 STOCK OPTION AND INCENTIVE PLAN

Summary

Our Board is asking you to approve an amendment and restatement of the Cogent Biosciences, Inc. Amended and Restated 2018 Stock Option and Incentive Plan (the "2018 Plan") to increase the number of shares reserved for issuance thereunder. If stockholders approve this proposal, the number of shares of our common stock that may be delivered pursuant to awards granted under the 2018 Plan will be increased by an additional 6,000,000 shares. There would be a corresponding increase in the number of shares that may be delivered pursuant to incentive stock options granted under the 2018 Plan (for clarity, such shares also count against, and are not in addition to, the aggregate share limit for the 2018 Plan).

On February 16, 2023, our Board of Directors approved the amendment and restatement of the 2018 Plan, including the proposed increase to the shares issuable thereunder, subject to stockholder approval.

We also maintain the Cogent Biosciences, Inc. 2020 Inducement Plan (the "Inducement Plan," and together with the 2018 Plan, the "Plans"). As of March 31, 2023, (i) a total of 15,503,250 shares were then subject to outstanding options granted under the Plans, (ii) a total of up to 2,500,000 shares were then subject to outstanding and unvested performance-based restricted stock units ("PSUs") granted under the 2018 Plan that are contingent upon stockholder approval of this proposal as discussed below under "Specific Benefits under the 2018 Plan," (iii) 677,995 shares were available for new award grants under the Inducement Plan and (iv) 796,715 shares were available for new award grants under the 2018 Plan (without taking into account the 6,000,000 shares that would be added to the 2018 Plan if stockholders approve this proposal or the up to 2,500,000 shares subject to PSUs that are contingent on stockholder approval of this proposal). No other award types are outstanding under the Plans. As of March 31, 2023, the average weighted per share exercise price of all outstanding stock options granted under the Plans was $9.96 ($9.89 under the 2018 Plan only) and the weighted average remaining contractual term was 8.52 years (8.71 years under the 2018 Plan only). If stockholders approve this proposal, we currently expect the number of additional shares being requested for approval, combined with the evergreen provision in the 2018 Plan, will be sufficient to meet our expected needs through the first quarter of 2026 based on our historical grant practices and performance. If stockholders do not approve this proposal, we will continue to have the authority to grant awards under the 2018 Plan, but the proposed 6,000,000 share increase in the 2018 Plan share limit will not be effective and the PSUs covering up to 2,500,000 shares will be forfeited, both of which could result in a serious disruption of our compensation programs and will limit our ability to provide retention incentives to our executives and other employees. Equity awards are a significant component of total compensation for our executive officers and other employees and are vital to our ability to attract and retain outstanding and highly skilled individuals in the extremely competitive labor markets in which we must compete. If stockholders do not approve the proposal, we would need to grant cash and other non-equity rewards to these individuals. We believe that such alternative forms of compensation do not align employee interests with those of stockholders as efficiently as equity-based awards, and we feel it is important to provide compensation that continues to effectively align employees with stockholders and which provides a total compensation package that is competitive with other companies. We strongly believe that the approval of this proposal is instrumental to our continued success.

Please see the discussion below under "Specific Benefits under the 2018 Plan" and "Aggregate Past Grants Under the 2018 Plan" for detailed information on certain awards that we granted that are contingent on stockholder approval of this proposal, as well as past awards granted under the Plan.

Award Burn Rate

The following table presents information regarding our net burn rate for the past three fiscal years, with average annual net burn rate over such three years being 7.3%. For this purpose, the "net burn rate" for any one particular fiscal year means the total number of shares of our common stock issuable upon exercise or payment,

as the case may be, of the equity-based awards granted by us in that fiscal year, less the total number of such shares canceled, terminated or forfeited in the fiscal year without the awards having become vested or paid, as the case may be, divided by our weighted average number of shares of common stock issued and outstanding during that particular fiscal year on an as-converted basis, including the conversion of Series A convertible preferred stock and the exercise of pre-funded warrants.

	2022	2021	2020
Options granted	4,724,584	5,967,582	3,866,049
Restricted stock unit awards granted	—	10,000	—
Less: shares subject to canceled, terminated or forfeited awards	(531,617)	(411,231)	(1,396,861)
Net shares granted	4,192,967	5,566,351	2,469,188
Weighted average basic shares of common stock outstanding	81,068,292	66,105,963	29,654,447
Net burn rate[(1)(2)]	5.2%	8.4%	8.3%

(1) Net burn rate is equal to (x) divided by (y), where (x) is equal to the sum of total options granted during the fiscal year, plus the total restricted stock unit awards granted during the fiscal year, minus the total number of shares subject to stock options and restricted stock unit awards canceled, terminated or forfeited during the fiscal year without the awards having become vested or paid, as the case may be, and where (y) is equal to our weighted average basic shares of common stock outstanding for each respective year on an as-converted basis, including the conversion of Series A convertible preferred stock and the exercise of pre-funded warrants.

(2) For the three-year period ended December 31, 2022, our average annual net burn rate using the methodology described in note (1) above was 7.3%.

We currently expect that the additional shares requested for the 2018 Plan under this proposal (taking into account the PSUs that have been granted that are conditioned on stockholder approval of this proposal, as discussed above), along with the evergreen provision under the 2018 Plan, would provide us with flexibility to continue to grant equity-based awards through the first quarter of 2026, assuming a level of grants consistent with the number of equity-based awards granted historically and usual levels of shares becoming available for new awards as a result of forfeitures of outstanding awards throughout the projected period. However, this is only an estimate, in our management's judgment, based on current circumstances. The total number of shares that are awarded under the 2018 Plan in any one year or from year to year may change based on any number of variables, including, without limitation, the value of our common stock (since higher stock prices generally require that fewer shares be issued to produce awards of the same grant date fair value), changes in competitors' compensation practices or changes in compensation practices in the market generally, changes in the number of our employees, changes in the number of our directors and officers, acquisition activity and the potential need to grant awards to new employees in connection with acquisitions, the need to attract, retain and incentivize key talent, the types of awards we grant, and how we choose to balance total compensation between cash and equity-based awards. The type and terms of awards granted may also change in any one year or from year to year based on any number of variables, including, without limitation, changes in competitors' compensation practices or changes in compensation practices generally, and the need to attract, retain and incentivize key talent.

Dilution

The following table shows the total number of shares of our common stock that were (i) subject to outstanding stock options granted under the Plans, (ii) subject to outstanding and unvested PSUs that are subject to forfeiture if this proposal is not approved by stockholders, and (iii) available for new award grants under the 2018 Plan, in each case, as of each of December 31, 2022 and March 31, 2023. In this Proposal 2, the number of

shares of our common stock subject to awards granted during any particular period or outstanding on any particular date is presented based on the actual number of shares of our common stock covered by those awards.

	December 31, 2022	March 31, 2023
Shares subject to outstanding stock options[1]	12,831,771	15,503,250
Shares subject to unvested PSUs	—	2,500,000[2]
Shares available for new award grants under the 2018 Plan	686,585	796,715[3]

(1) Our outstanding options generally may not be transferred to third parties for value and do not include dividend equivalent rights.
(2) These PSUs are contingent on stockholder approval of this proposal and will be forfeited if stockholders do not approve this proposal.
(3) This does not take into account the 6,000,000 shares that would be added to the 2018 Plan if stockholders approve this proposal.

To help assess the potential dilutive impact of this proposal, the number of shares of our common stock outstanding at the end of each of the last three fiscal years and as of March 31, 2023 on an as-converted basis, including the conversion of Series A convertible preferred stock and the exercise of pre-funded warrants, is as follows: 65,408,906 shares outstanding at the end of fiscal year 2020, 69,628,172 shares outstanding at the end of fiscal year 2021, 90,761,994 shares outstanding at the end of fiscal year 2022, and 90,812,850 shares outstanding as of March 31, 2023.

The closing market price of our common stock on The Nasdaq Global Select Market on April 10, 2023 was $10.68.

Our Board believes that approval of the amendment and restatement of the 2018 Plan, including the proposed increase to the shares reserved for issuance thereunder, will promote our interests and those of our stockholders and will help us continue to be able to attract, motivate, retain and reward persons important to our success. All members of our Board and all of our executive officers are eligible for awards under the 2018 Plan and thus have a personal interest in the approval of the proposed amendment and restatement of the 2018 Plan.

Board Recommendation

The Board recommends a vote "**FOR**" the increase to the shares reserved for issuance pursuant to our Amended and Restated 2018 Stock Option and Incentive Plan.

Summary Description of the 2018 Plan

The principal terms of the 2018 Plan are summarized below. The following summary is qualified in its entirety by the full text of the 2018 Plan, which appears as Appendix A to this Proxy Statement and reflects the impact of the proposed increase in the shares reserved for issuance pursuant to the 2018 Plan in Section 3(a) thereof.

Purpose

The purpose of the 2018 Plan is to encourage and enable the officers, employees, non-employee directors and consultants of the Company and its subsidiaries upon whose judgment, initiative and efforts the Company largely depends for the successful conduct of its businesses to acquire a proprietary interest in the Company. It is anticipated that providing such persons with a direct stake in the Company's welfare will help align their interests with those of the Company and its stockholders, thereby stimulating their efforts on the Company's behalf and strengthening their desire to remain with the Company.

Administration

Our Compensation Committee administers the 2018 Plan (the "Administrator"). The Administrator has broad authority under the 2018 Plan including, without limitation, the authority:

- to select the individuals to whom awards may from time to time be granted;
- to determine the time or times of grant, and the extent, if any, of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, cash-based awards and dividend equivalent rights, or any combination of the foregoing, granted to any one or more grantees;
- to determine the number of shares of stock to be covered by any award;
- to determine and modify from time to time the terms and conditions, including restrictions, not inconsistent with the terms of the 2018 Plan, of any award, which terms and conditions may differ among individual awards and grantees, and to approve the forms of award certificates;
- to accelerate at any time the exercisability or vesting of all or any portion of any award;
- subject to certain provisions, to extend at any time the period in which stock options may be exercised; and
- at any time to adopt, alter and repeal such rules, guidelines and practices for administration of the 2018 Plan and for its own acts and proceedings as it shall deem advisable; to interpret the terms and provisions of the 2018 Plan and any award (including related written instruments); to make all determinations it deems advisable for the administration of the 2018 Plan; to decide all disputes arising in connection with the 2018 Plan; and to otherwise supervise the administration of the 2018 Plan.

No Repricing

In no case (except due to an adjustment to reflect a stock split, merger or other event referred to under "Adjustments" below, or any repricing that may be approved by stockholders) will the Administrator reduce the exercise price of outstanding stock options or stock appreciation rights or effect repricing through cancellation and re-grants or cancellation of stock options and stock appreciation rights in exchange for cash or other awards.

Eligibility

Persons eligible to receive awards under the 2018 Plan include our full or part-time officers and other employees, non-employee directors and consultants of the Company and its subsidiaries. As of March 31, 2023, approximately 146 of our officers and employees (including all of our named executive officers currently employed by us), each of our six non-employee directors and other individuals who provide services to us as consultants were considered eligible under the 2018 Plan. While consultants are generally considered eligible under the 2018 Plan to preserve our flexibility, over the last five years we have only granted equity awards under the 2018 Plan to the five members of our Scientific Advisory Board, plus one other individual who, at the time of grant of the awards, was neither employed by us, nor a member of our Board. We do not expect to grant any equity awards under the 2018 Plan to consultants who are not members of our Scientific Advisory Board in the future.

Authorized Shares and Limits on Awards

Assuming stockholders approve this proposal, subject to adjustment for certain dilutive events as provided in the 2018 Plan, the maximum number of shares of our common stock reserved and available for issuance under the 2018 Plan will be 19,085,985 (the "Initial Limit"), plus on January 1, 2024 and each January 1 thereafter, the number of shares of stock reserved and available for issuance under the 2018 Plan will be cumulatively increased by four percent of the number of shares of our common stock issued and outstanding on the immediately preceding December 31 or such lesser number determined by the Administrator. In addition, the shares of common stock underlying any awards under the 2018 Plan and under the Company's previously outstanding

2015 Stock Incentive Plan that are forfeited, canceled, held back upon exercise of an option or settlement of an award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of common stock or otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2018 Plan. Subject to such overall limitation, the maximum aggregate number of shares of common stock that may be issued in the form of incentive stock options will not exceed the Initial Limit as cumulatively increased each year. In the event the Company repurchases shares of common stock on the open market, such shares will not be added to the shares of common stock available for issuance under the 2018 Plan. The shares available for issuance under the 2018 Plan may be authorized but unissued shares of common stock or shares of common stock reacquired by the Company.

The value of all awards granted under the 2018 Plan and all other cash compensation paid by the Company to any non-employee director in any calendar year may not exceed $1,000,000. For the purpose of this limitation, the value of any award is its grant date fair value, as determined in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation – Stock Compensation ("ASC Topic 718") or its successor provision but excluding the impact of estimated forfeitures related to service-based vesting provisions.

Types of Awards

The 2018 Plan authorizes incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights. A stock option is the right to purchase shares of our common stock at a future date at a specified price per share (the "exercise price"). The per share exercise price of an option generally may not be less than the fair market value of a share of our common stock on the date of grant. The maximum term of an option is ten years from the date of grant. An option may either be an incentive stock option or a non-qualified stock option. Incentive stock option benefits are taxed differently from non-qualified stock options, as described under "U.S. Federal Income Tax Consequences of Awards Under the 2018 Plan" below. Incentive stock options are also subject to more restrictive terms and are limited in amount by the Internal Revenue Code and the 2018 Plan. Incentive stock options may only be granted to employees.

A stock appreciation right is the right to receive payment of an amount equal to the excess of the fair market value of a share of our common stock on the date of exercise of the stock appreciation right over the base price of the stock appreciation right. The base price will be established by the Administrator at the time of grant of the stock appreciation right and generally may not be less than the fair market value of a share of our common stock on the date of grant. Stock appreciation rights may be granted in connection with other awards or independently. The maximum term of a stock appreciation right is ten years from the date of grant. Options and stock appreciation rights may be fully vested at grant or may be subject to time- and/or performance-based vesting requirements.

The other types of awards that may be granted under the 2018 Plan include, without limitation, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights that represent the right to receive credits based on cash dividends that would have been paid on the shares of stock specified in the right (or other award to which it relates) if such shares had been issued to and held by the grantee. Any awards under the 2018 Plan may be fully vested at grant or may be subject to time- and/or performance-based vesting requirements.

Assumption and Termination of Awards

The 2018 Plan provides that upon the effectiveness of a "sale event," as defined in the 2018 Plan, an acquirer or successor entity may assume, continue or substitute outstanding awards under the 2018 Plan. To the extent that awards granted under the 2018 Plan are not assumed or continued or substituted by the successor entity, upon the effective time of the sale event, such awards under the 2018 Plan shall terminate. In the event of such termination, individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event. In addition, in connection with the termination of the 2018 Plan upon a sale event, we may make or provide for a cash payment to participants holding vested and exercisable options and stock appreciation rights

equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights and we may make or provide for a cash payment to participants holding other vested awards.

