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, 2025

OR

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

For the transition period from _____to

Commission file number: 001-38443

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, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $772.9 million (based on the last reported sale price on the Nasdaq Global Select Market as of such date).

As of February 13, 2026, there were 162,308,820 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 2026 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.
Index

[This page intentionally left blank]

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 face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- 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.
- 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.
- 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 unacceptable side effects are identified during the development of our drug candidates, we may need to abandon or limit such development.
- 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 on our intended timelines, if at all.
- 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.
- 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.
- 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 may have difficulty building our sales, marketing and distribution infrastructure.
- 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 may require additional capital to finance our planned operations. If we fail to obtain additional financing when needed, or on attractive terms, we may be unable to complete the development and commercialization of our product candidates.
- The price of our stock may be volatile, and you could lose all or part of your investment.
- Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under our convertible notes.

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, anticipated regulatory approval and commercial launch of bezuclastinib, 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;
- 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 U.S. Food and Drug Administration ("FDA") for our bezuclastinib product candidate and any other product candidates we may develop;
- our ability to obtain and maintain regulatory approval for our bezuclastinib product candidate and any other product candidates we may develop, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the potential for our identified research priorities to advance our bezuclastinib product candidate or for our teams to discover and develop additional product candidates;
- the ability to license additional intellectual property rights relating to our bezuclastinib product candidate or future product candidates from third-parties and to comply with our existing or future license agreements and/or collaboration agreements;
- our ability to commercialize our bezuclastinib product candidate and future product candidates in light of the intellectual property rights of others;
- our ability to obtain funding for our operations, including funding necessary to complete further discovery, development and commercialization of our existing and future product candidates;
- the scalability and commercial viability of our manufacturing methods and processes;
- the commercialization of our product candidates, if approved;
- our ability to attract collaborators with development, regulatory, and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;

- the pricing and reimbursement of our product candidates, if approved;
- regulatory developments in the United States and foreign countries, including pharmaceutical and biological product marketing regulation;
- the impact of adverse business and economic conditions including inflationary pressures, general economic slowdown or a recession, high interest rates, changes in monetary policy, banking institution instability, changes in trade policies, including tariffs or other trade restrictions or the threat of such actions, and the prospect of a shutdown of the U.S. federal government;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the development and success of competing therapies that are or may be under development in clinical trials or become available commercially;
- our ability to attract and retain key scientific and management personnel;
- our ability to satisfy the conditions, covenants, and obligations applicable to our convertible notes;
- 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, debt issuance, 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 clinical-stage biotechnology company focused on developing precision therapies for genetically defined diseases. Our approach is to design rational precision therapies that treat the underlying cause of disease and improve the lives of patients. Our most advanced program is bezuclastinib, also known as CGT9486, a highly selective tyrosine kinase inhibitor that is designed to potently inhibit the KIT D816V mutation as well as other mutations in KIT exon 17. In the vast majority of cases, KIT D816V is responsible for driving Systemic Mastocytosis ("SM"), a serious and rare disease caused by unchecked proliferation of mast cells. Exon 17 mutations are also found in patients with advanced gastrointestinal stromal tumors ("GIST"), a type of cancer with strong dependence on oncogenic KIT signaling. Bezuclastinib is a highly selective and potent KIT inhibitor with the potential to provide a new treatment option for these patient populations. We are developing bezuclastinib to treat patients living with Non-Advanced Systemic Mastocytosis ("NonAdvSM"), Advanced Systemic Mastocytosis ("AdvSM") and GIST, and in 2025 we reported positive top-line results from registrational trials in each of these indications. We are building an internal commercial organization and expect to launch bezuclastinib commercially in the United State in the second half of 2026, pending regulatory approval. We also have an ongoing Phase 1 study of our novel internally developed FGFR2/3 inhibitor and have initiated a Phase 1 study of our CNS-penetrant, selective mutant ErbB2 inhibitor. In addition, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases targeting mutations in PI3Kα, KRAS and JAK2.

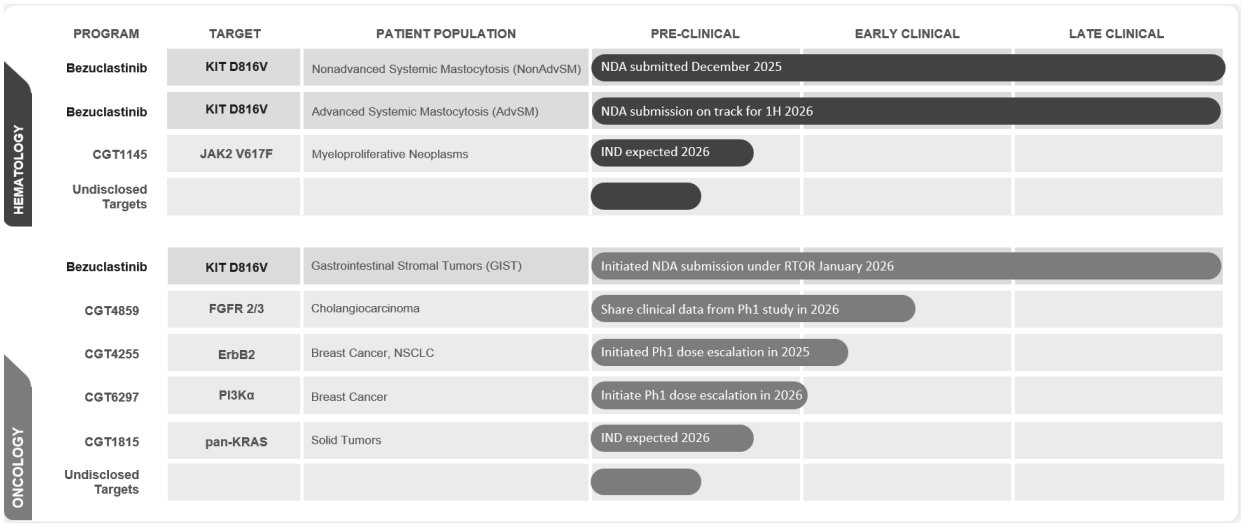
We have assembled a management team with extensive experience in the research, development, manufacturing and commercialization of pharmaceutical products, specifically including numerous successful precision medicines for genetically defined diseases. With the support of our board of directors and their 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:

- Advance bezuclastinib toward regulatory approval and, if approved, commercialize the product in the United States and select international markets for patients with SM and GIST;
- Evaluate potential collaborations, partnerships, and licensing opportunities that could enhance the value of our existing programs and enable us to leverage the capabilities of strategic partners, including in geographies where partners can provide local expertise or operational scale;
- Explore the clinical utility of CGT4859, our selective and potent FGFR2/3 inhibitor, CGT4255, our CNS-penetrant, selective mutant ErbB2 inhibitor and CGT6297, our selective PI3Kα inhibitor; and
- Advance our JAK2 and KRAS preclinical programs, as well as our other undisclosed preclinical programs.

Our Pipeline



Program Overviews

Bezuclastinib

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 PDGFRα, PDGFRβ, VEGFR2, FLT3, CSF1R and KDR. In preclinical studies of bezuclastinib, limited blood-brain-barrier penetration was observed, and there have been no clinically significant CNS toxicities identified. 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.

We licensed the exclusive worldwide rights to develop and commercialize bezuclastinib from Plexxikon Inc., a Daiichi Sankyo subsidiary ("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. We are developing bezuclastinib in both SM and GIST.

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 mast 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 SM patients present with NonAdvSM and 10% of patients present with AdvSM, a rare and 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").

Based on the characteristics of bezuclastinib, we are pursuing development of the compound in both patients with AdvSM and patients with NonAdvSM, 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.

SUMMIT is our registration-directed randomized, global, multicenter, double-blind, placebo-controlled, multi-part Phase 2 clinical trial for patients with NonAdvSM. The study is designed to explore the safety and efficacy of bezuclastinib in patients with moderate to severe NonAdvSM, which includes Indolent Systemic Mastocytosis ("ISM"), Smoldering Systemic Mastocytosis ("SSM") and Bone Marrow Mastocytosis. APEX is our registration-directed global, open-label, multi-center, Phase 2 clinical trial in patients with AdvSM evaluating the safety, efficacy, pharmacokinetic, and pharmacodynamic profiles of bezuclastinib.

We reported top-line results from our SUMMIT trial in July 2025 and full results in December 2025, as well as top-line results from our APEX trial in December 2025, all of which were positive and achieved all primary and key secondary endpoints. We submitted the first New Drug Application ("NDA") for bezuclastinib in patients with NonAdvSM in December 2025 and expect to submit an NDA in the first half of 2026 for patients with AdvSM. In October 2025, the FDA granted Breakthrough Therapy Designation for bezuclastinib in NonAdvSM patients previously treated with avapritinib as well as in patients with SSM, both patient populations with no currently approved standard of care. The FDA and European Medicines Agency ("EMA") have granted orphan drug designation to bezuclastinib for the treatment of Mastocytosis. In 2025, we initiated an expanded access program in the United States to allow eligible SM patients to receive investigational bezuclastinib prior to potential regulatory approval. Pending regulatory approval, we expect to launch bezuclastinib commercially in the United States in the second half of 2026 to treat patients with NonAdvSM.

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 progression free survival ("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. Bezuclastinib is designed to be a potent and selective inhibitor of KIT exon 17 mutations. Sunitinib, a tyrosine kinase inhibitor known to inhibit KIT exon 13 mutations, is the current standard of care for treating patients in second-line GIST. By combining bezuclastinib with sunitinib, in this setting, we believe this combination has the potential to offer a new, active treatment option for imatinib resistant GIST patients.

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.