Transfer Restrictions

Subject to certain exceptions contained in the 2018 Plan, awards under the 2018 Plan generally are not transferable by the recipient other than by will or the laws of descent and distribution and are generally exercisable, during the recipient's lifetime, only by the recipient. Any amounts payable or shares issuable pursuant to an award generally will be paid only to the recipient or the recipient's beneficiary or legal representative. The Administrator has discretion, however, to establish written conditions and procedures for the transfer of awards to his or her immediate family members, to trusts for the benefit of such family members or to partnerships in which such family members are the only partners, provided that the transferee agrees in writing with the Company to be bound by all of the terms and conditions of the 2018 Plan and the applicable award. In no event may an award be transferred by a grantee for value.

Adjustments

As is customary in incentive plans of this nature, each share limit and the number and kind of shares available under the 2018 Plan and any outstanding awards, as well as the exercise or purchase prices of awards, and performance targets under certain types of performance-based awards, are subject to adjustment in the event of certain reorganizations, mergers, combinations, recapitalizations, stock splits, stock dividends or other similar events that change the number or kind of shares outstanding and extraordinary dividends or distributions of property to the stockholders.

Term

No awards may be granted under the 2018 Plan after the date that is ten years from the date of stockholder approval of the 2018 Plan.

Termination of or Changes to the 2018 Plan

Our Board may amend or discontinue the 2018 Plan, and our Compensation Committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2018 Plan require the approval of our stockholders.

U.S. Federal Income Tax Consequences of Awards Under the 2018 Plan

The U.S. federal income tax consequences of the 2018 Plan under current federal law, which is subject to change, are summarized in the following discussion of the general tax principles applicable to the 2018 Plan. This summary is not intended to be exhaustive and, among other considerations, does not describe the deferred compensation provisions of Section 409A of the Internal Revenue Code to the extent an award is subject to and does not satisfy those rules, nor does it describe state, local or international tax consequences.

With respect to non-qualified stock options, we are generally entitled to deduct and the participant recognizes taxable income in an amount equal to the difference between the option exercise price and the fair market value of the shares at the time of exercise. With respect to incentive stock options, we are generally not entitled to a deduction (unless the employee sells the underlying shares upon exercise before the tax holding period) nor does the participant recognize income at the time of exercise, although the participant may be subject to the U.S. federal alternative minimum tax. Upon the sale or exchange of the shares more than two years after grant of an incentive stock option and one year after exercising an incentive stock option, any gain or loss will be treated as long-term capital gain or loss. If these holding periods are not satisfied, the optionee will recognize ordinary income and we will be entitled to a deduction at the time of sale or exchange equal to the difference

between the exercise price and the lower of (i) the fair market value of the shares at the date of the option exercise, or (ii) the sale price of the shares. A different rule for measuring ordinary income upon such a premature disposition may apply if the optionee is also an officer or director of the Company. Any gain or loss recognized on such a premature disposition of the shares in excess of the amount treated as ordinary income will be characterized as long-term or short-term capital gain or loss, depending on the holding period.

The current U.S. federal income tax consequences of other awards authorized under the 2018 Plan generally follow certain basic patterns: nontransferable restricted stock subject to a substantial risk of forfeiture results in income recognition equal to the excess of the fair market value over the price paid (if any) only at the time the restrictions lapse (unless the recipient elects to accelerate recognition as of the date of grant); bonuses, stock appreciation rights, cash and stock-based performance awards, dividend equivalents, restricted stock units and other types of awards are generally subject to tax at the time of payment; and compensation otherwise effectively deferred is taxed when paid. In each of the foregoing cases, we will generally have a corresponding deduction at the time the participant recognizes income.

If an award is accelerated under the 2018 Plan in connection with a "change in control" (as this term is used under the Internal Revenue Code), we may not be permitted to deduct the portion of the compensation attributable to the acceleration ("parachute payments") if it exceeds certain threshold limits under the Internal Revenue Code (and certain related excise taxes may be triggered).

U.S. federal income tax law generally prohibits a publicly held company from deducting compensation paid to certain current or former officers that qualify as "covered employees" within the meaning of Section 162(m) of the Internal Revenue Code that exceeds $1 million during the tax year.

Specific Benefits Under the 2018 Plan

The Administrator has approved certain PSU awards under the 2018 Plan that are contingent on stockholder approval of this proposal. These grants are set forth in the following table. If stockholders do not approve this proposal, these grants will be forfeited, and we will not be able to grant the equity incentives we believe are necessary to provide retention incentives. The number of PSUs included in the table below assumes that "target" performance is achieved. A participant can generally receive between 0% and 200% of the target award based on achievement of specified stock price hurdles and development milestones over a three-year performance period ending in February 2026. PSUs generally vest, if at all, in a single tranche in February 2026.

Awards Subject to Stockholder Approval of 2018 Plan Proposal

Name and Position	Number of Shares Underlying Contingent PSUs (Target)
Named Executive Officers and Directors	
Andrew Robbins	
Chief Executive Officer, President and Director	420,000
Jessica Sachs, M.D.	
Chief Medical Officer	160,000
John Robinson, Ph.D.	
Chief Science Officer	160,000
Chris Cain, Ph.D.	—
Karen Ferrante, M.D.	—
Peter Harwin	—
Arlene M. Morris	—
Matthew E. Ros	—
Todd Shegog	—
All Other Employees	510,000

If the proposed amendments to the 2018 Plan had been in effect in fiscal year 2022, we expect that our award grants for fiscal year 2022 would not have been substantially different from those actually made in that year. For information regarding stock-based awards granted to our named executive officers during fiscal year 2022, see "Executive Compensation."

Aggregate Past Grants Under the 2018 Plan

Other than the contingent PSUs presented in the table above, the benefits that will be awarded or paid in the future under the 2018 Plan are not currently determinable; provided, however, that pursuant to our outside director compensation policy, beginning in 2023, new non-employee directors are eligible to receive a one-time stock option grant to purchase 73,400 shares of our common stock and continuing directors are eligible to receive, at the time of the Company's annual meeting, a stock option grant to purchase 36,700 shares of our common stock. As a result, we anticipate our non-employee directors will receive the foregoing grants, as applicable, subject to continued service through the grant date. Other than the foregoing, awards under the 2018 Plan are within the discretion of the Compensation Committee, and the Compensation Committee has not determined future awards or who might receive them. As of March 31, 2023, awards covering 13,681,245 shares of our common stock have been granted under the 2018 Plan. The following table shows information regarding the distribution of awards, including the contingent PSUs (at target), covering such shares as of such date among the persons and groups identified below. The closing market price of our common stock on The Nasdaq Global Select Market on April 10, 2023 was $10.68.

Name of Individual or Group	Number of Shares Underlying Options		Number of Shares Underlying PSUs (at Target)[1]
	Exercisable	Unexercisable	
Andrew Robbins *Chief Executive Officer, President and Director*	633,245	1,353,648	420,000
Jessica Sachs, M.D. *Chief Medical Officer*	449,940	586,032	160,000
John Robinson, Ph.D. *Chief Science Officer*	76,250	333,750	160,000
All Current Executive Officers as a Group:	1,159,435	2,273,430	740,000
All Current Non-Executive Directors as a Group (6 persons):	399,707	305,148	—
Each Associate of any Such Directors or Executive Officers	—	—	—
Each Other Person Who Has Received 5% or More of the Options, Warrants or Rights Under the 2018 Plan	—	—	—
All Other Current Employees, Including Any Current Officers Who Are Not Executive Officers, as a Group	2,196,431	6,097,094	510,000
Total	3,755,573	8,675,672	1,250,000

(1) The shares presented in this column are subject to the PSUs that are contingent on stockholder approval of this proposal. Such shares are presented assuming target performance.

Registration

The Company intends to file with the SEC a registration statement on Form S-8 covering the new shares reserved for issuance under the 2018 Plan in the second half of 2023.

PROPOSAL 3: RATIFICATION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM SELECTION

Our Audit Committee has selected PricewaterhouseCoopers LLP ("PwC") as the Company's independent registered public accounting firm for the year ending December 31, 2023. In this Proposal 3, we are asking stockholders to vote to ratify this selection. Representatives of PwC are expected to be present at the Annual Meeting. They will have the opportunity to make a statement, if they desire to do so, and are expected to be available to respond to appropriate questions from stockholders.

Stockholder ratification of the selection of PwC as the Company's independent auditor is not required by law or our Bylaws. However, we are seeking stockholder ratification as a matter of good corporate practice. If our stockholders fail to ratify the selection, the committee will reconsider its selection. Even if the selection is ratified, the committee, in its discretion, may direct the selection of a different independent auditor at any time during the year if it determines that such a change would be in the best interests of the Company and our stockholders.

PwC has served as our independent auditor since 2015. The following table summarizes the audit fees billed and expected to be billed by PwC for the indicated fiscal years and the fees billed by PwC for all other services rendered during the indicated fiscal years. All services associated with such fees were pre-approved by our Audit Committee in accordance with the "Pre-Approval Policies and Procedures" described below.

	Year Ended December 31,	
Fee Category	**2022**	**2021**
Audit Fees[1]	$ 963,000	$748,000
Audit-Related Fees[2]	—	—
Tax Fees[3]	153,400	41,250
All Other Fees[4]	956	956
Total Fees	$1,117,356	$790,206

(1) Consists of aggregate fees for professional services provided in connection with the annual audit of our consolidated financial statements, the review of our quarterly condensed consolidated financial statements and comfort letters, consents and review of documents filed with the SEC.
(2) Consists of fees for assurance and related services associated with consultations on matters reasonably related to the audit.
(3) Consists of fees for tax compliance, advice and tax services.
(4) Consists of fees for all other services.

Pre-Approval Policies and Procedures

Our Audit Committee has adopted policies and procedures relating to the approval of all audit and non-audit services performed by our independent auditor in order to ensure that these services do not impair the auditor's independence. In accordance with these policies and procedures, we will not engage our independent auditor to render audit or non-audit services unless the service is specifically approved in advance by our Audit Committee or the engagement is entered into pursuant to the pre-approval procedure described below. The Audit Committee does not delegate its responsibility to approve services performed by the independent registered public accounting firm to any member of management.

From time to time, our Audit Committee may pre-approve specified types of services that are expected to be provided to us by our independent auditor during the next 12 months. Any such pre-approval details the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

Report of the Audit Committee

The Audit Committee has reviewed and discussed the audited financial statements for the year ended December 31, 2022 with the Company's management and with PwC, the Company's independent registered public accounting firm. The Audit Committee has discussed with PwC the matters required to be discussed by the applicable standards of the Public Company Accounting Oversight Board ("PCAOB") and the SEC. The Audit Committee has also received the written disclosures and the letter from PwC pursuant to applicable PCAOB requirements regarding its communications with the Audit Committee concerning independence, and the Audit Committee has discussed with PwC its independence. Based on the foregoing, the Audit Committee recommended to the Board that the audited consolidated financial statements be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 for filing with the SEC.

This report is provided by the following directors, who serve on the Audit Committee:

Todd Shegog (Chair)
Arlene M. Morris
Matthew E. Ros

Board Recommendation

The Board recommends a vote "**FOR**" the ratification of the selection of PwC to serve as our independent registered public accounting firm.

CORPORATE GOVERNANCE

Our business affairs are managed under the direction of our Board. Our Board has adopted a set of Corporate Governance Guidelines as a framework for the governance of the Company, which is posted on our website located at *https://investors.cogentbio.com/*, under "Corporate Governance."

Board Composition

Director Nomination Process

The Nominating Committee is responsible for, among other things, overseeing succession planning for directors and building a qualified board to oversee management's execution of the Company's strategy and safeguard the long-term interests of stockholders. In this regard, the committee is charged with developing and recommending Board membership criteria to the Board for approval, evaluating the composition of the Board annually to assess the skills and experience that are currently represented on the Board and the skills and experience that the Board may find valuable in the future, and identifying, evaluating and recommending potential director candidates.

In identifying potential candidates for Board membership, the Nominating Committee considers recommendations from directors, stockholders, management and others, including, from time to time, third-party search firms to assist it in locating qualified candidates. Once potential director candidates are identified, the committee, with the assistance of management, undertakes a vetting process that considers each candidate's background, independence and fit with the Board's priorities. As part of this vetting process, the committee, as well as other members of the Board and the CEO, may conduct interviews with the candidates. If the committee determines that a potential candidate meets the needs of the Board and has the desired qualifications, it recommends the candidate to the full Board for appointment or nomination and to the stockholders for election at the annual meeting.

Criteria for Board Membership

In assessing potential candidates for Board membership and in assessing Board composition, the Nominating Committee considers a wide range of factors, including directors' experience, knowledge, integrity, understanding of our business environment and specific skills they may possess that are helpful to the Company (including leadership experience, financial expertise and industry knowledge). The committee generally believes that it is important for all Board members to possess the following qualifications:

- The candidate shall have experience at a strategic or policymaking level in a business, government, non-profit or academic organization of high standing.
- The candidate shall be highly accomplished in his or her respective field, with superior credentials and recognition.
- The candidate shall be well regarded in the community and shall have a long-term reputation for high ethical and moral standards.
- The candidate shall have sufficient time and availability to devote to the affairs of the Company, particularly in light of the number of boards of directors on which such candidate may serve.
- To the extent such candidate serves or has previously served on other boards, the candidate shall have a demonstrated history of actively contributing at board meetings.

The Nominating Committee seeks to balance the experiences, skills and characteristics represented on the Board and does not assign specific weight to any of these factors.

Board Diversity

In addition to the factors discussed above, the Board and the Nominating Committee actively seek to achieve a diversity of occupational and personal backgrounds on the Board. The Nominating Committee

considers a potential director candidate's ability to contribute to the diversity of personal backgrounds on the Board, including with respect to gender, race, ethnic and national background, geography, age and sexual orientation. The Nominating Committee assesses its effectiveness in balancing these considerations in connection with its annual evaluation of the composition of the Board. In this regard, our current Board of seven directors includes two directors (28%) who self-identify as female and one director (14%) who self-identifies as a member of the LGBTQ+ community.

In accordance with Nasdaq's board diversity listing standards, we are disclosing aggregated statistical information about our Board's self-identified gender and racial characteristics and LGBTQ+ status as voluntarily confirmed to us by each of our directors.

Board Diversity Matrix
(as of April 25, 2023)

	Female	Male	Non-Binary	Did Not Disclose Gender
Total number of directors: 7	2	5	—	—
Number of directors who identify in any of the categories below:				
African American or Black	—	—	—	—
Alaskan Native or Native American	—	—	—	—
Asian	—	—	—	—
Hispanic or Latinx	—	—	—	—
Native Hawaiian or Pacific Islander	—	—	—	—
White	2	5	—	—
Two or More Races or Ethnicities	—	—	—	—
LGBTQ+			1	
Did Not Disclose Demographic Background			—	

Stockholder Recommendations for Directors

It is the Nominating Committee's policy to consider written recommendations from stockholders for director candidates. The committee considers candidates recommended by our stockholders in the same manner as a candidate recommended by other sources. Any such recommendations should be submitted to the committee as described under "Stockholder Communications" not less than 120 days prior to the date on which the Company's proxy statement was released to the stockholders in connection with the previous year's annual meeting and should include the following information: (i) the name and address of record of the stockholder; (ii) a representation that the stockholder is a record holder of the Company's securities, or if the stockholder is not a record holder, evidence of ownership in accordance with Rule 14a-8(b)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); (iii) the name, age, business and residential address, educational background, current principal occupation or employment, and principal occupation or employment for the preceding five full fiscal years of the proposed director candidate; (iv) a description of the qualifications and background of the proposed director candidate which addresses the minimum qualifications and other criteria for Board membership approved by the Board from time to time and set forth in the charter of the Nominating Committee; (v) a description of all arrangements or understandings between the stockholder and the proposed director candidate; (vi) the consent of the proposed director candidate (1) to be named in the proxy statement relating to the Company's annual meeting of stockholders and (2) to serve as a director if elected at such annual meeting; and (vii) any other information regarding the proposed director candidate that is required to be included in a proxy statement filed pursuant to the rules of the SEC.

Board Leadership Structure

Mr. Harwin serves as our independent Chairman while Mr. Robbins serves as our President and CEO. Our Corporate Governance Guidelines provide our Board with the flexibility to combine or separate the positions of

Chairman and CEO. Currently, the Board believes that the roles of Chairman and CEO should be separate and that the Chairman should be an independent director as this structure enables our independent Chairman to oversee corporate governance matters and our CEO to focus on leading the Company's business.

The independent directors have the opportunity to meet in executive sessions without management present at every regular Board meeting and at such other times as may be determined by the Chairman. The purpose of these executive sessions is to encourage and enhance communication among the independent directors.

The Board believes that its programs for overseeing risk, as described under "Board Risk Oversight," would be effective under a variety of leadership frameworks. Accordingly, the Board's risk oversight function did not significantly impact its selection of the current leadership structure.

Director Independence

Nasdaq listing rules require a majority of a listed company's board of directors to be comprised of independent directors who, in the opinion of the board of directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Subject to specified exceptions, each member of a listed company's audit, compensation and nominating committees must be independent, and audit and compensation committee members must satisfy additional independence criteria under the Exchange Act.

Our Board undertook a review of its composition and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, our Board has determined that each of our current directors listed under "Information Regarding Director Nominees and Continuing Directors," with the exception of Andrew Robbins, is an "independent director" as defined under the Nasdaq listing rules. Mr. Robbins is not an independent director because he is our CEO. In making such determinations, our Board considered the relationships that each such non-employee director has with our Company and all other facts and circumstances our Board deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director. Our Board also determined that each of the directors currently serving on the Audit Committee and the Compensation Committee satisfy the additional independence criteria applicable to directors on such committees under Nasdaq listing rules and the rules and regulations established by the SEC.

Board Committees

Our Board has a separately designated Audit Committee, Compensation Committee, Nominating Committee and Science Committee, each of which is comprised solely of independent directors with the membership and responsibilities described below. Members serve on these committees until their resignation or until otherwise determined by our Board. Other than the Science Committee, each of these committees is empowered to retain outside advisors as it deems appropriate, regularly reports its activities to the full Board and has a written charter which is posted on our website located at *https://investors.cogentbio.com/*, under "Corporate Governance."

Name	Audit Committee	Compensation Committee	Nominating Committee	Science Committee
Andrew Robbins				
Chris Cain, Ph.D.		X		Chair
Karen Ferrante, M.D.			Chair	X
Peter Harwin			X	X
Arlene M. Morris	X	Chair		
Matthew E. Ros	X		X	
Todd Shegog	Chair	X		
# of Meetings in 2022	4	7	4	—(1)

(1) The Board formed the Science Committee in April 2023.

Audit Committee. The primary responsibilities of our Audit Committee are to oversee the accounting and financial reporting processes of the Company and its subsidiaries, including the audits of the Company's financial statements, the integrity of the financial statements and the annual review of the performance, effectiveness and independence of the outside auditor. This includes reviewing the financial information provided to stockholders and others and the adequacy and effectiveness of the Company's internal controls. The committee also makes recommendations to the Board as to whether financial statements should be included in the Company's Annual Report on Form 10-K.

Mr. Shegog qualifies as an "audit committee financial expert," as that term is defined in the rules and regulations established by the SEC, and all members of the Audit Committee are "financially literate" under Nasdaq listing rules.

Compensation Committee. The primary responsibilities of our Compensation Committee are to periodically review and approve, or recommend to the Board for review and approval, where appropriate, the compensation and other benefits for our senior officers and directors. This includes reviewing and approving corporate goals and objectives relevant to the compensation of our senior officers, evaluating the performance of these officers in light of the goals and objectives, and setting the officers' compensation based on those evaluations. The committee also administers and makes recommendations to the Board regarding equity incentive plans that are subject to the Board's approval and approves the grant of equity awards under the plans. For compensation matters and equity grants to our CEO and Board members, the committee makes recommendations to the Board, and the Board is responsible for reviewing and approving all such matters.

The Compensation Committee may delegate its authority to one or more subcommittees. The committee may also delegate authority to review and approve the compensation of our employees to certain of our executive officers. Even where the committee does not delegate authority, our executive officers will typically make recommendations to the committee regarding compensation to be paid to our employees and the size of equity awards under our equity incentive plans, but will not be present during voting or deliberations on their own compensation. The committee has the authority to engage outside advisors, such as compensation consultants, to assist it in carrying out its responsibilities. The committee engaged Compensia, Inc. ("Compensia") in 2022 to provide advice regarding the amount and form of executive and director compensation. The committee has determined that (1) the compensation consultant satisfies applicable independence criteria and (2) the compensation consultant's work with the Company does not raise any conflicts of interest, in each case under applicable Nasdaq listing rules and the rules and regulations established by the SEC.

Nominating Committee. The primary responsibilities of our Nominating Committee are to engage in succession planning for the Board, develop and recommend to the Board criteria for identifying and evaluating qualified director candidates, and make recommendations to the Board regarding candidates for election or reelection to the Board at each annual stockholders' meeting. In addition, the committee is responsible for overseeing our corporate governance practices and making recommendations to the Board concerning corporate governance matters. The committee is also responsible for making recommendations to the Board concerning the structure, composition and functioning of the Board and its committees.

Science Committee. The Science Committee assists our Board in ensuring that our research and development function is optimized to support our strategic goals, including to review and monitor the science, technology, process, procedures and infrastructure underlying our major discovery and development programs. The Science Committee makes recommendations to the Board regarding research and development strategies and opportunities.

Board Risk Oversight

We believe that risk management is an important part of establishing and executing on the Company's business strategy. Our Board, as a whole and at the committee level, focuses its oversight on the most significant

risks facing the Company and on the Company's processes to identify, prioritize, assess, manage and mitigate those risks. The committees oversee specific risks within their purview, as follows:

- **The Audit Committee** has overall responsibility for overseeing the Company's practices with respect to risk assessment and management. Additionally, the committee is responsible for overseeing management of risks related to our accounting and financial reporting processes, and information technology and cybersecurity, as detailed below.
- **The Compensation Committee** is responsible for overseeing management of risks related to our compensation policies and programs.
- **The Nominating Committee** is responsible for overseeing management of risks related to director succession planning and corporate governance practices.

Our Board and its committees receive regular reports from members of the Company's senior management on areas of material risk to the Company, including strategic, operational, financial, information technology and cybersecurity, and legal and regulatory risks. While our Board has an oversight role, management is principally tasked with direct responsibility for assessing and managing risks, including implementing processes and controls to mitigate their effects on the Company.

Oversight of Cybersecurity Risk

We collect, store and transmit sensitive information, including intellectual property, proprietary business information and personal information in connection with our business operations. The secure maintenance of this information is critical to our operations and business strategy. We have adopted oversight and management controls on our data security and have a process in place for incident detection, containment, response and remediation. We mitigate our cybersecurity risk in various ways, including by leveraging standard industry tools from a software and hardware perspective, maintaining a cybersecurity risk insurance policy and engaging with third-party security consultants to perform periodic data security risk assessments. We have established policies and procedures governing cybersecurity and data protection and conduct regular employee trainings on the current threat environment and phishing risk. In our industry, cyber-attacks are of ever-increasing levels of frequency and sophistication. However, to date, no cyber event has caused a material disruption to our business, or to our knowledge, involved a material security breach. We have retained VeraSafe, LLC ("VeraSafe") to help review and monitor our practices and processes related to personal data and compliance with applicable data protection laws. VeraSafe acts as our Data Protection Officer and has served in this capacity since May 2021.

While everyone at the Company plays a part in maintaining our data security, the Audit Committee has been designated by our Board to oversee these specific risks. The Audit Committee receives reports from management and reviews business-related risk exposures and other risks relating to data privacy and cybersecurity, including a review of our policies and procedures, the integrity of our information technology systems and processes, the adequacy of our controls and contingency plans in the event of a cyber incident. The Board receives updates from management and the Audit Committee on cybersecurity risks on at least an annual basis.

Other Corporate Governance Practices and Policies

Director Attendance

During the year ended December 31, 2022, the Board met seven times and acted by unanimous written consent three times. During 2022, each current member of the Board attended at least 75% of the aggregate number of meetings of the Board and the committees on which he or she served during the period in which he or she was on the Board or committee. Directors are encouraged to attend the annual meeting of stockholders. All of our directors then serving on the Board attended the 2022 Annual Meeting of Stockholders.

Stockholder Communications

Stockholders and other interested parties may communicate with our Board or a particular director by sending a letter addressed to the Board or a particular director to our Corporate Secretary at the address set forth on the first page of this Proxy Statement. These communications will be compiled and reviewed by our Corporate Secretary, who will determine whether the communication is appropriate for presentation to the Board or the particular director. The purpose of this screening is to allow the Board to avoid having to consider irrelevant or inappropriate communications (such as advertisements, solicitations and hostile communications).

To enable the Company to speak with a single voice, as a general matter, senior management serves as the primary spokesperson for the Company and is responsible for communicating with various constituencies, including stockholders, on behalf of the Company. Directors may participate in discussions with stockholders and other constituencies on issues where Board-level involvement is appropriate. In addition, the Board is kept informed by senior management of the Company's stockholder engagement efforts.

Code of Business Conduct and Ethics

Our Board has adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is available on our website located at *https://investors.cogentbio.com/*, under "Corporate Governance." We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by applicable rules.

Anti-Hedging Policy

Certain transactions in our securities (such as purchases and sales of publicly traded put and call options, and short sales) create a heightened compliance risk or could create the appearance of misalignment between management and stockholders. In addition, securities held in a margin account or pledged as collateral may be sold without consent if the owner fails to meet a margin call or defaults on the loan, thus creating the risk that a sale may occur at a time when an officer or director is aware of material, non-public information or otherwise is not permitted to trade in Company securities. Our insider trading policy expressly prohibits short sales of our stock by our executive officers, directors, employees and certain designated consultants and contractors. Our insider trading policy also expressly prohibits, without the advance approval of our audit committee, purchases or sales of puts, calls or other derivative securities of the Company or any derivative securities or any hedging transactions that provide the economic equivalent of ownership.

Director Compensation

Outside Director Compensation Policy

We adopted a policy for compensating our non-employee directors with a cash retainer for service on the Board and for service on each committee on which the director is a member. The chairman of each committee receives a higher retainer for such service. These fees are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment is prorated for any portion of such quarter that the director is not serving on our Board. The Compensation Committee periodically reviews compensation paid to our non-employee directors, considering input from the Compensation Committee's independent compensation consultant, and makes recommendations for adjustments, as appropriate, to the full

Board. The Board recently approved changes to the outside director compensation program, as reflected below, in order to maintain compensation levels for our non-employee directors that are at the 50th percentile of our peer companies. The fees payable to non-employee directors for service on the Board and for service on each committee of the Board on which the director was or is a member in 2022 and 2023 are as follows:

	2022 Annual Retainer	2023 Annual Retainer
Board of Directors:		
All non-employee directors	$40,000	$40,000
Additional retainer for Non-Executive Chairman of the Board	$30,000	$30,000
Audit Committee:		
Chairman	$15,000	$15,000
Non-Chairman members	$ 7,500	$ 7,500
Compensation Committee:		
Chairman	$11,000	$13,500
Non-Chairman members	$ 5,500	$ 6,750
Nominating Committee:		
Chairman	$ 8,000	$10,000
Non-Chairman members	$ 4,000	$ 5,000
Science Committee:		
Chairman	—	$13,500
Non-Chairman members	—	$ 6,750

We also reimburse our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending any in-person Board and committee meetings.

Pursuant to our director compensation policy, directors are given the opportunity to elect to receive all or a portion of their retainer and committee fees in the form of an equity award of: (a) unrestricted shares having a grant date fair value equal to the amount (or portion thereof) of such retainer and committee fees or (b) fully vested stock options to purchase common stock based on the Black-Scholes option-pricing model as of the date of grant. Any such election must be made: (i) for any continuing non-employee director, before the start of the calendar year with respect to any cash compensation for such calendar year and (ii) for any new non-employee director, within 30 days of her or his election to the Board. Any such stock options are fully vested upon grant and expire ten years from the date of grant.

In addition, our director compensation policy provides that each new non-employee director elected to our Board receives an initial, one-time stock option grant to purchase 61,400 (increased to 73,400 beginning in 2023) shares of our common stock (the "Initial Award"), which vests in equal monthly installments over three years, subject to continued service as a member of the Board. In addition, each continuing non-employee director, other than a director receiving an Initial Award, receives, at the time of the Company's annual meeting, an annual equity grant of options to purchase 30,700 (increased to 36,700 beginning in 2023) shares of our common stock, which vests in full upon the earlier of the first anniversary of the date of grant or the date of the Company's next annual meeting of stockholders, subject to continued service as a member of the Board through such date. This program is intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors' interests with those of our stockholders.

Fiscal Year 2022 Director Compensation Table

The table below shows all compensation paid to or earned in 2022 by our non-employee directors. Executives who serve as directors do not receive any compensation for service as a director. The compensation received by Mr. Robbins for his service to us during 2022 as our Chief Executive Officer is presented in the 2022 Summary Compensation Table in "Executive Compensation" below.

Name	Fees Earned or Paid In Cash ($)[1]	Option Awards ($)[2][3]	Total ($)
Chris Cain, Ph.D.[4]	$45,500	$90,221	$135,721
Karen Ferrante, M.D.	$53,470	$90,221	$143,691
Peter Harwin[4]	$77,271	$90,221	$167,492
Arlene M. Morris	$58,500	$90,221	$148,721
Matthew E. Ros	$51,470	$90,221	$141,691
Todd Shegog	$59,000	$90,221	$149,221

(1) Amounts represent fees earned in cash for services rendered by each member of the Board. Dr. Ferrante and Mr. Ros elected to receive their cash compensation in the form of fully vested options to purchase our common stock.

(2) Amounts shown reflect the grant date fair value of option awards granted during 2022. The grant date fair value was computed in accordance with ASC Topic 718, disregarding the effect of estimated forfeitures related to service-based vesting. See Note 7 to the financial statements in the Company's Annual Report on Form 10-K regarding assumptions we made in determining the fair value of option awards.