We announced positive top-line results from our PEAK trial in November 2025, which demonstrated a substantial and highly statistically significant clinical benefit on the primary endpoint of PFS. Median PFS was 16.5 months for the bezuclastinib combination vs. 9.2 months for sunitinib monotherapy, and the bezuclastinib combination reduced the risk of disease progression or death by 50% compared to sunitinib monotherapy. In January 2026, we announced that the FDA agreed to accept our NDA for bezuclastinib in combination with sunitinib for patients with GIST who have received prior treatment with imatinib under the Real-Time Oncology Review ("RTOR") program, and shortly thereafter we initiated our NDA submission to FDA under this program. We expect to complete the GIST NDA submission in April 2026. In January 2026, the FDA also granted Breakthrough Therapy Designation ("BTD") for bezuclastinib in combination with sunitinib for patients with GIST who have received prior treatment with imatinib. Bezuclastinib has been granted orphan drug designation for the treatment of GIST by the FDA and under the Orphan Drug Act and the EMA. Pending regulatory approval, we expect to launch bezuclastinib commercially in the United States in the second half of 2026 to treat second-line GIST patients.

In mid-2026, we expect to initiate a Phase 2 trial investigating the benefit of the bezuclastinib combination for first-line GIST patients with exon 9 mutations who are naive to, or recently initiated treatment with, imatinib.

In 2025, we initiated an expanded access program in the United States for patients affected with advanced, metastatic, and/or unresectable GIST, intolerant to or progressed on prior imatinib therapy, and who meet other inclusion and exclusion criteria.

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

CGT4859 (FGFR2/3)

We are building a pipeline of small molecule inhibitors, with our first efforts aimed toward targeting currently undrugged mutations in fibroblast growth factor receptor ("FGFR"). FGFR mutations are well-established oncogenic drivers in multiple diseases, but approved medicines fail to capture the full landscape of FGFR altered tumor types, with FGFR1-mediated hyperphosphatemia serving as the most common dose-limiting toxicity for pan-FGFR inhibitors. We are actively enrolling our Phase 1 study of CGT4859 in patients with tumors bearing FGFR2/3 mutations, including advanced cholangiocarcinoma. The trial will explore the safety, tolerability and clinical activity of escalating doses of CGT4859 with a goal of selecting an active and well tolerated dose for further clinical investigation. We expect to share clinical data from our Phase 1 study in 2026.

CGT4255 (ErbB2)

We are also advancing a novel, ErbB2 mutant program, which is focused on actionable and underserved mutations in a variety of solid tumor systemic and CNS involved indications. HER2 alterations such as amplification, overexpression, insertions, and point mutations, are established oncogenic drivers in many solid tumors. Activating HER2 mutations are found in 2-4% of advanced lung cancers and have emerged as mechanisms of acquired resistance to targeted therapies. Patients with HER2 mutant lung tumors develop more brain metastasis during treatment than patients with any other oncogenic drivers in lung cancer. Addressing brain metastasis in this group of patients remains a clinical challenge with limited therapeutic options. Approved HER2 tyrosine kinase inhibitors have inferior potency against key mutations and lack sufficient brain penetration to be an impactful treatment option for patients with brain metastasis. We received clearance from the FDA on our investigational new drug application ("IND") submission for CGT4255 and initiated a Phase 1 dose escalation study in the fourth quarter of 2025.

CGT6297 (PI3Kα)

Our research team is also developing a potential best-in-class, wild-type-sparing, PI3Kα inhibitor that provides coverage of both the H1047R mutation as well as E542K and E545K helical mutants, which affects >30,000 cancer patients each year. The phosphoinositide 3-kinase ("PI3K") pathway is a key cell cycle regulating pathway that has an established role in tumor growth and development. PI3Kα mutations are highly prevalent in many solid tumors and are present in 36% of all breast cancer patients. The approved agents for these patients often lead to dose limitations, resulting from activity against wild-type PI3Kα. IND-enabling studies have been completed for CGT6297 and we submitted an IND application for this program in the fourth quarter of 2025. We expect to initiate a Phase 1 dose escalation in the first quarter of 2026.

Research Programs

The Cogent Research Team, based in Boulder, Colorado, is focused on pioneering best-in-class, small molecule therapeutics to expand our pipeline and deliver novel precision therapies for patients living with unmet medical needs. For KRAS and JAK2 we see opportunities to provide a more robust molecular response compared to existing therapies.

KRAS

Our research team is developing a potent and selective KRAS inhibitor. Mutations in KRAS are among the most prevalent mutations found in cancer, occurring most often in colorectal cancer, non-small cell lung cancer and pancreatic cancer. We plan to submit an IND for this program in 2026.

JAK2

Our research team is developing a novel, wild-type-sparing, JAK2 V617F mutant-selective inhibitor. The JAK2 V617F mutation is the most prevalent molecular abnormality in BCR-ABL-negative myeloproliferative neoplasms, occurring in approximately 95% of patients with polycythemia vera, and 50% of patients with essential thrombocythemia or primary myelofibrosis. We plan to submit an IND for this program in 2026.

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 primarily 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.

Bezuclastinib

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, Hong Kong, India, 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 addition, we own two patent families directed to bezuclastinib. The first patent family seeks to protect our optimized formulation of bezuclastinib, which could potentially provide exclusivity through at least 2043. As of December 31, 2025, this family has pending applications in the United States, Europe, Australia, Brazil, Canada, China, Colombia, Egypt, Indonesia, Israel, India, Japan, Korea, Mexico, New Zealand, Peru, Philippines, Russia, Singapore, Thailand, Vietnam, and South Africa. The second patent family is directed to methods of administering bezuclastinib. As of December 31, 2025, this patent family has one pending U.S. provisional application. Any patents issuing from or claiming priority to this application would be expected to expire in 2046 without consideration of potential patent term extensions. 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.

FGFR2/3

We own two patent families directed to inhibitors of FGFR2/3 mutations. A first patent family covers compositions of matter of certain inhibitors of FGFR2/3 and methods of use. As of December 31, 2025, this patent family has one issued U.S. patent, one pending U.S. application, and one pending international application. Any patents issuing from or claiming priority to these applications would be expected to expire in 2044 without consideration of potential patent term extensions. A second patent family covers compositions of matter of certain inhibitors of FGFR2/3 mutations and methods of use. As of December 31, 2025, this patent family has pending applications in the United States, Europe, Canada, China, Japan, Korea, and Singapore. Any patents issuing from or claiming priority to these applications would be expected to expire in 2044 without consideration of potential patent term extensions.

ErbB2

We own one patent family directed to inhibitors of ErbB2 mutations. This patent family covers compositions of matter of certain inhibitors of ErbB2 mutations and methods of use. As of December 31, 2025, this patent family has pending applications in the United States, Europe, Australia, Brazil, Canada, China, Colombia, Indonesia, Israel, India, Japan, Korea, Mexico, New Zealand, Peru, Philippines, Singapore, Vietnam, and South Africa. Any patents issuing from or claiming priority to these applications would be expected to expire in 2044 without consideration of potential patent term extensions.

KRAS

We own one patent family directed to inhibitors of KRAS mutations and related compounds. The patent family covers compositions of matter of certain inhibitors of KRAS mutations and methods of use. As of December 31, 2025, this patent family has one pending international application. Any patents issuing from or claiming priority to this application would be expected to expire in 2045 without consideration of potential patent term extensions.

PI3K

We own one patent family directed to inhibitors of PI3K mutations. This patent family covers compositions of matter of certain inhibitors of PI3K mutations and methods of use. As of December 31, 2025, this patent family has one pending international application. Any patents issuing from or claiming priority to this application would be expected to expire in 2044 without consideration of potential patent term extensions.

JAK

We own one patent family directed to inhibitors of Janus kinase (JAK). This patent family covers compositions of matter of certain inhibitors of JAK and methods of use. As of December 31, 2025, this patent family has one pending international application. Any patents issuing from or claiming priority to this application would be expected to expire in 2045 without consideration of potential patent term extensions.

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 or our licensors' patents and other intellectual property. Disputes regarding ownership or inventorship of our or our licensors' 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. In the fourth quarter of 2025, $5.0 million became payable upon the achievement of certain regulatory milestones and an additional $15.0 million may become payable in the next twelve months as a result of additional regulatory milestones.

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 License 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 have completed or are completing pivotal and registration-enabling clinical studies and are pursuing regulatory approval, will compete with the drugs discussed below and with other therapies currently in development.

In SM approved therapies are limited. Blueprint Medicines' (a Sanofi company) avapritinib and Novartis AG's midostaurin are approved for AdvSM patients with the KIT D816V mutation. Additionally, Novartis AG's imatinib is approved for AdvSM patients without the KIT D816V mutation or mutational status unknown. Blueprint Medicines' avapritinib has also been approved for the treatment of Non-AdvSM. We may also face competition from other drug candidates in preclinical or clinical development for SM.

In GIST, the current approved standards of care for unresectable or metastatic patients are Novartis AG's imatinib in first-line, followed by Pfizer Inc.'s sunitinib in second-line upon imatinib progression, followed by Bayer HealthCare Pharmaceuticals Inc.'s regorafenib in third-line upon sunitinib progression, followed by Deciphera Pharmaceuticals, LLC.'s, a member of Ono Pharmaceuticals, Co. Ltd ("Deciphera") ripretinib in fourth-line for patients who have received three or more prior kinase inhibitors. We may face competition from the above and other drug candidates in preclinical or clinical development including, Taiho Pharmaceutical Co. Ltd, and GSK plc.

In cholangiocarcinoma ("CC"), the only approved drugs for the treatment of FGFR related CC are Incyte's Pemigatinib, and Taiho Pharma's Futibatinib. We may face competition from other drug candidates in preclinical or clinical development including, Elevar Therapeutics Inc., TransThera Sciences (Nanjing), Inc., Tyra Biosciences Inc., Abbisko Therapeutics Co., Ltd., HutchMed (China) Limited and Amgen Inc.

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 and our other drug candidates to support preclinical and clinical testing. We have obtained our supplies from these manufacturers on a purchase-order basis and are in the process of negotiating long-term supply arrangements. These agreements may require binding forecasts or commitments to purchase minimum amounts for the manufacture of drug product supply, which may be material to our consolidated financial statements.

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 ("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 preclinical laboratory tests, which may include animal and *in vitro* studies, and formulation studies in compliance with the FDA's good laboratory practice ("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 and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB"), representing each clinical site before each clinical trial may be initiated;
- manufacture of the proposed drug candidate in accordance with Current Good Manufacturing Practices ("cGMPs");
- performance of adequate and well-controlled human clinical trials in accordance with the FDA's good clinical practice ("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 an 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 ("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 to permit commercial marketing of the product for particular indications for use in the United States; and
- compliance with any post-approval requirements, such as any Risk Evaluation and Mitigation Strategies ("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. In April 2025, the FDA published a roadmap to reduce animal testing in preclinical safety studies, including those required in INDs, with scientifically validated new approach methodologies ("NAMs"). 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 National Institutes of Health 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.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval or licensure, including that the study was conducted in accordance with GCP, including review and approval by an independent ethics committee and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the study through an onsite inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies.

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 approximately $4.3 million for fiscal year 2025, for applications requiring clinical data, and the sponsor of an approved NDA is also subject to an annual program fee, currently approximately $0.4 million for fiscal year 2025. 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 United States, 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 ensure 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 current GCP.

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. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. The FDA also has increased authority for expedited procedures to withdraw approval of a product or indication approved under accelerated approval if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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 ("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.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the "Hatch-Waxman Amendments") amending the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application ("ANDA") to the agency. Upon approval of an ANDA, the FDA indicates that the generic product is "therapeutically equivalent" to the drug product previously approved under an NDA, known as the reference listed drug ("RLD"), and it assigns a therapeutic equivalence rating to the approved generic drug in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider the therapeutic equivalence rating to mean that a generic drug is fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of a therapeutic equivalence rating often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of nonpatent exclusivity for the RLD has expired. The FDCA provides a period of five years of data exclusivity for NDAs containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification (discussed further below), in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

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. 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.

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.

505(b)(2) New Drug Applications

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA pursuant to an NDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant, and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous findings of safety and effectiveness is scientifically and legally appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional bridging studies or measurements, including clinical trials, to support the change from the previously approved reference drug. The FDA may then approve the new drug candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) 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.

U.S. Data Privacy and Security Laws

There are numerous U.S. federal, state, and local laws and regulations, as well as foreign legislation, in particular in the EU and UK, which regulate personal information, including health-related information and how that information may be used, processed, and disclosed. These regulations also cover sensitive and confidential personal information, including medical and health information, and impose requirements on entities that handle such information to implement certain privacy and security measures. We and/or our partners may be subject to these laws.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information and could apply to our operations or the operations of our partners.

For example, at the federal level, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH Act"), and their respective implementing regulations impose data privacy, security, and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates and their covered subcontractors that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually identifiable protected health information ("PHI") for or on behalf of such covered entities. These requirements imposed by HIPAA and the HITECH on covered entities and business associates include entering into agreements that require business associates protect PHI provided by the covered entity against improper use or disclosure, among other things; following certain standards for the privacy of PHI, which limit the disclosure of a patient's past, present, or future physical or mental health or condition or information about a patient's receipt of health care if the information identifies, or could reasonably be used to identify, the individual; ensuring the confidentiality, integrity, and availability of all PHI created, received, maintained, or transmitted in electronic form, to identify and protect against reasonably anticipated threats or impermissible uses or disclosures to the security and integrity of such PHI; and reporting of breaches of PHI to individuals and regulators.

Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. HITECH also increased the civil and criminal penalties applicable to covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

In addition, state health information privacy laws, such as California's Confidentiality of Medical Information Act and Washington's My Health My Data Act, that govern the privacy and security of health-related information, specifically, may apply even when HIPAA does not and impose additional requirements.

Even when HIPAA and state health information privacy laws do not apply, according to the FTC and state attorneys general, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act and state consumer protection laws.

In addition, certain state laws, such as the California Consumer Privacy Act of 2018 ("CCPA"), as amended by the California Privacy Rights Act of 2020, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA in various ways. Numerous other states have passed similar laws, but many differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The CCPA applies to personal data of consumers, business representatives, and employees, and imposes obligations on certain businesses that do business in California, including to provide specific disclosures in privacy notices, and affords rights to California residents in relation to their personal information. Health information falls under the CCPA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked, directly or indirectly, with a particular consumer or household and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. The CCPA and numerous other comprehensive privacy laws that have passed or are being considered in other states, as well as at the federal and local levels, exempt PHI that is subject to HIPAA; and others exempt covered entities and business associates subject to HIPAA altogether, further complicating compliance efforts, and increasing legal risk and compliance costs for us and the third parties upon whom we rely.

Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Review and Approval of Drug Products in the European Union and United Kingdom

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.

The United Kingdom ("UK") formally left the EU on January 31, 2020 and EU laws now only apply to the UK in respect of Northern Ireland as laid out in the Protocol on Ireland and Northern Ireland. The EU and the UK agreed on a trade and cooperation agreement ("TCA"), which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of GMP and issued GMP documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

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.

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 conducted a comprehensive consultation in 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 recognized 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. Core aspects of the new regime are planned to come into force on July 1, 2025, with strengthened post-market surveillance proposals to be introduced in advance of such date.

Under the Medical Devices (Amendment) (Great Britain) Regulations 2023, CE marked European medical devices will continue to be accepted for sale in the UK until 2028 or 2030 (depending on the type of device).

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.

Under the new CTR, a sponsor is able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal (the Clinical Trials Information System or "CTIS"). 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, including a layperson's summary. For one year, until January 31, 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. Since January 31, 2023, submission of initial clinical trial authorization applications ("CTAs") via CTIS is mandatory and CTIS serves as the single-entry point for submission of clinical trial-related information and data. By January 31, 2025, all ongoing trials approved under the current Clinical Trials Directive will need to comply with the CTR and have to be transitioned to CTIS.

Under the CTR, national laws, regulations, and the applicable GCP and GLP 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 GCP and the ethical principles that have their origin in the Declaration of Helsinki. 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 National Competent Authority and to the Ethics Committees of the EU member state where they occur.

During the development of a medicinal product, the 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 a 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 (Iceland, Norway and Liechtenstein). 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 expected to be of major public health interest, particularly from the point 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. RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available. New RMPs are required to be submitted (i) at the request of EMA or a national competent authority, or (ii) whenever the risk-management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit-risk profile or as a result of an important pharmacovigilance or risk-minimization milestone being reached. The regulatory authorities may also impose specific obligations as a condition of the MA. Since October 20, 2023, all RMPs for centrally authorized products are published by the EMA subject to only 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.

On April 26, 2023, the EC submitted a proposal for the reform of the European pharmaceutical legislation and negotiations are still ongoing. The timing for finalization of these negotiations and entry into force are unclear.

The current drafts envisage:

- a shortening of the periods of data exclusivity from eight to six years (with transferable vouchers for an additional year of market protection as an incentive for the development of new antibiotics),
- earlier regulatory guidance and extension of market exclusivity for orphan medicines (depending on certain conditions),
- four-year data exclusivity for additional indications of existing products, and
- rules governing the availability of products (including shortage prevention plans and some supply obligations for manufacturers).

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. Innovative medicinal products, referred to as 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 preclinical 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 change 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.

In the UK, following the post-Brexit transition period, a system for incentivizing the development of orphan medicines was introduced. Overall, the requirements for orphan designation largely replicate the requirements in the EU and the benefit of market exclusivity has been retained. Products with an orphan designation in the EU can be considered for an orphan MA in Great Britain and, marketing authorizations granted for products that fulfil UK orphan criteria are valid UK-wide regardless of whether there is an EU orphan designation. The Medicines and Healthcare Products Regulatory Agency ("MHRA") will review applications for orphan designation at the time of a MA, and will offer incentives, such as market exclusivity and full or partial refunds for MA fees to encourage the development of medicines in rare diseases. Separately, the MHRA has stated that it is considering updating its licensing framework for orphan medicines, with a draft framework expected by spring 2026.

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.

In the UK, the MHRA has published guidance on the procedures for UK Paediatric Investigation Plans ("PIPs") which, where possible, mirror the submission format and requirements of the EU system. From January 1, 2025, EU pediatric requirements are addressed via Windsor Framework categorization: for Category 2 products, both UK and EU pediatric requirements apply, and an EU-agreed PIP must also be in place (unless waived).

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The Priority Medicines ("PRIME") scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small-and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, once a candidate medicine has been selected for the PRIME scheme, a dedicated contact point and rapporteur from the CHMP or from CAT are appointed facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of multidisciplinary experts to provide guidance on the overall development plan and regulatory strategy. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

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 Periodic Safety Update Reports ("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 risk-benefit 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 (repealed by Directive 2017/1572 on January 31, 2022), Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. 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. Amendments or replacements of at least Directive 2001/83/EC and Regulation (EC) No 726/2004 are part of the reform proposal for European pharmaceutical legislation.

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.

On October 27, 2025, the Council of the European Union approved a framework for compulsory licensing of crisis-relevant products (including medicinal products) in crisis situations. While the proposal focuses on voluntary agreements with intellectual property rights holders, it includes rules on compulsory licensing as a measure of last resort upon activation / declaration of a crisis or emergency mode. The European Parliament has not yet voted on the proposal.

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 Privacy and Security Laws

The processing of personal data, including health-related personal data in the EEA is mainly governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 ("GDPR"), and related data protection laws in individual EEA countries.