(3) As of December 31, 2022, our non-employee directors held outstanding options to purchase the following number of shares of common stock: Dr. Cain – 97,865, Dr. Ferrante – 162,219, Mr. Harwin – 97,865, Ms. Morris – 101,448, Mr. Ros – 151,104 and Mr. Shegog – 90,700.

(4) All or a portion of such director's fees is remitted directly to Fairmount and such director is obligated to turn over to Fairmount any net cash or stock received from the options pursuant to their arrangement with Fairmount. The director disclaims beneficial ownership of the options and underlying shares.

Compensation Committee Interlocks and Insider Participation

None of the members of our Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board or compensation committee of any entity that has one or more executive officers serving on our Board or Compensation Committee.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE

Environmental, social and governance ("ESG") matters are a priority to us. Our Nominating Committee oversees this commitment, our ESG initiatives and progress towards related goals and targets. Our current ESG focus areas are as follows:

Our Patients

Our mission is to deliver the next best-in-class therapy for patients with genetically defined diseases – to move beyond incremental improvements and solely treating symptoms, to address the real causes of disease. We are methodical, rational and intentional in our approach to identify pragmatic solutions to complex health challenges with the goal of restoring health and allowing patients to live better, longer lives. In pursuing our mission, patient safety is of the utmost importance. We follow the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines on Good Clinical Practice ("GCP") and the ethical principles that have their origin in the Declaration of Helsinki in designing and conducting our clinical trials. Our protocols are approved by national and local bodies and all of our participants undergo thorough and informed consent processes. Furthermore, we provide travel reimbursement to help reduce barriers so that patients with diverse backgrounds are able to participate in our clinical trials.

Our Diverse Workforce

We believe that our future success largely depends upon our continued ability to attract and retain a diverse group of highly skilled employees. As of March 31, 2023, women comprise 57% of our total employee population and 50% of our employee leaders at the level of Vice President or above. We do not ask our employees to self-identify by race or ethnicity and therefore do not maintain metrics on this information. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off.

Our Environment

We currently lease our office facilities and lab spaces. Nonetheless, we periodically review our environmental impact and consider opportunities to optimize our operations. We are committed to the responsible management of hazardous materials and lab waste and have various initiatives in place to foster a more sustainable and safer environment. Our corporate headquarters are located at 275 Wyman St. in Waltham, Massachusetts, which has a LEED Platinum certification. Our research team and laboratory facilities are located at 4840 Pearl East Circle in Boulder, Colorado, which is Boulder's first LEED-EB (Existing Building) certified building. Our Boulder research facility uses a system that recovers energy from the lab exhaust to precondition the air supplied to the labs, thereby reducing the energy needed to heat and cool them. At both of our facilities, we have implemented robust composting and recycling programs, including recycling of lab specific plastic waste streams in Boulder that are not accepted by the municipal program, and we aim to reduce our water use and consumption of single-use plastics. We also provide certain commuter benefits, including bike-to-work and public transportation subsidies, and have a flexible work-from-home program for certain roles to help reduce carbon emissions.

Our Community

We are committed to the communities in which we operate. The Company and our employees participate in multiple charitable endeavors each year. We also believe it is important to invest in the next generation of scientists, and we have engaged with local schools and students in the Boston and Boulder areas to facilitate interest in the science and technology fields.

EXECUTIVE OFFICERS

Biographical and other information regarding our executive officers is set forth below. There are no family relationships among any of our directors or executive officers.

Name	Age (as of April 25)	Position
Andrew Robbins[1]	47	Chief Executive Officer, President and Director
John Green	42	Chief Financial Officer
Evan Kearns	42	Chief Legal Officer and Corporate Secretary
John Robinson, Ph.D.	49	Chief Scientific Officer
Jessica Sachs, M.D.	48	Chief Medical Officer

(1) For Mr. Robbins's biographical information, see "Information Regarding Director Nominees and Continuing Directors" above.

John Green. Mr. Green has served as our Chief Financial Officer, principal accounting officer and principal financial officer since July 2020. Prior to his promotion, Mr. Green was our Vice President of Finance and Controller from April 2018 to June 2020. Mr. Green brings nearly 20 years of strategic finance and accounting experience to his position, nearly half of which has been in the biotechnology industry for both public and private companies. Prior to joining Cogent, Mr. Green served as Principal Accounting Officer at Merrimack Pharmaceuticals, Inc. (Nasdaq: MACK), a biopharmaceutical company, from March 2017 to June 2018. From November 2015 to March 2017, he served as the Controller at Fractyl Laboratories, Inc., a medical technology company. From June 2014 to November 2015, Mr. Green served as Director of Accounting at Dicerna Pharmaceuticals, Inc. (Nasdaq: DRNA), a biopharmaceutical company. Mr. Green is a Chartered Professional Accountant and holds a B.S. in Chemistry and Biology from Acadia University.

Evan Kearns. Mr. Kearns has served as our Chief Legal Officer and Corporate Secretary since May 2021 and is responsible for the Company's legal and compliance functions. Mr. Kearns has over 16 years of experience in and serving the biotechnology industry. Prior to joining the Company, Mr. Kearns served as Vice President, General Counsel, Corporate Secretary and Chief Compliance Officer at Agenus Inc. (Nasdaq: AGEN), a biotechnology company, from July 2018 to April 2021, where he was responsible for corporate and securities law matters, as well as M&A, financing and licensing transactions and corporate governance matters. From December 2017 to July 2018, he served as Vice President, Associate General Counsel at Agenus in a similar capacity. Before joining Agenus, he served as a life sciences corporate associate in the Boston office of Goodwin Proctor LLP, an international law firm. Mr. Kearns received his J.D. from the University of Toledo College of Law and his B.A. in Economics from Colby College.

John Robinson, Ph.D. Dr. Robinson has served as our Chief Scientific Officer since April 2021. He has over 20 years of small molecule drug discovery experience. Prior to joining the Company, Dr. Robinson served as Vice President of Medicinal Chemistry at Pfizer Boulder Research and Development, a drug discovery and development center, from July 2019 to March 2021. From December 2002 to July 2019, he served in a variety of scientific and leadership positions at Array BioPharma Inc., a biopharmaceutical company, including most recently, as Executive Director and Head of Chemistry. Dr. Robinson received his B.S. in Biochemistry from Indiana University of Pennsylvania and his Ph.D. in Synthetic Organic Chemistry from the University of Delaware.

Jessica Sachs, M.D. Dr. Sachs has served as our Chief Medical Officer since June 2019. Prior to assuming this role, she served as our Vice President of Clinical Sciences from April 2017 to June 2019, and she was responsible for the clinical development strategy and medical and translational oversight of the Cogent portfolio. Dr. Sachs has over 20 years of experience in oncology and pediatrics. From 2012 to April 2017, Dr. Sachs served as Senior Medical Director of Clinical Research at Takeda Pharmaceutical Company Limited (NYSE: TAK), a

global biopharmaceutical company, where she led multiple clinical programs in oncology and transplantation. From 2010 to 2012, Dr. Sachs was Associate Director at Genzyme Corporation, a biotechnology company, where she was responsible for post-marketing safety surveillance and risk management activities for a variety of oncology products. Dr. Sachs has been a faculty member of the Harvard Medical School since 2007 and is an Assistant in Pediatrics in the Division of Pediatric Hematology/Oncology at the Massachusetts General Hospital. She completed her fellowship in pediatric hematology and oncology at the Dana Farber Cancer Institute and Children's Hospital Boston. She received her M.D. from Washington University in St. Louis and her B.S. from Duke University.

EXECUTIVE COMPENSATION

Our named executive officers ("NEOs") for 2022, which consist of our principal executive officer and the next two most highly compensated executive officers, are:

- Andrew Robbins, our Chief Executive Officer;
- Jessica Sachs, M.D., our Chief Medical Officer; and
- John Robinson, Ph.D., our Chief Scientific Officer.

2022 Summary Compensation Table

The following table summarizes the compensation awarded to, earned by or paid to our NEOs for 2022 and 2021.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Andrew Robbins	2022	624,283	344,920	3,409,773	12,200[2]	4,391,176
Chief Executive Officer	2021	592,648	357,075	1,901,555	11,600[2]	2,862,878
Jessica Sachs, M.D.	2022	482,558	177,744	1,235,425	12,200[2]	1,907,927
Chief Medical Officer	2021	415,769	167,868	3,213,956	11,600[2]	3,809,193
John Robinson, Ph.D.	2022	454,178	167,348	1,235,425	12,200[2]	1,869,151
Chief Scientific Officer	2021	315,481	128,082	3,017,950	11,600[2]	3,473,113

(1) Amounts reflect the grant-date fair value of option awards granted in 2022 and 2021 in accordance with ASC Topic 718 disregarding the effect of any estimated forfeitures related to service-vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 7 to the financial statements in the Company's Annual Report on Form 10-K. These amounts do not correspond to the actual value that may be recognized by the executives upon exercise of the options.

(2) Represents the value of 401(k) contributions made by the Company.

Narrative to Summary Compensation Table

Our Board and Compensation Committee review compensation practices and philosophy annually for all employees, including our executives. In setting executive base salaries and bonuses and granting equity incentive awards, they consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short-and long-term results that are in the best interests of our stockholders and our desire to incentivize a long-term commitment to our Company. We target a general competitive position, based on independent third-party benchmark analytics to inform the mix of compensation of base salary, bonus and long-term incentives.

Our Compensation Committee is responsible for approving all executive compensation matters other than for our CEO, which must be recommended to the Board for approval. Our Compensation Committee typically reviews and discusses management's proposed compensation with the CEO for all executives other than the CEO. Based on those discussions and its discretion, taking into account the factors noted above, the Compensation Committee then determines the compensation for each executive officer other than the CEO. In 2022, the Compensation Committee retained the services of Compensia as its external compensation consultant and the Board and the Compensation Committee considered Compensia's input on certain compensation matters as they deemed appropriate.

Annual Base Salary

Each named executive officer's base salary is a fixed component of annual compensation for performing specific duties and functions, and has been established by our Board taking into account each individual's role, responsibilities, skills and experience. Base salaries for our named executive officers are reviewed annually by our Compensation Committee, typically in connection with our annual performance review process, and adjusted from time to time, based on the recommendation of the Compensation Committee, to realign salaries with market levels after taking into account individual responsibilities, performance and experiences.

Cash Bonus

From time to time, our Board or Compensation Committee may approve annual bonuses for our named executive officers based on individual performance, Company performance or as otherwise determined appropriate. Cash bonuses for the 2022 performance year were funded at 92% of target based on achievement of corporate goals in 2022.

Long-Term Equity Incentives

Our equity grant program is intended to align the interests of our named executive officers with those of our stockholders and to motivate them to make important contributions to our performance. During the year ended December 31, 2022, we made grants of stock options to each of our named executive officers. The grant date fair values of such awards are set forth in the "2022 Summary Compensation Table" above and the number of shares underlying such awards and the vesting terms of such awards are set forth in the "Outstanding Equity Awards at 2022 Fiscal Year End Table" below.

Outstanding Equity Awards at 2022 Fiscal Year End Table

The following table sets forth information regarding outstanding equity awards at the end of 2022 for each of our NEOs.

		Option Awards			
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Andrew Robbins	10/23/2020	1,007,828	852,777[1]	11.16	10/22/2030
	12/07/2020	228,347	228,346[1]	12.76	12/06/2030
	02/10/2021	144,467	170,733[2]	10.17	02/09/2031
	01/25/2022	158,125	531,875[2]	7.60	01/24/2032
Jessica Sachs, M.D.	05/07/2020	99,472	—	1.67	05/06/2030
	02/01/2021	183,333	216,667[1]	9.10	01/31/2031
	02/10/2021	57,979	68,521[2]	10.17	02/09/2031
	01/25/2022	57,292	192,708[2]	7.60	01/24/2032
John Robinson, Ph.D.	03/31/2021	218,750	281,250[1]	8.78	03/30/2031
	01/25/2022	57,292	192,708[2]	7.60	01/24/2032

(1) Stock options vest over four years, with 25% of the shares vesting on the first anniversary of the grant date, and the remaining shares vesting in 36 equal monthly installments thereafter, subject to continuous service with us.

(2) Stock options vest in equal monthly installments over a four-year period, subject to continuous service with us.

Employment Arrangements with our Named Executive Officers

We have entered into employment agreements with each of our named executive officers. Each of our named executive officers is employed at will.

Andrew Robbins. Mr. Robbins's employment agreement provides for "at will" employment. Pursuant to the terms of his employment agreement, Mr. Robbins is entitled to an annual base salary, which was set at $624,855 for 2022. Mr. Robbins is also eligible for annual incentive compensation targeted at 60% of his base salary. Mr. Robbins is eligible to participate in the employee benefit plans generally available to full-time employees, subject to the terms of those plans. Pursuant to the terms of his employment agreement, if Mr. Robbins's employment is terminated by the Company without cause (as defined in his employment agreement) or by Mr. Robbins for good reason (as defined in his employment agreement), Mr. Robbins will receive any base salary through the date of termination, unpaid expense reimbursements, unused vacation accrued through the date of termination and any vested benefits under any employee benefit plan through the date of termination. Additionally, subject to Mr. Robbins's execution of a release of potential claims against the Company, Mr. Robbins will be entitled to receive: (i) a lump sum in cash in an amount equal to 12 months of base salary, (ii) a monthly cash payment for 12 months for medical and dental benefits or Mr. Robbins's COBRA health continuation period, whichever ends earlier, (iii) a lump sum in cash in an amount equal to 100% of Mr. Robbins's target bonus for the then-current year and (iv) acceleration of vesting on any time-based options in which Mr. Robbins would have vested if he had remained employed for an additional 12 months. However, in the event that Mr. Robbins's employment is terminated by the Company without cause, or Mr. Robbins terminates his employment with the Company for good reason, in either case for a period of 90 days prior to or 12 months following the occurrence of a change in control (as defined in his employment agreement), in lieu of the severance payments and benefits described in the preceding sentence and subject to Mr. Robbins's execution of a release of potential claims against the Company, Mr. Robbins will be entitled to receive: (i) a lump sum in cash in an amount equal to 18 months of base salary, (ii) a lump sum in cash in an amount equal to 150% of Mr. Robbins's target bonus for the then-current year, (iii) a monthly cash payment for 18 months for medical and dental benefits or Mr. Robbins's COBRA health continuation period, whichever ends earlier and (iv) acceleration of vesting on any options.