In the UK, the processing of personal data is mainly governed by the GDPR as incorporated into UK law pursuant to the European Union (Withdrawal) Act 2018 (the UK GDPR). The GDPR and UK GDPR impose a number of strict obligations and requirements for the processing, including collecting, analyzing and transferring, of personal data of individuals in the EEA or in the UK, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR and UK GDPR include requirements relating to the legal basis of the processing (such as obtaining consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the personal data breaches which may have to be notified to the national data protection authorities and data subjects, the measures to be taken when engaging processors, and obligations relating to the security and confidentiality of the personal data. EEA countries may also impose additional requirements in relation to the processing of health, genetic and biometric data through their national legislation.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the EEA that are not considered by the European Commission to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the standard contractual clauses ("SCCs") adopted by the European Commission. When relying on the appropriate safeguards, data exporters, with the assistance of the data importers, are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country to which the data is being transferred may impinge on the effectiveness of the safeguards in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the transferred data to the EU standard of 'essential equivalence'. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer. With regard to the transfer of data from the EEA, UK and Switzerland to the United States, the EU-U.S. Data Privacy Framework (DPF), UK Extension to the EU-U.S. DPF, and Swiss-U.S. DPF were developed by the U.S. Department of Commerce and the European Commission, UK Government, and Swiss Federal Administration respectively, to provide U.S. organizations with reliable mechanisms for the transfer of personal data from the EU, UK, and Switzerland to the U.S., while ensuring data protection that is consistent with EU, UK, and Swiss law. With regard to the transfer of data from the EU to the UK, personal data may freely flow from the EEA to the UK since the UK is deemed to have an adequate data protection level. However, the adequacy decisions include a 'sunset clause' which entails that the decisions will automatically expire four years after their entry into force, unless renewed.

Failure to comply with the requirements of the GDPR or UK GDPR and the related national data protection laws of the EEA countries may result in significant monetary fines for noncompliance of up to €20 million or £17.5 million (as applicable), 4% of the total worldwide annual turnover (for higher-tier infringements). This is enforced by ICO and is entirely separate from fines under EU GDPR. In addition, violations of national laws can trigger additional administrative penalties, investigations, corrective orders, temporary or definitive bans, and, in some jurisdictions, and a number of criminal offenses 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 EU.

Furthermore, there are specific requirements relating to processing health data from clinical trials, including public disclosure obligations provided in the new EU CTR, EMA disclosure initiatives and voluntary commitments by industry. Failure 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. On February 2, 2022, the UK Secretary of State laid before the UK Parliament the international data transfer agreement ("IDTA") and the international data transfer addendum to the EC's standard contractual clauses for international data transfers ("UK Addendum") and a document setting out transitional provisions. The IDTA and UK Addendum came into force on March 21, 2022 and are the primary UK-approved mechanisms for putting in place appropriate safeguards for UK restricted transfers, subject to transitional arrangements for legacy SCCs. With regard to the transfer of data from the UK to the U.S., the UK government has adopted an adequacy decision for the US, the UK-US Data Bridge, which came into force on October 12, 2023. The UK-US Data Bridge recognizes the U.S. as offering an adequate level of data protection where the transfer is to a U.S. company participating in the EU-US Data Privacy Framework and its UK Extension.

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.

In the UK, the pharmaceutical sector is recognized as being particularly vulnerable to corrupt practices, some of which fall within the scope of the Bribery Act 2010. Due to the Bribery Act 2010's far-reaching territorial application, the potential penalized act does not have to occur in the UK to become within its scope. If the act or omission does not take place in the UK, but the person's act or omission would constitute an offense if carried out there and the person has a close connection with the UK, an offense will still have been committed.

The Bribery Act 2010 is comprised of four offenses that cover (i) individuals, companies and partnerships that give, promise or offer bribes, (ii) individuals, companies and partnerships that request, agree to receive or accept bribes, (iii) individuals, companies and partnerships that bribe foreign public officials, and (iv) companies and partnerships that fail to prevent persons acting on their behalf from paying bribes. The penalties imposed under the Bribery Act 2010 depend on the offence committed, harm and culpability and penalties range from unlimited fines to imprisonment for a maximum term of ten years and in some cases both.

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); repealed by Directive 2017/1572 on January 31, 2022; this directive also lays out standards and principles for manufacturing practices of medicinal products for human use and investigational medicinal products for human use.
- 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).

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow it to establish or maintain pricing sufficient to realize a sufficient return on its investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- cost-effective; and
- neither experimental nor investigational.

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

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. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. The Inflation Reduction Act ("IRA") provides the Centers for Medicaid & Medicare Services ("CMS") with significant new authorities intended to curb drug costs and to encourage market competition. For the first time, CMS will be able to directly negotiate prescription drug prices and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition. On August 29, 2023, HHS announced the list of the first ten drugs subject to price negotiations. These price negotiations occurred in 2024. In January 2025, CMS announced a list of 15 additional Medicare Part D drugs that will be subject to price negotiations. The IRA also provides a new "inflation rebate" covering Medicare patients that took effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision requires drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Part B and Part D increases faster than the rate of inflation. To support biosimilar competition, beginning in October 2022, qualifying biosimilars may receive a Medicare Part B payment increase for a period of five years. Separately, if a biologic drug for which no biosimilar exists delays a biosimilar's market entry beyond two years, CMS will be authorized to subject the biologics manufacturer to price negotiations intended to ensure fair competition. Notwithstanding these provisions, the IRA's impact on commercialization and competition remains largely uncertain.

In addition, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we may commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Finally, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. 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 product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

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 and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. There are a number of statutory exceptions and regulatory safe harbors protecting some common commercial activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, for persons in a position to refer or recommend federally reimbursable healthcare business may be alleged to be intended to induce prescribing, purchasing or recommending, and may be subject to scrutiny if they do not qualify for an exception or regulatory safe harbor. Qualifying for a statutory exception or regulatory safe harbor requires satisfying all of the criteria for the exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS, but it does increase the risk of regulatory scrutiny. Ultimately, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. 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;
- 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;
- 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 Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the CMS information related to payments or other transfers of value to various healthcare professionals including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning on January 1, 2023, California Assembly Bill 1278 requires California physicians and surgeons to notify patients of the Open Payments database established under the federal Physician Payments Sunshine Act;
- the FDCA addresses, among other things, the design, production, labeling, promotion, manufacturing, and testing of drugs, biologics and medical devices, and prohibits such acts as the introduction into interstate commerce of adulterated or misbranded drugs or devices. The Public Health Service Act ("PHSA") also prohibits the introduction into interstate commerce of unlicensed or mislabeled biological products;
- 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.

Regulations in the UK and Other Markets

The UK formally left the EU on January 31, 2020 and EU laws now only apply to the UK in respect of Northern Ireland as laid out in the protocol on Ireland and Northern Ireland and as amended by the Windsor Framework sets out a long-term set of arrangements for the supply of medicines into Northern Ireland. The EU and the UK agreed on a trade and cooperation agreement, which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP issued documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

The UK government has adopted the Medicines and Medical Devices Act 2021 (the "MMDA") to enable the UK's regulatory frameworks to be updated following the UK's departure from the EU. The MMDA introduces regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. The MHRA has since been consulting on future regulations for medicines and medical devices in the UK.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Additional Regulation

In addition to the foregoing, local, state, and federal laws regarding such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control 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 our use, handling, and disposal of various biological, chemical, and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous or biohazardous substances, we could be liable for damages, environmental remediation, and/or governmental fines. We believe that we are in material compliance with applicable environmental laws and occupational health and safety laws that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations. We may incur significant costs to comply with such laws and regulations now or in the future.

Human Capital

As of December 31, 2025, we had 258 employees. To allow us flexibility in meeting varying workflow demands, we also engage consultants and temporary workers when needed.

We believe that our future success largely depends upon our continued ability to attract and retain a diverse group of highly skilled employees. We offer comprehensive compensation packages, including competitive base pay, incentive compensation and equity programs, and provide a broad range of benefits, including 401(k) plan with employer match, healthcare and insurance benefits, paid time off, paid family and medical leave, flexible work schedules, and various health and wellness programs. We also provide development programs that enable continued learning and growth.

Our Code of Business Conduct and Ethics ensures that our core values of respect, integrity, collaboration, innovation, trust, and excellence are applied throughout our operations. Our Code of Business Conduct and Ethics serves as a tool to help all of us recognize and report unethical conduct, while preserving our culture of honesty and accountability.

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.

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 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, 2025, we have 182,955,584 shares outstanding on an as-converted basis, which consists of (i) 160,980,024 shares of common stock outstanding, (ii) pre-funded warrants that are exercisable for 606,060 shares of common stock, (iii) 67,414 shares of Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock") that are convertible into 16,853,500 shares of common stock, and (iv) 4,516 shares of Series B Non-Voting Convertible Preferred Stock ("Series B Preferred Stock") that are convertible into 4,516,000 shares of common stock.

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. Moreover, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future. References to past events are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not such factors have occurred in the past.

Risks Related to our Business

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. We submitted the first New Drug Application ("NDA") for NonAdvSM in 2025; we initiated our NDA submission for GIST in January 2026 and expect to complete the submission in April 2026; and we plan to submit an NDA in AdvSM in the first half of 2026. There is no guarantee that bezuclastinib will be approved for any or all of these indications. Even if approved, bezuclastinib will require 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 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.

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 bezuclastinib and our other product 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.

Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future from segments of the pharmaceutical, biotechnology and other related markets that pursue precision medicines. Our commercial opportunity could also be reduced or eliminated if our competitors develop and commercialize additional 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.

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 bezuclastinib, 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.

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 bezuclastinib and our other drug candidates, our business, operating results, prospects, or financial condition may be harmed and our stock price may decrease.

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.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for bezuclastinib or any of our other product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The pricing, coverage, and reimbursement of bezuclastinib and any other product candidates, if approved, must be adequate to support our commercial infrastructure. Our per-patient prices must be sufficient to recover our development and manufacturing costs and potentially achieve profitability. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to afford expensive treatments such as ours. Sales of bezuclastinib will depend substantially, both domestically and abroad, on the extent to which their costs will be paid for by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government authorities, private health insurers, and other payors. If coverage and reimbursement are not available, are available only to limited levels, or are not available on a timely basis, we may not be able to successfully commercialize bezuclastinib. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to sustain our overall enterprise.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services (the "HHS"), decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS or private payors will decide with respect to reimbursement for a product such as ours. In addition, an executive order issued by the White House on May 12, 2025, directs the HHS to implement a "Most Favored Nation" drug pricing policy. See also "*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.*" And the One Big Beautiful Bill Act (the "OBBBA") imposes new restrictions on funding for government health care programs and on individual eligibility for coverage under those programs, which may lead to lower reimbursement for drugs covered by those programs.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for bezuclastinib. We expect to experience pricing pressures in connection with the sales bezuclastinib due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, additional legislative changes, and statements by elected officials. The downward pressure on healthcare costs in general, and with respect to prescription drugs, surgical procedures, and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

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

We plan to seek regulatory approval of bezuclastinib and our other product candidates outside of the United States (either ourselves or through a partner) and, accordingly, we expect that we or any future partner will be subject to additional risks and regulatory requirements related to operating in foreign countries if we or they obtain the necessary approvals. Risks associated with any 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 bezuclastinib or any of our other 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 bezuclastinib or any of other product candidates. If we cannot successfully defend ourselves against claims that any of our product candidates caused injuries, we could incur substantial liabilities. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability, or losses may exceed the amount of insurance that we carry. A product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, and decreased demand for bezuclastinib or any of our other product candidates, if approved for commercial sale.

Information obtained from expanded access studies may not reliably predict the efficacy of our future product candidates in company-sponsored clinical trials and may lead to adverse events that could limit approval.

We have expanded access programs in the United States for patients with SM and GIST to receive investigational bezuclastinib after meeting certain eligibility criteria. These programs are uncontrolled, carried out by individual physicians and not typically conducted in strict compliance with GCPs, all of which can lead to a treatment effect that may differ from that in placebo-controlled trials. These programs provide only anecdotal evidence of efficacy and contain no control or comparator group for reference. This patient data is not designed to be aggregated or reported as study results. Moreover, expanded access programs provide supportive safety information for regulatory review, and many of the patients in our programs will have life-threatening illnesses where the risk for serious adverse events is high. If serious adverse events in these programs are determined to be bezuclastinib-related, they could have a negative impact on the safety profile of bezuclastinib, which could cause significant delays or an inability to successfully obtain regulatory approval with labeling that we consider desirable, if at all.

In addition, our supply capabilities may limit the number of patients who are able to enroll in the programs, which could prompt adverse publicity or other disruptions related to current or potential participants in these programs.

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.

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.

If 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. 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 approved products as well as 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 take an approved product or otherwise enroll in a trial being conducted by one of our competitors. Any delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, our expected timelines for delivering top-line results across all three of our active studies, and any subsequent regulatory approvals or commercialization activities.

Since the number of patients that we have dosed to date in some of 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 some of 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.

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. Collaborative relationships are generally complex and can give rise to disputes regarding the relative rights, including the ownership of intellectual property and associated rights and obligations, especially when the applicable collaborative provisions have not been fully negotiated and documented. 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.

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 on our intended timelines, if at all.

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 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, 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 and timelines.

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.

If any of our product candidates receive regulatory approval and we are not able to negotiate commercial supply terms with any third-party manufacturers, we may be unable to commercialize our products, 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 United States 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 and on sufficient timelines 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 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 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

Breakthrough Therapy Designation for bezuclastinib and our other product candidates or participation in the FDA's Real-Time Oncology Review ("RTOR") program may not lead to a faster development or review process.

We have been granted a Breakthrough Therapy Designation for bezuclastinib in the United States in NonAdvSM patients previously treated with avapritinib as well as in patients with SSM, both patient populations with no currently approved standard of care. We have also been granted Breakthrough Therapy Designation for bezuclastinib in combination with sunitinib in the United States for patients with GIST who have received prior treatment with imatinib. We may seek Breakthrough Therapy Designation for other current or future product candidates. Breakthrough Therapy Designation is intended to facilitate the development and expedite the review of new therapies to treat serious conditions with unmet medical needs by providing sponsors with the opportunity for frequent interactions with and additional drug development guidance from the FDA and its senior managers. Breakthrough Therapy Designation applies to the combination of the product candidate and the specific indication for which it is being studied. Product candidates that receive Breakthrough Therapy Designation may receive more frequent interactions with the FDA regarding the product candidate's development plan and clinical trials and may be eligible for the FDA's rolling or priority review.

Despite receiving Breakthrough Therapy Designation, bezuclastinib or other product candidates may not actually benefit from faster clinical development or regulatory review or approval any sooner than other product candidates that do not have such designation, or at all. Furthermore, such a designation does not increase the likelihood that bezuclastinib will receive marketing approval in the United States. The FDA may also rescind Breakthrough Therapy Designation if it determines that bezuclastinib no longer meets the relevant criteria.

In January 2026, we announced that the FDA agreed to accept our NDA for bezuclastinib in combination with sunitinib for patients with GIST who have received prior treatment with imatinib under the RTOR program, and shortly thereafter we initiated our NDA submission to FDA under this program. Our acceptance into RTOR does not guarantee or influence approval of our application, which is subject to the same statutory and regulatory requirements for approval as applications that are not included in RTOR. Although early approvals have occurred with applications selected for RTOR, this may not be the case for our application. If at any time the FDA determines our participation in RTOR is no longer appropriate, the FDA may rescind our acceptance and instruct us to follow routine submission procedures for marketing approval.

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 for three indications. 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 or our other drug candidates have or develop mutations that confer resistance to treatment. If patients have or develop resistance to treatment with bezuclastinib or our other 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.

We may seek priority review designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to faster development or regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months from the NDA filing date, rather than the standard review period of ten months. We may request priority review for bezuclastinib or any other product candidate. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily guarantee a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures and timelines. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

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

We are conducting clinical trials with our lead product candidate, bezuclastinib, in patients with GIST, AdvSM and NonAdvSM. We submitted the first NDA for bezuclastinib in NonAdvSM in 2025 and initiated our NDA for patients with GIST under the RTOR program in January 2026 and plan to submit an NDA for bezuclastinib in GIST in April 2026 and in AdvSM in the first half of 2026. The FDA may not agree with some or all of 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. Moreover, our clinical trial results may also not support approval.

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.

Evolving regulatory standards, including as a result of changes in government leadership, make it difficult to accurately predict the likelihood of marketing approval even when clinical trials meet their endpoints.

Regulatory standards are promulgated by various government entities and are subject to change based on factors such as scientific developments, public perceptions of risk, and political forces. Because clinical trials often take years to complete, it is sometimes possible for standards that exist during the conception and initiation of a clinical trial to change before the clinical trial is completed or ultimately reviewed by government regulators. For example, we may initiate clinical trials that are designed to show benefits on relatively short-term endpoints, but ultimately may be required to show benefits in longer-term outcome studies. While some government entities have safeguards intended to ensure standards agreed upon by sponsors and regulators at the outset of a clinical trial are applied during regulatory review processes, those safeguards generally permit regulators to apply more rigorous standards where regulators believe doing so is necessary. As such, there can be no assurance that regulatory standards that are appropriate at the outset of a clinical trial program will not become more rigorous during the regulatory approval process and could potentially result in a delayed approval or denial of marketing authorization.

In addition, the FDA, EMA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, including as a result of changes in leadership at the FDA and other federal agencies under the current U.S. administration, which may prevent or delay approval of our product candidates on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. In June 2024, the Supreme Court overruled the *Chevron* doctrine, which had given deference to regulatory agencies' statutory interpretations of ambiguous regulations in litigation against federal government agencies, such as the FDA. The overruling of the *Chevron* doctrine may significantly increase the number of challenges brought by companies and other stakeholders against federal agencies such as the FDA and its longstanding decisions and policies, including the FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.

Further, under the new leadership at the HHS under the current administration, agency reorganization, mass layoffs due to the reduction in force initiative and other measures implemented by the Department of Government Efficiency may impact the normal operations of the FDA as well as other federal agencies. FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines and may have a material impact on the industry and our clinical development plans. For example, average review times at the FDA have fluctuated in recent years as a result. Our business depends upon the ability of the FDA to accept and review our potential regulatory filings. If a prolonged government shutdown occurs or if a significant number of federal employees are laid off or leave federal agencies, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our ability to advance clinical development of our product candidates.

In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. In January 2025, an executive order entitled "Unleashing Prosperity Through Deregulation", was issued which calls for at least 10 existing regulations to be repealed whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation. Recent developments at the FDA include announcement of a plan to phase out animal testing for monoclonal antibodies and certain other drugs, the proposed rare disease evidence principles (RDEP) program to facilitate approval of drugs to treat rare diseases with very small patient populations with significant unmet medical need and with a known genetic defect that is the major driver of the pathophysiology, and the announcement of a new Commissioner's National Priority Voucher program for companies supporting certain U.S. national health priorities and interests. To the extent our competitors are selected for this new voucher pilot program, or are otherwise able to participate in any of these initiatives intended to accelerate drug development and application review, and obtain faster approval than us, our competitive position may be harmed. It is unclear how our industry and our clinical programs will be impacted by policies and regulations implemented under the current administration and FDA leadership, or other executive orders. There is significant uncertainty in the industry and how federal agencies like the FDA will change in the coming years under the current administration. To the extent the agency reorganization and other agency changes lead to disruptions in FDA's operations, our correspondence and regulatory review processes with the FDA may be materially delayed.