Jessica Sachs, M.D. Dr. Sachs's employment agreement provides for "at will" employment. Pursuant to the terms of her employment agreement, Dr. Sachs is entitled to an annual base salary, which was set at $483,000 for 2022. Dr. Sachs is also eligible for annual incentive compensation targeted at 40% of her base salary. Dr. Sachs is eligible to participate in the employee benefit plans generally available to full-time employees, subject to the terms of those plans. Pursuant to the terms of her employment agreement, if Dr. Sachs's employment is terminated by us without cause (as defined in her employment agreement) or by Dr. Sachs for good reason (as defined in her employment agreement), Dr. Sachs will receive any base salary through the date of termination, unpaid expense reimbursements, unused vacation accrued through the date of termination and any vested benefits under any employee benefit plan through the date of termination. Additionally, subject to Dr. Sachs's execution of a release of potential claims against us, Dr. Sachs will be entitled to receive: (i) a lump sum in cash in an amount equal to 12 months of base salary, (ii) a monthly cash payment for nine months for medical and dental benefits or Dr. Sachs's COBRA health continuation period, whichever ends earlier, (iii) a lump sum in cash in an amount equal to Dr. Sachs' target bonus for the then-current year pro-rated based on the portion of the year that Dr. Sachs was employed, and (iv) acceleration of vesting on any time-based equity awards in which Dr. Sachs would have vested if she had remained employed for an additional nine months. However, in the event that Dr. Sachs's employment is terminated by us without cause, or Dr. Sachs terminates her employment with us for good reason, in either case within 12 months following the occurrence of a change in control (as defined in her employment agreement), in lieu of the severance payments and benefits described in the preceding sentence and subject to Dr. Sachs's execution of a release of potential claims against us, Dr. Sachs will be entitled to receive: (i) a lump sum in cash in an amount equal to 12 months of base salary, (ii) a lump sum in cash in an amount equal to 100% of Dr. Sachs's target bonus for the then-current year, (iii) a monthly cash payment for 12 months for medical and dental benefits or Dr. Sachs's COBRA health continuation period, whichever ends earlier and (iv) acceleration of vesting on all equity awards.

John Robinson, Ph.D. Dr. Robinson's employment agreement provides for "at will" employment. Pursuant to the terms of his employment agreement, Dr. Robinson is entitled to an annual base salary, which was set at $454,750 for 2022. Dr. Robinson is also eligible for annual incentive compensation targeted at 40% of his base salary. Dr. Robinson is eligible to participate in the employee benefit plans generally available to full-time employees, subject to the terms of those plans. Pursuant to the terms of his employment agreement, if Dr. Robinson's employment is terminated by us without cause (as defined in his employment agreement) or by Dr. Robinson for good reason (as defined in his employment agreement), Dr. Robinson will receive any base salary through the date of termination, unpaid expense reimbursements, unused vacation accrued through the date of termination and any vested benefits under any employee benefit plan through the date of termination. Additionally, subject to Dr. Robinson's execution of a release of potential claims against us, Dr. Robinson will be entitled to receive: (i) a lump sum in cash in an amount equal to 12 months of base salary, (ii) a monthly cash payment for nine months for medical and dental benefits or Dr. Robinson's COBRA health continuation period, whichever ends earlier, (iii) a lump sum in cash in an amount equal to Dr. Robinson's target bonus for the then-current year pro-rated based on the portion of the year that Dr. Robinson was employed and (iv) acceleration of vesting on any time-based equity awards in which Dr. Robinson would have vested if he had remained employed for an additional nine months. However, in the event that Dr. Robinson's employment is terminated by us without cause, or Dr. Robinson terminates his employment with us for good reason, in either case within 12 months following the occurrence of a change in control (as defined in his employment agreement), in lieu of the severance payments and benefits described in the preceding sentence and subject to Dr. Robinson's execution of a release of potential claims against us, Dr. Robinson will be entitled to receive: (i) a lump sum in cash in an amount equal to 12 months of base salary, (ii) a lump sum in cash in an amount equal to 100% of Dr. Robinson's target bonus for the then-current year, (iii) a monthly cash payment for 12 months for medical and dental benefits or Dr. Robinson's COBRA health continuation period, whichever ends earlier and (iv) acceleration of vesting on all equity awards.

Additional Narrative Disclosure

401(k) Plan

We maintain the Cogent Biosciences, Inc. 401(k) Plan, a tax-qualified retirement plan for our employees. The 401(k) Plan is intended to qualify under Section 401(k) of the Internal Revenue Service Code of 1986, as amended, so that contributions to the 401(k) Plan by employees or by us, and the investment earnings thereon, are not taxable to the employees until withdrawn from the 401(k) Plan, and so that contributions by us, if any, will be deductible by us when made. Under the 401(k) Plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit and to have the amount of such reduction contributed to the 401(k) Plan. We currently match 100% of an employee's contributions to the 401(k) Plan up to 4% of an employee's compensation.

Health and Welfare Benefits

All of our full-time employees, including our executive officers, are eligible to participate in certain medical, disability and life insurance benefit programs offered by us. We pay the premiums for term life insurance and long-term disability for all of our employees, including our executive officers. We also provide all employees, including executive officers, with a flexible spending account plan, an employee stock purchase plan and paid time off benefits, including vacation, sick time and holidays. We do not sponsor any qualified or non-qualified defined benefit plans for any of our employees or executives.

Other Retirement Benefits

We do not maintain any defined benefit pension plans. In 2021, we adopted a nonqualified deferred compensation plan pursuant to which eligible participants, including our executive officers, may elect to defer a portion of their eligible compensation. None of the NEOs participated in the plan during 2022.

CERTAIN INFORMATION ABOUT OUR COMMON STOCK

Security Ownership of Certain Beneficial Owners and Management

The following table presents information regarding beneficial ownership of our common stock as of March 31, 2023 by:

- each stockholder or group of stockholders known by us to be the beneficial owner of more than 5% of our outstanding common stock;
- each of our directors and nominees;
- each of our NEOs; and
- all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. Under such rules, beneficial ownership includes any shares of common stock over which the individual or entity has sole or shared voting power or investment power as well as any shares of common stock that the individual or entity has the right to acquire within 60 days after March 31, 2023. To our knowledge and subject to applicable community property rules, and except as otherwise indicated below, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned.

The percentage ownership information shown in the column titled "Percentage of Shares Beneficially Owned" in the table below is based on 70,946,790 shares of our common stock outstanding as of March 31, 2023 (plus, as to any particular beneficial owner, any shares as to which such person has the right to acquire beneficial ownership within 60 days thereafter). Unless otherwise indicated, the address of each beneficial owner listed in this table is the Company's address set forth on the first page of this Proxy Statement.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders:		
Entities affiliated with Fairmount Funds Management LLC[1]	17,036,225	19.9%
Entities affiliated with Venrock Healthcare Capital Partners II, L.P.[2]	7,315,367	9.9%
Entities affiliated with RA Capital Management, L.P.[3]	5,999,481	8.5%
Entities affiliated with BlackRock, Inc.[4]	4,946,443	7.0%
Entities affiliated with Commodore Capital LP[5]	4,926,000	6.9%
Entities affiliated with State Street Corporation[6]	4,261,381	6.0%
Entities affiliated with TCG Crossover Fund I, L.P.[7]	3,631,042	5.1%
Named Executive Officers, Directors and Nominees:		
Andrew Robbins[8]	1,917,673	2.6%
John Robinson, Ph.D.[8]	353,750	*
Jessica Sachs, M.D.[9]	490,257	*
Chris Cain, Ph.D.[10]	49,901	*
Karen Ferrante, M.D.[8]	116,714	*
Peter Harwin[10]	49,901	*
Arlene M. Morris[8]	54,081	*
Matthew E. Ros[8]	105,529	*
Todd Shegog[8]	44,375	*
All current executive officers and directors as a group (11 persons)[11]	3,831,669	5.1%

* Represents beneficial ownership of less than one percent.

(1) Based on Company records and the Schedule 13D/A filed by Fairmount with the SEC on June 21, 2022. Includes (i) 2,472,124 shares held by Fairmount Healthcare Fund II LP, (ii) 286,851 shares held by

Fairmount Healthcare Fund LP and (iii) 14,277,250 shares issuable upon conversion of 57,109 shares of Series A Preferred Stock. Excludes an estimated 2,576,250 shares issuable upon conversion of an estimated 10,305 shares of Series A Preferred Stock, the conversion of which is subject to a beneficial ownership limitation of 19.99% of the outstanding shares. Fairmount Healthcare Fund GP LLC is the general partner of Fairmount Healthcare Fund LP and Fairmount Healthcare Fund II GP LLC is the general partner of Fairmount Healthcare Fund II LP. Fairmount is the investment manager of Fairmount Healthcare Fund LP and Fairmount Healthcare Fund II LP. Fairmount, as the investment manager, along with Fairmount Healthcare Fund GP LLC and Fairmount Healthcare Fund II GP LLC, as the general partners, exercise voting and investment power over Fairmount Healthcare Fund LP and Fairmount Healthcare Fund II LP. The address for the entities listed above is 2001 Market Street, Suite 2500, Philadelphia, Pennsylvania 19103.

(2) Based on Company records and the Schedule 13G/A filed by Venrock Healthcare Capital Partners II, L.P. with the SEC on February 14, 2023. Includes (i) 594,156 shares owned by Venrock Healthcare Capital Partners II, L.P., (ii) 240,940 shares owned by VHCP Co-Investment Holdings II, LLC, (iii) 1,953,314 shares owned by Venrock Healthcare Capital Partners III, L.P., (iv) 195,411 shares owned by VHCP Co-Investment Holdings III, LLC, (v) 2,054,296 shares owned by Venrock Healthcare Capital Partners EG, L.P. and (vi) 2,277,250 shares issuable upon conversion of 9,109 shares of Series A Preferred Stock. Excludes an estimated 131,750 shares issuable upon conversion of an estimated 527 shares of Series A Preferred Stock, the conversion of which is subject to a beneficial ownership limitation of 9.99% of the outstanding shares. VHCP Management II, LLC is the general partner of Venrock Healthcare Capital Partners II, L.P. and the manager of VHCP Co-Investment Holdings II, LLC. VHCP Management III, LLC is the general partner of Venrock Healthcare Capital Partners III, L.P. and the manager of VHCP Co-Investment Holdings III, LLC. VHCP Management EG, LLC is the general partner of Venrock Healthcare Capital Partners EG, L.P. Messrs. Nimish Shah and Bong Koh are the voting members of VHCP Management II, LLC and VHCP Management III, LLC. The address for the individuals and entities listed above is 3340 Hillview Avenue, Palo Alto, California 94304.

(3) Based on a Schedule 13G/A filed by RA Capital Management L.P. ("RA Capital") with the SEC on February 14, 2023. RA Capital Healthcare Fund GP, LLC is the general partner of RA Capital Healthcare Fund, L.P. (the "Fund"). RA Capital Management GP, LLC is the general partner of RA Capital. Dr. Peter Kolchinsky and Rajeev Shah are the controlling persons of RA Capital Management GP, LLC. RA Capital serves as the investment advisor for the Fund and may be deemed a beneficial owner of any shares held by the Fund. The Fund has delegated to RA Capital the sole power to vote and the sole power to dispose of all of its shares, and the Fund disclaims beneficial ownership of the shares. As managers of RA Capital, Dr. Kolchinsky and Mr. Shah may be deemed beneficial owners of any shares beneficially owned by RA Capital. RA Capital, Dr. Kolchinsky and Mr. Shah disclaim beneficial ownership of these shares. The address for the individuals and entities listed above is c/o RA Capital Management, L.P., 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.

(4) Based on a Schedule 13G filed by BlackRock, Inc. ("BlackRock") with the SEC on February 3, 2023. The address of BlackRock is 55 East 52nd Street, New York, New York 10055.

(5) Based on a Schedule 13G/A filed by Commodore Capital LP with the SEC on February 14, 2023. Consists of (i) 4,319,940 shares and (ii) 606,060 shares underlying a warrant, which is subject to a beneficial ownership limitation of 9.99%. Commodore Capital LP (the "Firm") is the investment manager of Commodore Capital Master LP ("Commodore Master"), and may be deemed to beneficially own the securities held by Commodore Master. The Firm holds shared voting and investment power over these shares. Michael Kramarz and Robert Egen Atkinson are the managing partners of the Firm and exercise investment discretion with respect to the shares. The address for the individuals and entities listed above is 444 Madison Avenue, Floor 35, New York, New York 10022.

(6) Based on a Schedule 13G filed by State Street Corporation ("State Street") with the SEC on February 3, 2023. State Street holds shared voting power over 4,196,781 shares and shared dispositive power over 4,261,381 shares. The address of State Street is State Street Financial Center, One Lincoln Street, Boston, Massachusetts 02111.

(7) Based on a Schedule 13G/A filed by TCG Crossover Fund I, L.P. ("TCG Crossover I") with the SEC on February 14, 2023. TCG Crossover GP I, LLC ("TCG Crossover GP I") is the general partner of TCG Crossover I and may be deemed to have voting, investment and dispositive power with respect to these securities. Chen Yu is the sole managing member of TCG Crossover GP I and may be deemed to share voting, investment and dispositive power with respect to these securities. Each of TCG Crossover GP I and Chen Yu disclaim beneficial ownership except to the extent of their pecuniary interest therein. The address for individual and entities listed above is 705 High Street, Palo Alto, California 94301.

(8) Consists entirely of shares underlying options exercisable within 60 days of March 31, 2023.

(9) Includes 1,296 shares and 488,961 shares underlying options exercisable within 60 days of March 31, 2023.

(10) Consists entirely of shares underlying options exercisable within 60 days of March 31, 2023 that Dr. Cain and Mr. Harwin hold for one or more investment vehicles managed by Fairmount (each, a "Fairmount Fund"). The options were granted to Dr. Cain and Mr. Harwin in connection with their service as a member of our Board. Pursuant to their arrangement with Fairmount, each of Dr. Cain and Mr. Harwin is obligated to turn over to Fairmount any net cash or stock received from the options for the benefit of such Fairmount Fund. Each of Dr. Cain and Mr. Harwin disclaims beneficial ownership of the options and underlying shares.

(11) Includes 5,137 shares and 3,826,532 shares underlying options exercisable within 60 days of March 31, 2023.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2022 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)
Equity compensation plans approved by stockholders[1]	9,798,994	$ 8.84	1,090,853
Equity compensation plans not approved by stockholders[2]	3,072,005	$10.27	677,995
Total	12,870,999	$ 9.18	1,768,848

(1) Includes the following plans: our 2018 Plan and our 2018 Employee Stock Purchase Plan (the "ESPP"), including 39,228 shares subject to purchase thereunder during the purchase periods in effect as of December 31, 2022. Excludes 2,795,737 and 125,000 shares that were added to our 2018 Plan and our ESPP, respectively, on January 1, 2023 pursuant to the evergreen provisions thereunder that provide for automatic annual increases on January 1 of each year during the term of the respective plan equal to 4% of our outstanding shares as of the preceding December 31 (or such lesser amount as approved by the Board), in the case of the 2018 Plan, or the lesser of 125,000 shares, 1% of our outstanding shares as of the preceding December 31, or such lesser amount as approved by the Board, in the case of the ESPP.