Even if we receive regulatory approval for any investigational product, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

Following potential approval of any our investigational products, the FDA may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a REMS as a condition of approval of our investigational products, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our investigational products, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our investigational products and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, if any of our investigational products are approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug and biological products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for an investigational product, physicians may nevertheless, in their independent medical judgment, prescribe it to their patients in a manner that is inconsistent with the approved label. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. If we are found to have promoted such off-label uses, we may become subject to liability. 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 sanctions.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our investigational products. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our investigational products. We also cannot predict the likelihood, nature or extent of government If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Pharmaceutical and biological product marketing is subject to substantial regulation in the United States. and any failure by us or our commercial and collaborative partners to comply with applicable statutes or regulations can adversely affect our business.

Any marketing activities associated with our product candidates, if approved for commercialization, will be subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical and biological products. The FDA regulates post-approval promotional labeling and advertising to ensure that they conform to statutory and regulatory requirements. In addition to FDA restrictions, the marketing of prescription drugs is subject to laws and regulations prohibiting fraud and abuse under government healthcare programs. Similarly, many states have similar statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, and, in some states, such statutes or regulations apply regardless of the payor. In addition, government authorities may also seek to hold us responsible for any failure of our commercialization or collaborative partners to comply with applicable statutes or regulations. If we, or our commercial or collaborative partners, fail to comply with applicable FDA regulations or other laws or regulations relating to the marketing of our product candidates, if approved for commercialization, we could be subject to criminal prosecution, civil penalties, seizure of products, injunctions and exclusion of our product candidates from reimbursement under government programs, as well as other regulatory or investigatory actions against our future product candidates, our commercial or collaborative partners or us.

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.

Many federal and state legislatures have considered, and adopted, healthcare policies intended to curb rising healthcare costs, such as the Inflation Reduction Act of 2022. These cost-containment measures may include, among other measures: requirements for pharmaceutical companies to negotiate prescription drug prices with government healthcare programs; controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government healthcare programs, including if drug prices increase at a higher rate than inflation; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; and public funding for cost effectiveness research, which may be used by government and private third-party payors to make coverage and payment decisions. In addition, in May 2025, the Trump administration issued an executive order entitled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," which, among other things, directs the HHS and other agencies to communicate most-favored-nation ("MFN") price targets to pharmaceutical manufacturers to bring prices for U.S. patients in line with comparably developed nations and to facilitate direct-to-consumer purchasing programs. The HHS subsequently issued guidance indicating the MFN target price is the lowest price paid in an Organization for Economic Co-operation and Development country with a gross domestic product ("GDP") per capita of at least 60% of the U.S. GDP per capita. It is currently unclear whether and to what extent these measures will be implemented and what impact any such implementation would have on our business. Further, there can be no assurance that the current administration or future administrations will not pursue different or additional measures that could impact drug pricing in the United States. Political, economic and regulatory developments may further complicate developments in healthcare systems and pharmaceutical drug pricing. These developments could, for example, impact our potential licensing agreements as commercial and collaborative partners may also consider the impact of these pressures on their licensing strategies.

Any new laws or regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the industry, could adversely affect our ability to successfully commercialize our product candidates. The implementation of any price controls, caps on prescription drugs or price transparency requirements could adversely affect our business, operating results and financial condition.

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.

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 and initiating additional clinical trials 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.

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. While we undertake efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is challenging and the outcome is unpredictable. In addition, courts outside of the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

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 in-licensed patent applications pending in Australia, Brazil, Canada, China, Egypt, Europe, India, Indonesia, Israel, Japan, Korea, Mexico, Philippines, Singapore, South Africa, and the United States. In addition, we have our own applications pending in the United States, Europe, Australia, Brazil, Canada, China, Colombia, Egypt, Indonesia, Israel, India, Japan, Korea, Mexico, New Zealand, Peru, Philippines, Russia, Singapore, Thailand, Vietnam, and South Africa as well as our own international patent application and United States provisional applications. 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.

In addition, patent grant standards by the U.S. Patent and Trademark Office (the "USPTO") and its foreign counterparts are not always uniform or predictable, and subject to change. For example, the America Invents Act enacted a number of changes to U.S. patent laws, which may prevent us from adequately protecting our or our licensors' inventions and discoveries, including our ability to seek injunctive relief, pursue infringement claims, and obtain substantial damage awards. An example of a major provision of the America Invents Act is the change in the U.S. patent policy from a first-to-invent to a first-to-file practice. Additionally, the USPTO and patent offices in other jurisdictions have often required that patent applications directed to pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Accordingly, even if we or our licensors are able to obtain patents, the patents might be substantially narrower than anticipated. Thus, there is no assurance as to the degree and range of protections any of our or our licensors' patents, if issued, may afford us or whether patents will be issues. Foreign counterparts to this law are also not uniform, and there is no worldwide policy governing the subject matter and scope of claims granted in a pharmaceutical or biotechnology patent. Uncertainty arising from changing laws can impact our ability to protect our or our licensors' patents and other proprietary rights.

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 or our licensors' 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 or our licensors' patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our or our licensors' 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 or our licensors' 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.

Patent terms may be inadequate to protect our competitive position on our product candidates and any future products for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The patent term of a U.S. patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent having an earlier expiration date.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a Patent Term Extension, or PTE, of up to five years beyond the normal expiration of the patent to compensate patent owners for loss of enforceable patent term due to the lengthy regulatory approval process. A PTE grant cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product approval. Further, PTE may only be applied once per product, and only with respect to an approved indication—in other words, only one patent (for example, covering the product itself, an approved use of said product, or a method of manufacturing said product) can be extended by PTE. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. We anticipate applying for PTE in the United States. Similar extensions may be available in other countries where we are prosecuting patents and we likewise anticipate applying for such extensions.

The granting of such patent term extensions is not guaranteed and is subject to numerous requirements. We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents, failure to exercise due diligence during the testing phase or regulatory review process or any other failure to satisfy any of the numerous applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our or our licensors' patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our or our licensors' patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates and future products.

As is the case with other biotechnology and biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain.

Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our or our licensors' existing patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our or our licensors' patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights.

Further, a new court system recently became operational in the European Union. The Unified Patent Court ("UPC"), began accepting patent cases on June 1, 2023. The UPC is a common patent court with jurisdiction over patent infringement and revocation proceedings effective for multiple member states of the European Union. The broad geographic reach of the UPC could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the individual European Union member states in which the European patent is validated. Under the UPC, a successful revocation proceeding for a European Patent under the UPC would result in loss of patent protection in those European Union countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European Union countries. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates. Moreover, the controlling laws and regulations of the UPC will develop over time and we cannot predict what the outcomes of cases tried before the UPC will be. The case law of the UPC may adversely affect our ability to enforce or defend the validity of our or our licensors' European patents. Patent owners have the option to opt-out their European Patents from the jurisdiction of the UPC, defaulting to pre-UPC enforcement mechanisms.

We may not be able to seek or obtain patent protection throughout the world or enforce such patent protection once obtained.

We may not be able to pursue patent coverage of our product candidates in certain countries outside of the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. The breadth and strength of our or our licensors' patents issued in foreign jurisdictions or regions may not be the same as the corresponding patents issued in the United States. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, or from selling or importing products made using our or our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to certain territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protections, particularly those relating to biotechnology and biopharmaceutical products. This difficulty with enforcing patents could make it difficult for us to stop the infringement of our or our licensors' patents or marketing of competing products otherwise generally in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our or our licensors' patents at risk of being invalidated or interpreted narrowly, put our or our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our trademarks of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. We may not be able to protect our rights to our trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

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, our Chief Commercial 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 experienced significant growth and expect to continue to expand our company to support research, development and commercial capabilities and may face challenges in managing our growth.

During the past two years we increased our headcount from 164 to 258 full time employees through the expansion of our research, development, manufacturing and G&A infrastructure. In addition, we are building an internal commercial organization as we prepare to launch bezuclastinib in the United States, and we expect our commercial organization to include up to 100 additional employees inclusive of both home office and field-based employees. We need to continue to recruit, train and retain qualified personnel to support our growth and we may be unable to do so effectively.

We continue to enhance our operational, financial and management controls and systems, reporting systems and infrastructure, and policies and procedures to support the establishment and maintenance of effective disclosure and financial controls and corporate governance. Our management and other personnel devote a substantial amount of time to these compliance initiatives, and these increase our legal and financial costs and make some activities more time-consuming and costly. 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. 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.

Further, as we launch bezuclastinib or as demand for bezuclastinib changes, our initial estimate of the size of the required field force may be materially more or less than the size of the field force actually required to effectively commercialize bezuclastinib. As such, we may be required to hire larger teams to adequately support the commercialization of our products and product candidates or we may incur excess costs in an effort to optimize the hiring of commercial personnel. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. See also "*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 on our intended timelines, if at all*." If our future collaborators do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product sales to sustain our business. We face competition from companies that currently have extensive and well-funded marketing and sales operations. Without a large internal team or the support of a third party to perform key commercial functions, we may be unable to compete successfully against these more established companies.

We may have difficulty building our sales, marketing and distribution infrastructure.

To market bezuclastinib or any approved product candidate in the future, we must continue building our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, as we do not presently have all of these capabilities.

To develop our internal sales, distribution and marketing capabilities, we must invest significant amounts of financial and management resources in the future. For bezuclastinib and any other drug products where we decide to perform sales, marketing and distribution functions ourselves, we could face a number of challenges, including that:

- we may not be able to attract, build and retain an effective marketing or sales organization;
- the cost of establishing, training and providing regulatory oversight for a marketing or sales force may not be justifiable in light of the revenue generated by any particular product;
- our direct or indirect sales and marketing efforts may not be successful; and
- there are significant legal and regulatory risks in drug marketing and sales that we have never faced, and any failure to comply with all legal and regulatory requirements for sales, marketing and distribution could result in enforcement action by the FDA or other authorities that could jeopardize our ability to market the product or could subject us to substantial liabilities.

Alternatively, we may rely on third parties to launch and market our future product candidates, if approved, and we may rely on third parties to launch and market bezuclastinib outside of the United States. We may have limited or no control over the sales, marketing and distribution activities of these third parties and our future revenue may depend on the success of these third parties. Additionally, if these third parties fail to comply with all applicable legal or regulatory requirements, the FDA or another governmental agency could take enforcement action that could jeopardize their ability and our ability to market our product candidates.

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, use and transmit personal information and sensitive information including intellectual property, proprietary business information, and health-related information, in connection with business operations. The secure maintenance of this information is critical to our operations and business strategy. Due to the size and complexity and the increasing amounts of confidential information that are maintained, our internal information technology systems and those of our third-party CROs, vendors and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security incidents or breaches from inadvertent or intentional actions by our employees and/or third parties with whom we do business, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, digital extortion, denial-of-service attacks, supply chain attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or those of our partners or lead to data leakage. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, similar events relating to the information technology systems of our third-party collaborators who we rely on for the manufacture of our product candidates and to conduct clinical trials could also have a material adverse effect on our business. In addition, changes in how our employees work and access our systems, when part of our workforce is working remotely, could also lead to opportunities for bad actors to launch cyber-attacks or for employees to cause inadvertent security risks or incidents. The prevalent use of mobile devices also increases the risk of data security incidents.

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, under certain circumstances, be subject to notification obligations to affected individuals and/or 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 which could take the form of, amongst other things, administrative fines, and the development and potential commercialization of our product candidates could be delayed. While we maintain cyber insurance at levels that we believe are appropriate for our business, we cannot assure our investors that it will be sufficient in type or amount to cover us against all claims related to security compromises or breaches, cyberattacks and other related breaches.

Risks Related to Our Financial Position and Need for Additional Capital

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

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

There can be no assurance that bezuclastinib or any other product candidate 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. The commercial success of our products, if approved, will depend on many factors, including, but not limited to:

- the availability of coverage and adequate and timely reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid and similar foreign authorities) and other third-party payors for our products;
- patients' ability and willingness to pay out-of-pocket for our products in the absence of coverage and/or adequate reimbursement from third-party payors;
- patient demand for our products;
- our ability to establish and enforce intellectual property rights in and to our products; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

Even if we succeed in commercializing bezuclastinib or any other product candidates we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We may require additional capital to finance our planned operations. 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 support the planned commercialization of bezuclastinib and continued clinical and preclinical development of our current and future product candidates. Even if bezuclastinib is approved, we may require significant additional funding in order to reach profitability, if ever, and to launch and commercialize any other product candidate. We cannot be certain that additional funding, if needed, 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.

Our ability to use net operating losses and tax credit carryforwards 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, we have 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 our 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. As of December 31, 2025, approximately $73.0 million and $1.5 million of federal and state net operating losses, respectively, were subject to the July 2020 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 our 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. We have not performed a Section 382 analysis since December 2020. Subsequent ownership changes, as defined by Section 382, may potentially further limit the amount of net operating loss and tax credit carryforwards that could be utilized to offset future taxable income and tax.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For example, the United States enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act eliminated the previously available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. The One Big Beautiful Bill Act, enacted in 2025, permits the expensing of certain research and development expenditures in the United States incurred in tax years beginning in 2025, while amortization over fifteen years continues to be required for foreign-based expenditures. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business condition.

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 35% of our outstanding common stock as of December 31, 2025. 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.

Risks Related to our Convertible Notes

Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under the notes.

As of December 31, 2025, we had $230.0 million in aggregate principal of Convertible Notes (the "Notes") outstanding, and we may incur additional indebtedness to meet future financing needs. The interest rate for the Notes is fixed at 1.625% per annum and is payable semi-annually in arrears on May 15 and November 15 of each year, beginning on May 15, 2026. Our ability to make scheduled payments of the principal, to pay interest on or to refinance our indebtedness, or to make cash payments in connection with any conversions of the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional debt financing or equity capital on terms that may be onerous or highly dilutive. Our ability to refinance any future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

In addition, our indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences. For example, it could:

- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry and competitive conditions and adverse changes in government regulation;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- place us at a disadvantage compared to our competitors who have less debt;
- limit our ability to borrow additional amounts to fund acquisitions, for working capital and for other general corporate purposes; and
- make an acquisition of our company less attractive or more difficult.

Any of these factors could harm our business, prospects, operating results and financial condition. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase.

We may be unable to raise the funds necessary to repurchase the Notes for cash following a fundamental change or to pay any cash amounts due upon maturity or conversion of the Notes.

Noteholders may, subject to a limited exception, require us to repurchase their Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. Upon maturity of the Notes, we must pay their principal amount and accrued and unpaid interest in cash, unless they have been previously converted, redeemed, or repurchased. In addition, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), all conversions of Notes will be settled partially or entirely in cash. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Notes or pay any cash amounts due upon their maturity or conversion. In addition, applicable law or regulatory authorities may restrict our ability to repurchase the Notes or to pay any cash amounts due upon their maturity or conversion. Our failure to repurchase the Notes or to pay any cash amounts due upon their maturity or conversion when required will constitute a default under the indenture. We may not have sufficient funds to satisfy all amounts due under the Notes.

The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and results of operations.

In the event the conditional conversion feature of the Notes is triggered, noteholders will be entitled to convert their Notes at any time during specified periods at their option. If one or more noteholders elect to convert their Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if noteholders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

Transactions relating to the Notes may affect the value of our common stock.

The conversion of some or all of the Notes would dilute the ownership interests of existing stockholders to the extent we satisfy our conversion obligation by delivering shares of our common stock upon any conversion of such Notes. The Notes may become convertible in the future at the option of their holders under certain circumstances. If holders of the Notes elect to convert their Notes, we may settle our conversion obligation by delivering to them a significant number of shares of our common stock, which would cause dilution to our existing stockholders.

The accounting method for the Notes could adversely affect our reported financial condition and results.

The accounting method for reflecting the Notes on our consolidated balance sheet, accruing interest expense for the Notes and reflecting the underlying shares of our common stock in our reported diluted earnings per share may adversely affect our reported earnings and financial condition.

In accordance with applicable accounting standards, the Notes are reflected as a liability on our balance sheets, with the initial carrying amount equal to the principal amount of the Notes, net of issuance costs. The issuance costs will be treated as a debt discount for accounting purposes, which will be amortized into interest expense over the term of the Notes. As a result of this amortization, the interest expense that we expect to recognize for the Notes for accounting purposes will be greater than the cash interest payments we will pay on the Notes, which will result in lower reported income.

Under this method, diluted earnings per share is generally calculated assuming that all the Notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the if-converted method may reduce our reported diluted earnings per share to the extent we are profitable in the future, and accounting standards may change in the future in a manner that may adversely affect our diluted earnings per share.

Furthermore, if any of the conditions to the convertibility of the Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the Notes as a current, rather than a long-term, liability. This reclassification could be required even if no noteholders convert their Notes and could materially reduce our reported working capital.

The conversion of the Notes could impair our financial position and liquidity.

Unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we must settle at least a portion of our conversion obligation in cash, and therefore, the conversion of the Notes could materially and adversely affect our financial position and liquidity. Before August 15, 2031, noteholders will have the right to convert their Notes only upon the occurrence of certain events. From and after August 15, 2031, noteholders may convert their Notes at any time at their election until the close of business on the scheduled trading day immediately before the maturity date. However, many of the conditions that permit the conversion of the Notes before August 15, 2031 are beyond our control. We could be required to expend a significant amount of cash to settle conversions, which could significantly harm our financial position and liquidity.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cyber Risk Management and Strategy

We have developed and maintain processes designed to assess, identify, and manage cybersecurity risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. The scope of these processes includes risks that may be associated with both our internally managed IT systems and key business functions and sensitive data operated or managed by or maintained at third-party service providers. These processes are managed and monitored by a dedicated information technology team, which is led by our Vice President, IT, who reports to our Chief Technology Officer, and include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable information technology environment. We monitor our information technology environment for abnormal behavior, conduct penetration and vulnerability testing, data recovery testing, security audits, and ongoing risk assessments, including due diligence on our key technology vendors and other third-party service providers that have access to the personal information we collect, use, store, and transmit. We also conduct periodic employee trainings on cyber and information security, among other topics. We leverage standard industry tools from a software and hardware perspective and maintain a cybersecurity risk insurance policy.

Our processes are designed to comply with the EU-U.S. DPF, the UK Extension to the EU-U.S. DPF, and the Swiss-U.S. DPF and have accordingly certified our adherence to the respective DPF principles to the U.S. Department of Commerce with regard to the processing of personal data received from the EU, UK and Switzerland respectively. This includes compliance with the information security requirements of the DPF that prescribe that organizations creating, maintaining, using or disseminating personal data must take reasonable and appropriate measures to protect it from loss, misuse and unauthorized access, disclosure, alteration and destruction, taking into due account the risks involved in the processing and the nature of the personal data.

In addition, we consult with outside advisors and experts on a regular basis to assist with assessing, identifying, and managing cybersecurity risks, including to anticipate future threats and trends, and their impact on our risk environment. 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 pursuant to the European Union and UK General Data Protection Regulation and has served in this capacity since May 2021.

We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework. Since the beginning of the last fiscal year, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks threats that, if realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks we face is discussed in Part I, Item 1A, "Risk Factors," under the heading "Risks Related to Employee Matters and Managing Growth."

Governance Related to Cybersecurity Risks

The Board of Directors, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee, which is comprised solely of independent directors, has been designated by our Board to oversee cybersecurity risks. The Audit Committee receives periodic updates on cybersecurity and information technology matters and related risk exposures. The Board also receives updates from management and the Audit Committee on cybersecurity risks on at least an annual basis.