(2) Includes our Inducement Plan. The Inducement Plan was adopted by the Board in October 2020. 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 our common stock or capital structure. The purpose of the Inducement Plan is to secure and retain the services of eligible employees, to provide incentives for such eligible employees to exert maximum efforts for the success of the Company and to provide such eligible employees an opportunity to benefit from increases in value of the Company's common stock through the granting of certain stock awards. The Inducement Plan was approved by our Compensation Committee without stockholder approval pursuant to Nasdaq Stock Market Listing Rule 5635(c)(4), and is utilized exclusively for the grant of stock awards to individuals who were not previously

an employee or non-employee director of the Company (or following a bona fide period of non-employment with the Company) as an inducement material to such individual's entry into employment with the Company, within the meaning of Nasdaq Listing Rule 5635(c)(4). The Inducement Plan is administered by our Compensation Committee. Stock awards under the Inducement Plan may only be granted by: (i) the Compensation Committee, (ii) another committee of the Board composed solely of at least two members of the Board who meet the requirements for independence under the Nasdaq Stock Market Listing Rules (the "Independent Directors") or (iii) at the Board level by at least a majority of the Independent Directors (the foregoing subsections (i), (ii) and (iii) are collectively referred to as the "Committee"). The Committee may choose to grant (i) nonstatutory stock options, (ii) stock appreciation rights, (iii) restricted stock awards, (iv) restricted stock unit awards and (v) other stock awards to eligible recipients, with each grant to be evidenced by an award agreement setting forth the terms and conditions of the grant as determined by the Committee in accordance with the terms of the Inducement Plan.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of each transaction or series of similar transactions since January 1, 2021, or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeds $120,000; and
- any related person (including our directors, executive officers, beneficial owners of more than 5% of our common stock and any affiliates or members of their immediate family) had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled "Executive Compensation" or that were approved by our Compensation Committee.

Beneficial ownership of securities is determined in accordance with the rules of the SEC.

Related Party Transactions

Indemnification

Our Bylaws provide that we will indemnify, to the fullest extent permitted by law, any person who is or was a party or is threatened to be made a party to any action, suit or proceeding by reason of the fact that he or she is or was one of our directors or officers or is or was serving at our request as a director or officer of another corporation, partnership, joint venture, trust or other enterprise. Our Bylaws provide that we may indemnify to the fullest extent permitted by law any person who is or was a party or is threatened to be made a party to any action, suit or proceeding by reason of the fact that he or she is or was one of our employees or agents or is or was serving at our request as an employee or agent of another corporation, partnership, joint venture, trust or other enterprise. Our Bylaws also provide that we must advance expenses incurred by or on behalf of a director or officer in advance of the final disposition of any action or proceeding, subject to very limited exceptions. In addition, we have entered into and in the future plan to enter into agreements to indemnify our directors and executive officers. These agreements, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person's status as a member of our Board or officer, as applicable, to the maximum extent allowed under Delaware law.

Sublease Agreement

In April 2021, we entered into a sublease agreement with Viridian Therapeutics, Inc. ("Viridian"), which was subsequently amended in November 2021 and April 2022. This provided us with temporary office and laboratory space in Boulder, Colorado while our new office and laboratory space was being constructed. Entities associated with Fairmount beneficially own more than 5% of our capital stock and Viridian's capital stock. Under the terms of the sublease, which expired in June 2022, we paid Viridian an aggregate of $0.2 million in rent payments plus $0.2 million in related taxes and lease operating costs. The lease was negotiated on an arm's-length basis and was a market rate transaction on terms that we believed were no less favorable than would have been reached with an unrelated third party. Although we did not consider this transaction to be material to us, we are disclosing it in accordance with our related person transactions policy described below.

Related Person Transaction Policy

Our Board has adopted a written related person transactions policy providing that transactions with us and any related person (as defined above) must be approved by our Audit Committee. Pursuant to this policy, the Audit Committee has the primary responsibility for reviewing and approving or disapproving "related person transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or is expected to exceed $120,000 and in which a related person has or will have a direct or indirect

material interest. In determining whether to approve any such transaction, the Audit Committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar amount involved in the related person transaction;
- the approximate dollar amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose, and the potential benefits to us, of the related-party transaction; and
- any other information regarding the related-party transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

OTHER MATTERS

Stockholder Proposals and Director Nominations for Next Year's Annual Meeting

Pursuant to Rule 14a-8 of the Exchange Act, stockholders who wish to submit proposals for inclusion in the proxy statement for the 2024 Annual Meeting of Stockholders must send such proposals to our Corporate Secretary at the address set forth on the first page of this Proxy Statement. Such proposals must be received by us as of the close of business (6:00 p.m. Eastern Time) on December 27, 2023 and must comply with Rule 14a-8 of the Exchange Act. The submission of a stockholder proposal does not guarantee that it will be included in the proxy statement.

As set forth in our Bylaws, if a stockholder intends to make a nomination for director election or present a proposal for other business (other than pursuant to Rule 14a-8 of the Exchange Act) at the 2024 Annual Meeting of Stockholders, the stockholder's notice must be received by our Corporate Secretary at the address set forth on the first page of this Proxy Statement no earlier than the 120th day and no later than the 90th day before the anniversary of the last annual meeting; provided, however, that if the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, the stockholder's notice must be delivered not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the date on which the first public announcement of the date of such annual meeting is made by the Company. Therefore, unless the 2024 Annual Meeting of Stockholders is more than 30 days before or more than 60 days after the anniversary of the Annual Meeting, notice of proposed nominations or proposals (other than pursuant to Rule 14a-8 of the Exchange Act) must be received by our Corporate Secretary no earlier than February 8, 2024 and no later than the close of business (6:00 p.m. Eastern Time) on March 9, 2024. Any such director nomination or stockholder proposal must be a proper matter for stockholder action and must comply with the terms and conditions set forth in our Bylaws. If a stockholder fails to meet these deadlines and fails to satisfy the requirements of Rule 14a-4 of the Exchange Act, we may exercise discretionary voting authority under proxies we solicit to vote on any such proposal as we determine appropriate. In addition to satisfying the deadlines in the advance notice provisions of our Bylaws, a stockholder who intends to solicit proxies in support of nominees submitted under these advance notice provisions for the 2024 Annual Meeting of Stockholders must provide the notice required under Rule 14a-19 of the Exchange Act to our Corporate Secretary in writing not later than the close of business (6:00 p.m. Eastern Time) on April 8, 2024. We reserve the right to reject, rule out of order or take other appropriate action with respect to any nomination or proposal that does not comply with these and other applicable requirements.

Delivery of Documents to Stockholders Sharing an Address

A number of brokerage firms have adopted a procedure approved by the SEC called "householding." Under this procedure, certain stockholders who have the same address and do not participate in electronic delivery of proxy materials will receive only one copy of the proxy materials, including this Proxy Statement, the Notice and our Annual Report on Form 10-K for the year ended December 31, 2022, until such time as one or more of these stockholders notifies us that they wish to receive individual copies. This procedure helps to reduce duplicate mailings and save printing costs and postage fees, as well as natural resources. If you received a "householding" mailing this year and would like to have additional copies of the proxy materials mailed to you, please send a written request to our Corporate Secretary at the address set forth on the first page of this Proxy Statement, or call (617) 945-5576, and we will promptly deliver the proxy materials to you. Please contact your broker if you received multiple copies of the proxy materials and would prefer to receive a single copy in the future, or if you would like to opt out of "householding" for future mailings.

Availability of Additional Information

We will provide, free of charge, a copy of our Annual Report on Form 10-K for the year ended December 31, 2022, including exhibits, upon the written or oral request of any stockholder of the Company. Please send a written request to our Corporate Secretary at the address set forth on the first page of this Proxy Statement or call the number above.

APPENDIX A

AMENDED AND RESTATED COGENT BIOSCIENCES, INC. 2018 STOCK OPTION AND INCENTIVE PLAN

SECTION 1 GENERAL PURPOSE OF THE PLAN; DEFINITIONS

The name of the plan is the Cogent Biosciences, Inc. 2018 Stock Option and Incentive Plan (the "Plan"). The purpose of the Plan is to encourage and enable the officers, employees, Non-Employee Directors and Consultants of Cogent Biosciences, Inc. (the "Company") and its Subsidiaries upon whose judgment, initiative and efforts the Company largely depends for the successful conduct of its businesses to acquire a proprietary interest in the Company. It is anticipated that providing such persons with a direct stake in the Company's welfare will assure a closer identification of their interests with those of the Company and its stockholders, thereby stimulating their efforts on the Company's behalf and strengthening their desire to remain with the Company.

The following terms shall be defined as set forth below:

"Act" means the Securities Act of 1933, as amended, and the rules and regulations thereunder.

"Administrator" means either the Board or the compensation committee of the Board or a similar committee performing the functions of the compensation committee and which is comprised of not less than two Non-Employee Directors who are independent.

"Award" or *"Awards,"* except where referring to a particular category of grant under the Plan, shall include Incentive Stock Options, Non-Qualified Stock Options, Stock Appreciation Rights, Restricted Stock Units, Restricted Stock Awards, Unrestricted Stock Awards, Cash-Based Awards, and Dividend Equivalent Rights.

"Award Certificate" means a written or electronic document setting forth the terms and provisions applicable to an Award granted under the Plan. Each Award Certificate is subject to the terms and conditions of the Plan.

"Board" means the Board of Directors of the Company.

"Cash-Based Award" means an Award entitling the recipient to receive a cash-denominated payment.

"Code" means the Internal Revenue Code of 1986, as amended, and any successor Code, and related rules, regulations and interpretations.

"Consultant" means any natural person that provides bona fide services to the Company, and such services are not in connection with the offer or sale of securities in a capital-raising transaction and do not directly or indirectly promote or maintain a market for the Company's securities.

"Dividend Equivalent Right" means an Award entitling the grantee to receive credits based on cash dividends that would have been paid on the shares of Stock specified in the Dividend Equivalent Right (or other award to which it relates) if such shares had been issued to and held by the grantee.

"Effective Date" means the date on which the Plan becomes effective as set forth in Section 19.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder.

"Fair Market Value" of the Stock on any given date means the fair market value of the Stock determined in good faith by the Administrator; provided, however, that if the Stock is admitted to quotation on the National

Association of Securities Dealers Automated Quotation System, Nasdaq Global Market, The New York Stock Exchange or another national securities exchange, the determination shall be made by reference to the Stock's closing price on such exchange. If there is no closing price for such date, the determination shall be made by reference to the last date preceding such date for which there is a closing price; provided further, however, that if the date for which Fair Market Value is determined is the Registration Date, the Fair Market Value shall be the "Price to the Public" (or equivalent) set forth on the cover page for the final prospectus relating to the Company's Initial Public Offering.

"Incentive Stock Option" means any Stock Option designated and qualified as an "incentive stock option" as defined in Section 422 of the Code.

"Initial Public Offering" means the first underwritten, firm commitment public offering pursuant to an effective registration statement under the Act covering the offer and sale by the Company of its equity securities, or such other event as a result of or following which the Stock shall be publicly held.

"Non-Employee Director" means a member of the Board who is not also an employee of the Company or any Subsidiary.

"Non-Qualified Stock Option" means any Stock Option that is not an Incentive Stock Option.

"Option" or *"Stock Option"* means any option to purchase shares of Stock granted pursuant to Section 5.

"Registration Date" means the date upon which the registration statement on Form S-1 that is filed by the Company with respect to the Initial Public Offering is declared effective by the Securities and Exchange Commission.

"Restricted Shares" means the shares of Stock underlying a Restricted Stock Award that remain subject to a risk of forfeiture or the Company's right of repurchase.

"Restricted Stock Award" means an Award of Restricted Shares subject to such restrictions and conditions as the Administrator may determine at the time of grant.

"Restricted Stock Units" means an Award of stock units subject to such restrictions and conditions as the Administrator may determine at the time of grant.

"Sale Event" shall mean (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power and outstanding stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction, (iii) the sale of all of the Stock of the Company to an unrelated person, entity or group thereof acting in concert, or (iv) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company.

"*Sale Price*" means the value as determined by the Administrator of the consideration payable, or otherwise to be received by stockholders, per share of Stock pursuant to a Sale Event.

"Section 409A" means Section 409A of the Code and the regulations and other guidance promulgated thereunder.

"Stock" means the Common Stock, par value $0.001 per share, of the Company, subject to adjustments pursuant to Section 3.

"Stock Appreciation Right" means an Award entitling the recipient to receive shares of Stock (or cash, to the extent explicitly provided for in the applicable Award Certificate) having a value equal to the excess of the Fair Market Value of the Stock on the date of exercise over the exercise price of the Stock Appreciation Right multiplied by the number of shares of Stock with respect to which the Stock Appreciation Right shall have been exercised.

"Subsidiary" means any corporation or other entity (other than the Company) in which the Company has at least a 50 percent interest, either directly or indirectly.

"Ten Percent Owner" means an employee who owns or is deemed to own (by reason of the attribution rules of Section 424(d) of the Code) more than 10 percent of the combined voting power of all classes of stock of the Company or any parent or subsidiary corporation.

"Unrestricted Stock Award" means an Award of shares of Stock free of any restrictions.

SECTION 2 ADMINISTRATION OF PLAN; ADMINISTRATOR AUTHORITY TO SELECT GRANTEES AND DETERMINE AWARDS

(a) Administration of Plan. The Plan shall be administered by the Administrator.

(b) Powers of Administrator. The Administrator shall have the power and authority to grant Awards consistent with the terms of the Plan, including the power and authority:

(i) to select the individuals to whom Awards may from time to time be granted;

(ii) to determine the time or times of grant, and the extent, if any, of Incentive Stock Options, Non-Qualified Stock Options, Stock Appreciation Rights, Restricted Stock Awards, Restricted Stock Units, Unrestricted Stock Awards, Cash-Based Awards, and Dividend Equivalent Rights, or any combination of the foregoing, granted to any one or more grantees;

(iii) to determine the number of shares of Stock to be covered by any Award;

(iv) to determine and modify from time to time the terms and conditions, including restrictions, not inconsistent with the terms of the Plan, of any Award, which terms and conditions may differ among individual Awards and grantees, and to approve the forms of Award Certificates;

(v) to accelerate at any time the exercisability or vesting of all or any portion of any Award;

(vi) subject to the provisions of Section 5(c), to extend at any time the period in which Stock Options may be exercised; and

(vii) at any time to adopt, alter and repeal such rules, guidelines and practices for administration of the Plan and for its own acts and proceedings as it shall deem advisable; to interpret the terms and provisions of the Plan and any Award (including related written instruments); to make all determinations it deems advisable for the administration of the Plan; to decide all disputes arising in connection with the Plan; and to otherwise supervise the administration of the Plan.

All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and Plan grantees.

(c) Delegation of Authority to Grant Awards. Subject to applicable law, the Administrator, in its discretion, may delegate to a committee consisting of one or more officers of the Company all or part of the Administrator's authority and duties with respect to the granting of Awards to individuals who are (i) not subject to the reporting and other provisions of Section 16 of the Exchange Act and (ii) not members of the delegated committee. Any such delegation by the Administrator shall include a limitation as to the amount of Stock underlying Awards that may be granted during the period of the delegation and shall contain guidelines as to the determination of the exercise price and the vesting criteria. The Administrator may revoke or amend the terms of a delegation at any time but such action shall not invalidate any prior actions of the Administrator's delegate or delegates that were consistent with the terms of the Plan.

(d) Award Certificate. Awards under the Plan shall be evidenced by Award Certificates that set forth the terms, conditions and limitations for each Award which may include, without limitation, the term of an Award and the provisions applicable in the event employment or service terminates.

(e) Indemnification. Neither the Board nor the Administrator, nor any member of either or any delegate thereof, shall be liable for any act, omission, interpretation, construction or determination made in good faith in connection with the Plan, and the members of the Board and the Administrator (and any delegate thereof) shall be entitled in all cases to indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including, without limitation, reasonable attorneys' fees) arising or resulting therefrom to the fullest extent permitted by law and/or under the Company's articles or bylaws or any directors' and officers' liability insurance coverage which may be in effect from time to time and/or any indemnification agreement between such individual and the Company.

(f) Foreign Award Recipients. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws in other countries in which the Company and its Subsidiaries operate or have employees or other individuals eligible for Awards, the Administrator, in its sole discretion, shall have the power and authority to: (i) determine which Subsidiaries shall be covered by the Plan; (ii) determine which individuals outside the United States are eligible to participate in the Plan; (iii) modify the terms and conditions of any Award granted to individuals outside the United States to comply with applicable foreign laws; (iv) establish subplans and modify exercise procedures and other terms and procedures, to the extent the Administrator determines such actions to be necessary or advisable (and such subplans and/or modifications shall be attached to this Plan as appendices); provided, however, that no such subplans and/or modifications shall increase the share limitations contained in Section 3(a) hereof; and (v) take any action, before or after an Award is made, that the Administrator determines to be necessary or advisable to obtain approval or comply with any local governmental regulatory exemptions or approvals. Notwithstanding the foregoing, the Administrator may not take any actions hereunder, and no Awards shall be granted, that would violate the Exchange Act or any other applicable United States securities law, the Code, or any other applicable United States governing statute or law.

SECTION 3 STOCK ISSUABLE UNDER THE PLAN; MERGERS; SUBSTITUTION

(a) Stock Issuable. The maximum number of shares of Stock reserved and available for issuance under the Plan shall be 19,085,985 shares, plus the number of shares of Stock which were available for grant, as of the date of approval of the Plan by the Company's stockholders under the Company's 2015 Stock Incentive Plan, (the "Initial Limit"), subject to adjustment as provided in Section 3(d), plus on January 1, 2019 and each January 1 thereafter, the number of shares of Stock reserved and available for issuance under the Plan shall be cumulatively increased by 4 percent of the number of shares of Stock issued and outstanding on the immediately preceding December 31 or such lesser number determined by the Administrator (the "Annual Increase"). In addition, the shares of Stock underlying any awards under the Plan and under the Company's 2015 Stock Incentive Plan that are forfeited, canceled, held back upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of Stock or otherwise terminated (other than by exercise) shall be added back to the shares of Stock available for issuance

under the Plan. Subject to such overall limitation, the maximum aggregate number of shares of Stock that may be issued in the form of Incentive Stock Options shall not exceed the Initial Limit cumulatively increased on January 1, 2019 and on each January 1 thereafter by the Annual Increase for such year, subject in all cases to adjustment as provided in Section 3(d). In the event the Company repurchases shares of Stock on the open market, such shares shall not be added to the shares of Stock available for issuance under the Plan. The shares available for issuance under the Plan may be authorized but unissued shares of Stock or shares of Stock reacquired by the Company.

(b) Maximum Awards to Non-Employee Directors. Notwithstanding anything to the contrary in this Plan, the value of all Awards awarded under this Plan and all other cash compensation paid by the Company to any Non-Employee Director in any calendar year shall not exceed $1,000,000. For the purpose of this limitation, the value of any Award shall be its grant date fair value, as determined in accordance with ASC 718 or successor provision but excluding the impact of estimated forfeitures related to service-based vesting provisions.

(c) Reserved.

(d) Changes in Stock. Subject to Section 3(e) hereof, if, as a result of any reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock, the outstanding shares of Stock are increased or decreased or are exchanged for a different number or kind of shares or other securities of the Company, or additional shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such shares of Stock or other securities, or, if, as a result of any merger or consolidation, sale of all or substantially all of the assets of the Company, the outstanding shares of Stock are converted into or exchanged for securities of the Company or any successor entity (or a parent or subsidiary thereof), the Administrator shall make an appropriate or proportionate adjustment in (i) the maximum number of shares reserved for issuance under the Plan, including the maximum number of shares that may be issued in the form of Incentive Stock Options, (ii) the number and kind of shares or other securities subject to any then outstanding Awards under the Plan, (iii) the repurchase price, if any, per share subject to each outstanding Restricted Stock Award, and (iv) the exercise price for each share subject to any then outstanding Stock Options and Stock Appreciation Rights under the Plan, without changing the aggregate exercise price (i.e., the exercise price multiplied by the number of Stock Options and Stock Appreciation Rights) as to which such Stock Options and Stock Appreciation Rights remain exercisable. The Administrator shall also make equitable or proportionate adjustments in the number of shares subject to outstanding Awards and the exercise price and the terms of outstanding Awards to take into consideration cash dividends paid other than in the ordinary course or any other extraordinary corporate event. The adjustment by the Administrator shall be final, binding and conclusive. No fractional shares of Stock shall be issued under the Plan resulting from any such adjustment, but the Administrator in its discretion may make a cash payment in lieu of fractional shares.

(e) Mergers and Other Transactions. In the case of and subject to the consummation of a Sale Event, the parties thereto may cause the assumption or continuation of Awards theretofore granted by the successor entity, or the substitution of such Awards with new Awards of the successor entity or parent thereof, with appropriate adjustment as to the number and kind of shares and, if appropriate, the per share exercise prices, as such parties shall agree. To the extent the parties to such Sale Event do not provide for the assumption, continuation or substitution of Awards, upon the effective time of the Sale Event, the Plan and all outstanding Awards granted hereunder shall terminate. In such case, except as may be otherwise provided in the relevant Award Certificate, all Options and Stock Appreciation Rights that are not exercisable immediately prior to the effective time of the Sale Event shall become fully exercisable as of the effective time of the Sale Event, all other Awards with time-based vesting, conditions or restrictions shall become fully vested and nonforfeitable as of the effective time of the Sale Event, and all Awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with a Sale Event in the Administrator's discretion or to the extent specified in the relevant Award Certificate. In the event of such termination, (i) the Company shall have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the grantees holding Options and Stock Appreciation Rights, in exchange for the cancellation thereof, in an amount equal to the

difference between (A) the Sale Price multiplied by the number of shares of Stock subject to outstanding Options and Stock Appreciation Rights (to the extent then exercisable at prices not in excess of the Sale Price) and (B) the aggregate exercise price of all such outstanding Options and Stock Appreciation Rights (provided that, in the case of an Option or Stock Appreciation Right with an exercise price equal to or less than the Sale Price, such Option or Stock Appreciation Right shall be cancelled for no consideration); or (ii) each grantee shall be permitted, within a specified period of time prior to the consummation of the Sale Event as determined by the Administrator, to exercise all outstanding Options and Stock Appreciation Rights (to the extent then exercisable) held by such grantee. The Company shall also have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the grantees holding other Awards in an amount equal to the Sale Price multiplied by the number of vested shares of Stock under such Awards.

SECTION 4 ELIGIBILITY

Grantees under the Plan will be such full or part-time officers and other employees, Non-Employee Directors and Consultants of the Company and its Subsidiaries as are selected from time to time by the Administrator in its sole discretion.

SECTION 5 STOCK OPTIONS

(a) Award of Stock Options. The Administrator may grant Stock Options under the Plan. Any Stock Option granted under the Plan shall be in such form as the Administrator may from time to time approve.

Stock Options granted under the Plan may be either Incentive Stock Options or Non-Qualified Stock Options. Incentive Stock Options may be granted only to employees of the Company or any Subsidiary that is a "subsidiary corporation" within the meaning of Section 424(f) of the Code. To the extent that any Option does not qualify as an Incentive Stock Option, it shall be deemed a Non-Qualified Stock Option.

Stock Options granted pursuant to this Section 5 shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Administrator shall deem desirable. If the Administrator so determines, Stock Options may be granted in lieu of cash compensation at the optionee's election, subject to such terms and conditions as the Administrator may establish.

(b) Exercise Price. The exercise price per share for the Stock covered by a Stock Option granted pursuant to this Section 5 shall be determined by the Administrator at the time of grant but shall not be less than 100 percent of the Fair Market Value on the date of grant. In the case of an Incentive Stock Option that is granted to a Ten Percent Owner, the option price of such Incentive Stock Option shall be not less than 110 percent of the Fair Market Value on the grant date. Notwithstanding the foregoing, Stock Options may be granted with an exercise price per share that is less than 100 percent of the Fair Market Value on the date of grant pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code.

(c) Option Term. The term of each Stock Option shall be fixed by the Administrator, but no Stock Option shall be exercisable more than ten years after the date the Stock Option is granted. In the case of an Incentive Stock Option that is granted to a Ten Percent Owner, the term of such Stock Option shall be no more than five years from the date of grant.

(d) Exercisability; Rights of a Stockholder. Stock Options shall become exercisable at such time or times, whether or not in installments, as shall be determined by the Administrator at or after the grant date. The Administrator may at any time accelerate the exercisability of all or any portion of any Stock Option. An optionee shall have the rights of a stockholder only as to shares acquired upon the exercise of a Stock Option and not as to unexercised Stock Options.

(e) Method of Exercise. Stock Options may be exercised in whole or in part, by giving written or electronic notice of exercise to the Company, specifying the number of shares to be purchased. Payment of the purchase price may be made by one or more of the following methods except to the extent otherwise provided in the Option Award Certificate:

(i) In cash, by certified or bank check or other instrument acceptable to the Administrator;

(ii) Through the delivery (or attestation to the ownership following such procedures as the Company may prescribe) of shares of Stock that are not then subject to restrictions under any Company plan. Such surrendered shares shall be valued at Fair Market Value on the exercise date;

(iii) By the optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company for the purchase price; provided that in the event the optionee chooses to pay the purchase price as so provided, the optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Company shall prescribe as a condition of such payment procedure; or

(iv) With respect to Stock Options that are not Incentive Stock Options, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price.

Payment instruments will be received subject to collection. The transfer to the optionee on the records of the Company or of the transfer agent of the shares of Stock to be purchased pursuant to the exercise of a Stock Option will be contingent upon receipt from the optionee (or a purchaser acting in his stead in accordance with the provisions of the Stock Option) by the Company of the full purchase price for such shares and the fulfillment of any other requirements contained in the Option Award Certificate or applicable provisions of laws (including the satisfaction of any withholding taxes that the Company is obligated to withhold with respect to the optionee). In the event an optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the optionee upon the exercise of the Stock Option shall be net of the number of attested shares. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the exercise of Stock Options, such as a system using an internet website or interactive voice response, then the paperless exercise of Stock Options may be permitted through the use of such an automated system.

(f) Annual Limit on Incentive Stock Options. To the extent required for "incentive stock option" treatment under Section 422 of the Code, the aggregate Fair Market Value (determined as of the time of grant) of the shares of Stock with respect to which Incentive Stock Options granted under this Plan and any other plan of the Company or its parent and subsidiary corporations become exercisable for the first time by an optionee during any calendar year shall not exceed $100,000. To the extent that any Stock Option exceeds this limit, it shall constitute a Non-Qualified Stock Option.

SECTION 6 STOCK APPRECIATION RIGHTS

(a) Award of Stock Appreciation Rights. The Administrator may grant Stock Appreciation Rights under the Plan. A Stock Appreciation Right is an Award entitling the recipient to receive shares of Stock (or cash, to the extent explicitly provided for in the applicable Award Certificate) having a value equal to the excess of the Fair Market Value of a share of Stock on the date of exercise over the exercise price of the Stock Appreciation Right multiplied by the number of shares of Stock with respect to which the Stock Appreciation Right shall have been exercised.

(b) Exercise Price of Stock Appreciation Rights. The exercise price of a Stock Appreciation Right shall not be less than 100 percent of the Fair Market Value of the Stock on the date of grant.

(c) Grant and Exercise of Stock Appreciation Rights. Stock Appreciation Rights may be granted by the Administrator independently of any Stock Option granted pursuant to Section 5 of the Plan.

(d) Terms and Conditions of Stock Appreciation Rights. Stock Appreciation Rights shall be subject to such terms and conditions as shall be determined on the date of grant by the Administrator. The term of a Stock Appreciation Right may not exceed ten years. The terms and conditions of each such Award shall be determined by the Administrator, and such terms and conditions may differ among individual Awards and grantees.

SECTION 7 RESTRICTED STOCK AWARDS

(a) Nature of Restricted Stock Awards. The Administrator may grant Restricted Stock Awards under the Plan. A Restricted Stock Award is any Award of Restricted Shares subject to such restrictions and conditions as the Administrator may determine at the time of grant. Conditions may be based on continuing employment (or other service relationship) and/or achievement of pre-established performance goals and objectives.

(b) Rights as a Stockholder. Upon the grant of the Restricted Stock Award and payment of any applicable purchase price, a grantee shall have the rights of a stockholder with respect to the voting of the Restricted Shares and receipt of dividends; provided that if the lapse of restrictions with respect to the Restricted Stock Award is tied to the attainment of performance goals, any dividends paid by the Company during the performance period shall accrue and shall not be paid to the grantee until and to the extent the performance goals are met with respect to the Restricted Stock Award. Unless the Administrator shall otherwise determine, (i) uncertificated Restricted Shares shall be accompanied by a notation on the records of the Company or the transfer agent to the effect that they are subject to forfeiture until such Restricted Shares are vested as provided in Section 7(d) below, and (ii) certificated Restricted Shares shall remain in the possession of the Company until such Restricted Shares are vested as provided in Section 7(d) below, and the grantee shall be required, as a condition of the grant, to deliver to the Company such instruments of transfer as the Administrator may prescribe.

(c) Restrictions. Restricted Shares may not be sold, assigned, transferred, pledged or otherwise encumbered or disposed of except as specifically provided herein or in the Restricted Stock Award Certificate. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 16 below, in writing after the Award is issued, if a grantee's employment (or other service relationship) with the Company and its Subsidiaries terminates for any reason, any Restricted Shares that have not vested at the time of termination shall automatically and without any requirement of notice to such grantee from or other action by or on behalf of, the Company be deemed to have been reacquired by the Company at its original purchase price (if any) from such grantee or such grantee's legal representative simultaneously with such termination of employment (or other service relationship), and thereafter shall cease to represent any ownership of the Company by the grantee or rights of the grantee as a stockholder. Following such deemed reacquisition of Restricted Shares that are represented by physical certificates, a grantee shall surrender such certificates to the Company upon request without consideration.

(d) Vesting of Restricted Shares. The Administrator at the time of grant shall specify the date or dates and/or the attainment of pre-established performance goals, objectives and other conditions on which the non-transferability of the Restricted Shares and the Company's right of repurchase or forfeiture shall lapse. Subsequent to such date or dates and/or the attainment of such pre-established performance goals, objectives and other conditions, the shares on which all restrictions have lapsed shall no longer be Restricted Shares and shall be deemed "vested."

SECTION 8 RESTRICTED STOCK UNITS

(a) Nature of Restricted Stock Units. The Administrator may grant Restricted Stock Units under the Plan. A Restricted Stock Unit is an Award of stock units that may be settled in shares of Stock (or cash, to the extent explicitly provided for in the Award Certificate) upon the satisfaction of such restrictions and conditions at the time of grant. Conditions may be based on continuing employment (or other service relationship) and/or achievement of pre-established performance goals and objectives. The terms and conditions of each such Award shall be determined by the Administrator, and such terms and conditions may differ among individual Awards

and grantees. Except in the case of Restricted Stock Units with a deferred settlement date that complies with Section 409A, at the end of the vesting period, the Restricted Stock Units, to the extent vested, shall be settled in the form of shares of Stock. Restricted Stock Units with deferred settlement dates are subject to Section 409A and shall contain such additional terms and conditions as the Administrator shall determine in its sole discretion in order to comply with the requirements of Section 409A.

(b) Election to Receive Restricted Stock Units in Lieu of Compensation. The Administrator may, in its sole discretion, permit a grantee to elect to receive a portion of future cash compensation otherwise due to such grantee in the form of an award of Restricted Stock Units. Any such election shall be made in writing and shall be delivered to the Company no later than the date specified by the Administrator and in accordance with Section 409A and such other rules and procedures established by the Administrator. Any such future cash compensation that the grantee elects to defer shall be converted to a fixed number of Restricted Stock Units based on the Fair Market Value of Stock on the date the compensation would otherwise have been paid to the grantee if such payment had not been deferred as provided herein. The Administrator shall have the sole right to determine whether and under what circumstances to permit such elections and to impose such limitations and other terms and conditions thereon as the Administrator deems appropriate. Any Restricted Stock Units that are elected to be received in lieu of cash compensation shall be fully vested, unless otherwise provided in the Award Certificate.

(c) Rights as a Stockholder. A grantee shall have the rights as a stockholder only as to shares of Stock acquired by the grantee upon settlement of Restricted Stock Units; provided, however, that the grantee may be credited with Dividend Equivalent Rights with respect to the stock units underlying his Restricted Stock Units, subject to such terms and conditions as the Administrator may determine.

(d) Termination. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 16 below, in writing after the Award is issued, a grantee's right in all Restricted Stock Units that have not vested shall automatically terminate upon the grantee's termination of employment (or cessation of service relationship) with the Company and its Subsidiaries for any reason.

SECTION 9 UNRESTRICTED STOCK AWARDS

Grant or Sale of Unrestricted Stock. The Administrator may grant (or sell at par value or such higher purchase price determined by the Administrator) an Unrestricted Stock Award under the Plan. An Unrestricted Stock Award is an Award pursuant to which the grantee may receive shares of Stock free of any restrictions under the Plan. Unrestricted Stock Awards may be granted in respect of past services or other valid consideration, or in lieu of cash compensation due to such grantee.

SECTION 10 CASH-BASED AWARDS

Grant of Cash-Based Awards. The Administrator may grant Cash-Based Awards under the Plan. A Cash-Based Award is an Award that entitles the grantee to a payment in cash upon the attainment of specified performance goals. The Administrator shall determine the maximum duration of the Cash- Based Award, the amount of cash to which the Cash-Based Award pertains, the conditions upon which the Cash-Based Award shall become vested or payable, and such other provisions as the Administrator shall determine. Each Cash-Based Award shall specify a cash-denominated payment amount, formula or payment ranges as determined by the Administrator. Payment, if any, with respect to a Cash-Based Award shall be made in accordance with the terms of the Award and may be made in cash.

SECTION 11 DIVIDEND EQUIVALENT RIGHTS

(a) Dividend Equivalent Rights. The Administrator may grant Dividend Equivalent Rights under the Plan. A Dividend Equivalent Right is an Award entitling the grantee to receive credits based on cash dividends that

would have been paid on the shares of Stock specified in the Dividend Equivalent Right (or other Award to which it relates) if such shares had been issued to the grantee. A Dividend Equivalent Right may be granted hereunder to any grantee as a component of an award of Restricted Stock Units or as a freestanding award. The terms and conditions of Dividend Equivalent Rights shall be specified in the Award Certificate. Dividend equivalents credited to the holder of a Dividend Equivalent Right may be paid currently or may be deemed to be reinvested in additional shares of Stock, which may thereafter accrue additional equivalents. Any such reinvestment shall be at Fair Market Value on the date of reinvestment or such other price as may then apply under a dividend reinvestment plan sponsored by the Company, if any. Dividend Equivalent Rights may be settled in cash or shares of Stock or a combination thereof, in a single installment or installments. A Dividend Equivalent Right granted as a component of an Award of Restricted Stock Units shall provide that such Dividend Equivalent Right shall be settled only upon settlement or payment of, or lapse of restrictions on, such other Award, and that such Dividend Equivalent Right shall expire or be forfeited or annulled under the same conditions as such other Award.

(b) Termination. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 16 below, in writing after the Award is issued, a grantee's rights in all Dividend Equivalent Rights shall automatically terminate upon the grantee's termination of employment (or cessation of service relationship) with the Company and its Subsidiaries for any reason.

SECTION 12 TRANSFERABILITY OF AWARDS

(a) Transferability. Except as provided in Section 12(b) below, during a grantee's lifetime, his or her Awards shall be exercisable only by the grantee, or by the grantee's legal representative or guardian in the event of the grantee's incapacity. No Awards shall be sold, assigned, transferred or otherwise encumbered or disposed of by a grantee other than by will or by the laws of descent and distribution or pursuant to a domestic relations order. No Awards shall be subject, in whole or in part, to attachment, execution, or levy of any kind, and any purported transfer in violation hereof shall be null and void.

(b) Administrator Action. Notwithstanding Section 12(a), the Administrator, in its discretion, may provide either in the Award Certificate regarding a given Award or by subsequent written approval that the grantee (who is an employee or director) may transfer his or her Non-Qualified Stock Options to his or her immediate family members, to trusts for the benefit of such family members, or to partnerships in which such family members are the only partners, provided that the transferee agrees in writing with the Company to be bound by all of the terms and conditions of this Plan and the applicable Award. In no event may an Award be transferred by a grantee for value.

(c) Family Member. For purposes of Section 12(b), "family member" shall mean a grantee's child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, any person sharing the grantee's household (other than a tenant of the grantee), a trust in which these persons (or the grantee) have more than 50 percent of the beneficial interest, a foundation in which these persons (or the grantee) control the management of assets, and any other entity in which these persons (or the grantee) own more than 50 percent of the voting interests.

(d) Designation of Beneficiary. To the extent permitted by the Company, each grantee to whom an Award has been made under the Plan may designate a beneficiary or beneficiaries to exercise any Award or receive any payment under any Award payable on or after the grantee's death. Any such designation shall be on a form provided for that purpose by the Administrator and shall not be effective until received by the Administrator. If no beneficiary has been designated by a deceased grantee, or if the designated beneficiaries have predeceased the grantee, the beneficiary shall be the grantee's estate.

SECTION 13 TAX WITHHOLDING

(a) Payment by Grantee. Each grantee shall, no later than the date as of which the value of an Award or of any Stock or other amounts received thereunder first becomes includable in the gross income of the grantee for Federal income tax purposes, pay to the Company, or make arrangements satisfactory to the Administrator regarding payment of, any Federal, state, or local taxes of any kind required by law to be withheld by the Company with respect to such income. The Company and its Subsidiaries shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the grantee. The Company's obligation to deliver evidence of book entry (or stock certificates) to any grantee is subject to and conditioned on tax withholding obligations being satisfied by the grantee.

(b) Payment in Stock. Subject to approval by the Administrator, a grantee may elect to have the Company's minimum required tax withholding obligation satisfied, in whole or in part, by authorizing the Company to withhold from shares of Stock to be issued pursuant to any Award a number of shares with an aggregate Fair Market Value (as of the date the withholding is effected) that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid liability accounting treatment. The Administrator may also require Awards to be subject to mandatory share withholding up to the required withholding amount. For purposes of share withholding, the Fair Market Value of withheld shares shall be determined in the same manner as the value of Stock includible in income of the participants. The required tax withholding obligation may also be satisfied, in whole or in part, by an arrangement whereby a certain number of shares of Stock issued pursuant to any Award are immediately sold and proceeds from such sale are remitted to the Company in an amount that would satisfy the withholding amount due.

SECTION 14 SECTION 409A AWARDS

To the extent that any Award is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A (a "409A Award"), the Award shall be subject to such additional rules and requirements as specified by the Administrator from time to time in order to comply with Section 409A. In this regard, if any amount under a 409A Award is payable upon a "separation from service" (within the meaning of Section 409A) to a grantee who is then considered a "specified employee" (within the meaning of Section 409A), then no such payment shall be made prior to the date that is the earlier of (i) six months and one day after the grantee's separation from service, or (ii) the grantee's death, but only to the extent such delay is necessary to prevent such payment from being subject to interest, penalties and/or additional tax imposed pursuant to Section 409A. Further, the settlement of any 409A Award may not be accelerated except to the extent permitted by Section 409A.

SECTION 15 TERMINATION OF EMPLOYMENT, TRANSFER, LEAVE OF ABSENCE, ETC.

(a) Termination of Employment. If the grantee's employer ceases to be a Subsidiary, the grantee shall be deemed to have terminated employment for purposes of the Plan.

(b) For purposes of the Plan, the following events shall not be deemed a termination of employment:

(i) a transfer to the employment of the Company from a Subsidiary or from the Company to a Subsidiary, or from one Subsidiary to another; or

(ii) an approved leave of absence for military service or sickness, or for any other purpose approved by the Company, if the employee's right to re-employment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise so provides in writing.

SECTION 16 AMENDMENTS AND TERMINATION

The Board may, at any time, amend or discontinue the Plan and the Administrator may, at any time, amend or cancel any outstanding Award for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall adversely affect rights under any outstanding Award without the holder's consent. Except as provided in Section 3(d) or 3(e), without prior stockholder approval, in no event may the Administrator exercise its discretion to reduce the exercise price of outstanding Stock Options or Stock Appreciation Rights or effect repricing through cancellation and re-grants or cancellation of Stock Options or Stock Appreciation Rights in exchange for cash or other Awards. To the extent required under the rules of any securities exchange or market system on which the Stock is listed, to the extent determined by the Administrator to be required by the Code to ensure that Incentive Stock Options granted under the Plan are qualified under Section 422 of the Code, Plan amendments shall be subject to approval by the Company stockholders entitled to vote at a meeting of stockholders. Nothing in this Section 16 shall limit the Administrator's authority to take any action permitted pursuant to Section 3(d) or 3(e).

SECTION 17 STATUS OF PLAN

With respect to the portion of any Award that has not been exercised and any payments in cash, Stock or other consideration not received by a grantee, a grantee shall have no rights greater than those of a general creditor of the Company unless the Administrator shall otherwise expressly determine in connection with any Award or Awards. In its sole discretion, the Administrator may authorize the creation of trusts or other arrangements to meet the Company's obligations to deliver Stock or make payments with respect to Awards hereunder, provided that the existence of such trusts or other arrangements is consistent with the foregoing sentence.

SECTION 18 GENERAL PROVISIONS

(a) No Distribution. The Administrator may require each person acquiring Stock pursuant to an Award to represent to and agree with the Company in writing that such person is acquiring the shares without a view to distribution thereof.

(b) Issuance of Stock. To the extent certificated, stock certificates to grantees under this Plan shall be deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have mailed such certificates in the United States mail, addressed to the grantee, at the grantee's last known address on file with the Company. Uncertificated Stock shall be deemed delivered for all purposes when the Company or a Stock transfer agent of the Company shall have given to the grantee by electronic mail (with proof of receipt) or by United States mail, addressed to the grantee, at the grantee's last known address on file with the Company, notice of issuance and recorded the issuance in its records (which may include electronic "book entry" records). Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any evidence of book entry or certificates evidencing shares of Stock pursuant to the exercise or settlement of any Award, unless and until the Administrator has determined, with advice of counsel (to the extent the Administrator deems such advice necessary or advisable), that the issuance and delivery is in compliance with all applicable laws, regulations of governmental authorities and, if applicable, the requirements of any exchange on which the shares of Stock are listed, quoted or traded. Any Stock issued pursuant to the Plan shall be subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with federal, state or foreign jurisdiction, securities or other laws, rules and quotation system on which the Stock is listed, quoted or traded. The Administrator may place legends on any Stock certificate or notations on any book entry to reference restrictions applicable to the Stock. In addition to the terms and conditions provided herein, the Administrator may require that an individual make such reasonable covenants, agreements, and representations as the Administrator, in its discretion, deems necessary or advisable in order to comply with any such laws, regulations, or requirements. The Administrator shall have the right to require any individual to comply with any timing or other restrictions with respect to the settlement or exercise of any Award, including a window-period limitation, as may be imposed in the discretion of the Administrator.

(c) Stockholder Rights. Until Stock is deemed delivered in accordance with Section 18(b), no right to vote or receive dividends or any other rights of a stockholder will exist with respect to shares of Stock to be issued in connection with an Award, notwithstanding the exercise of a Stock Option or any other action by the grantee with respect to an Award.

(d) Other Compensation Arrangements; No Employment Rights. Nothing contained in this Plan shall prevent the Board from adopting other or additional compensation arrangements, including trusts, and such arrangements may be either generally applicable or applicable only in specific cases. The adoption of this Plan and the grant of Awards do not confer upon any employee any right to continued employment with the Company or any Subsidiary.

(e) Trading Policy Restrictions. Option exercises and other Awards under the Plan shall be subject to the Company's insider trading policies and procedures, as in effect from time to time.

(f) Clawback Policy. Awards under the Plan shall be subject to the Company's clawback policy, as in effect from time to time.

SECTION 19 EFFECTIVE DATE OF PLAN

This Plan shall become effective upon the date immediately preceding the Registration Date following stockholder approval of the Plan in accordance with applicable state law, the Company's bylaws and articles of incorporation, and applicable stock exchange rules. No grants of Stock Options and other Awards may be made hereunder after the tenth anniversary of the Effective Date and no grants of Incentive Stock Options may be made hereunder after the tenth anniversary of the date the Plan is approved by the Board.

SECTION 20 GOVERNING LAW

This Plan and all Awards and actions taken thereunder shall be governed by, and construed in accordance with, the laws of the State of Delaware, applied without regard to conflict of laws principles.

DATE APPROVED BY BOARD OF DIRECTORS: FEBRUARY 9, 2018

DATE APPROVED BY STOCKHOLDERS: MARCH 15, 2018

DATE AMENDMENT AND RESTATEMENT APPROVED BY BOARD OF DIRECTORS: APRIL 21, 2021

DATE AMENDMENT AND RESTATEMENT APPROVED BY STOCKHOLDERS: JUNE 16, 2021

DATE AMENDMENT AND RESTATEMENT APPROVED BY BOARD OF DIRECTORS: FEBRUARY 16, 2023

DATE AMENDMENT AND RESTATEMENT APPROVED BY STOCKHOLDERS: _____, 2023