Our Vice President, IT, who reports to the Chief Technology Officer, a member of the executive team, has over 20 years of experience managing information technology and cybersecurity matters. The Vice President, IT and the Chief Technology Officer, together with our senior leadership team, are responsible for assessing and managing cybersecurity risks and they work collaboratively across our company to implement policies and procedures designed to protect our information and systems from cybersecurity threats and to respond promptly to any material cybersecurity incidents in accordance with our incident response plans. A cross-functional team is responsible for responding to cybersecurity incidents.

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.

In September 2025, we entered into a new lease agreement pursuant to which we will lease approximately 31,518 square feet of office space in Waltham, Massachusetts. This will serve as our corporate headquarters and replace our existing headquarters in Waltham, Massachusetts. This lease is expected to commence in May 2026.

Boulder, Colorado

We lease approximately 44,657 square feet of office and laboratory space in Boulder, Colorado. The lease has an initial term of 12 years, commencing in June 2022 and expiring in June 2035, with the option to extend for three successive five-year terms. This facility primarily houses our research and other administrative personnel.

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."

Holders of Our Common Stock

As of February 13, 2026, there were approximately 3 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.

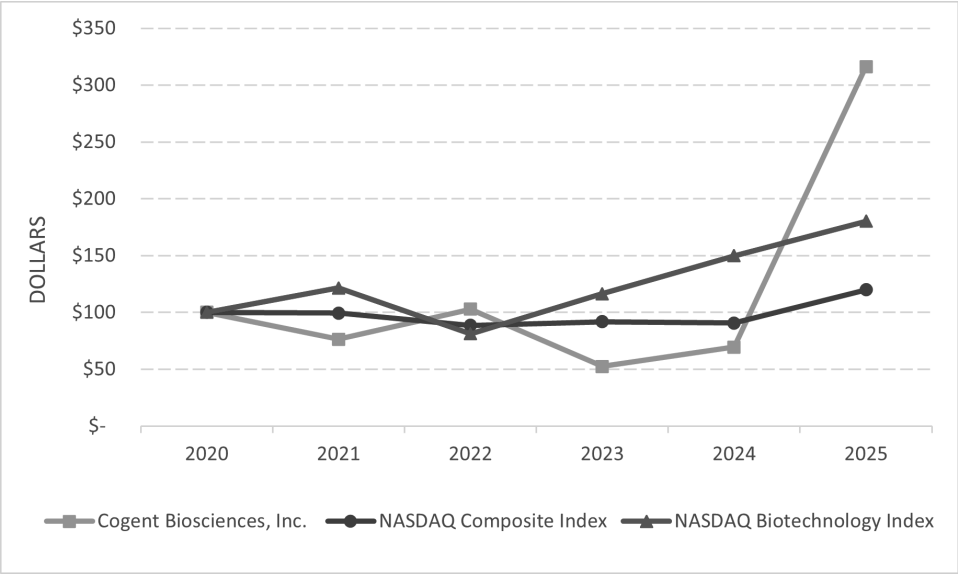
Dividends

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.

Stock Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the Securities and Exchange Commission ("SEC"), for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, nor shall such information be incorporated by reference into any future filing under the Exchange Act or Securities Act of 1933, as amended, or the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following performance graph compares the performance of our common stock to the Nasdaq Composite Index and to the Nasdaq Biotechnology Index from December 31, 2020 through December 31, 2025. The comparison assumes $100 was invested in our common stock and in each of the foregoing indices after the market closed on December 31, 2020, and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of, nor is it intended to forecast, future stock price performance.



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. The discussion below presents a discussion of our financial condition and results of operations for fiscal years 2025 and 2024. See Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on February 25, 2025, for a discussion of our financial condition and results of operations for the fiscal year ended December 31, 2024 and comparison to the fiscal year ended December 31, 2023.

Overview

We are a clinical-stage biotechnology company focused on developing precision therapies for genetically defined diseases. Our approach is to design rational precision therapies that treat the underlying cause of disease and improve the lives of patients. Our most advanced program is bezuclastinib, also known as CGT9486, a highly selective tyrosine kinase inhibitor that is designed to potently inhibit the KIT D816V mutation as well as other mutations in KIT exon 17. In the vast majority of cases, KIT D816V is responsible for driving Systemic Mastocytosis ("SM"), a serious and rare disease caused by unchecked proliferation of mast cells. Exon 17 mutations are also found in patients with advanced gastrointestinal stromal tumors ("GIST"), a type of cancer with strong dependence on oncogenic KIT signaling. Bezuclastinib is a highly selective and potent KIT inhibitor with the potential to provide a new treatment option for these patient populations. We are developing bezuclastinib to treat patients living with Non-Advanced Systemic Mastocytosis ("NonAdvSM"), Advanced Systemic Mastocytosis ("AdvSM") and GIST, and in 2025 we reported positive top-line results from registrational trials in each of these indications.

We believe bezuclastinib represents a significant commercial opportunity across each of these indications. Based on internal analyses and external market research, we estimate a global annual market opportunity of over $4 billion for bezuclastinib in combination with sunitinib as a potential second-line treatment for patients with GIST, approximately $3.5 billion for the treatment of patients with NonAdvSM, and approximately $500 million for the treatment of patients with AdvSM. We are building an internal commercial organization and expect to launch bezuclastinib commercially in the United States in the second half of 2026, pending regulatory approval.

We also have an ongoing Phase 1 study of our novel internally developed FGFR2/3 inhibitor and have initiated a Phase 1 study of our CNS-penetrant, selective mutant ErbB2 inhibitor. In addition, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases targeting mutations in PI3Kα, KRAS and JAK2.

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 mast 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 SM patients present with NonAdvSM and 10% of patients present with AdvSM, a rare and 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").

SUMMIT is our registration-directed randomized, global, multicenter, double-blind, placebo-controlled, multi-part Phase 2 clinical trial for patients with NonAdvSM. The study is designed to explore the safety and efficacy of bezuclastinib in patients with moderate to severe NonAdvSM, which includes Indolent Systemic Mastocytosis ("ISM"), Smoldering Systemic Mastocytosis ("SSM") and Bone Marrow Mastocytosis. APEX is our registration-directed global, open-label, multi-center, Phase 2 clinical trial in patients with AdvSM evaluating the safety, efficacy, pharmacokinetic, and pharmacodynamic profiles of bezuclastinib. We reported top-line results from our SUMMIT trial in July 2025 and full results in December 2025, as well as top-line results from our APEX trial in December 2025, all of which were positive and achieved all primary and key secondary endpoints.

We submitted the first New Drug Application ("NDA") for bezuclastinib in patients with NonAdvSM in December 2025 and expect to submit an NDA in the first half of 2026 for patients with AdvSM. In October 2025, the FDA granted Breakthrough Therapy Designation for bezuclastinib in NonAdvSM patients previously treated with avapritinib as well as in patients with SSM, both patient populations with no currently approved standard of care. The U.S. Food and Drug Administration ("FDA") and European Medicines Agency ("EMA") have granted orphan drug designation to bezuclastinib for the treatment of Mastocytosis.

In addition, in 2025, we initiated an expanded access program in the United States to allow eligible SM patients to receive investigational bezuclastinib prior to potential regulatory approval.

Bezuclastinib - GIST

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

PEAK 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. We announced positive top-line results from PEAK in November 2025, which demonstrated a substantial and highly statistically significant clinical benefit on the primary endpoint of progression free survival ("PFS"). Median PFS was 16.5 months for the bezuclastinib combination vs. 9.2 months for sunitinib monotherapy, and the bezuclastinib combination reduced the risk of disease progression or death by 50% compared to sunitinib monotherapy. In January 2026, we announced that the FDA agreed to accept our NDA for bezuclastinib in combination with sunitinib for patients with GIST who have received prior treatment with imatinib under the Real-Time Oncology Review ("RTOR") program, and shortly thereafter we initiated our NDA submission to FDA under this program. We expect to complete the GIST NDA submission in April 2026. In January 2026, the FDA also granted Breakthrough Therapy Designation ("BTD") for bezuclastinib in combination with sunitinib for patients with GIST who have received prior treatment with imatinib. Bezuclastinib has been granted orphan drug designation for the treatment of GIST by the FDA and under the Orphan Drug Act and the European Medicines Agency ("EMA").

In mid-2026, we expect to initiate a Phase 2 trial investigating the benefit of the bezuclastinib plus sunitinib combination for first-line GIST patients with exon 9 mutations who are naive to, or recently initiated treatment with, imatinib.

In 2025, we initiated an expanded access program in the United States for patients affected with advanced, metastatic, and/or unresectable GIST, intolerant to imatinib or received prior imatinib therapy for treatment that resulted in disease progression, and who meet other inclusion and exclusion criteria.

Other Bezuclastinib Information

Worldwide rights to develop and commercialize bezuclastinib are exclusively licensed from Plexxikon Inc., a member of the Daiichi Sankyo Group ("Plexxikon"). Under the terms of the license agreement, Plexxikon received an upfront payment and is eligible for additional development milestones of up to $7.5 million upon the satisfaction of certain clinical milestones and up to $25.0 million upon the satisfaction of certain regulatory milestones. During the second quarter of 2022, as a result of the progression of the PEAK study, the first clinical milestone was achieved, resulting in payment of $2.5 million to Plexxikon in June 2022. In the fourth quarter of 2025, $5.0 million became payable on achievement of regulatory milestones and another $15.0 million may become payable in the next twelve months as a result of achievement of additional regulatory milestones.

Patents protecting bezuclastinib include composition of matter claims which have been issued in the United States and other key territories and provide exclusivity through 2033 and potentially beyond through patent term extensions. In addition, we have pending patent applications in the United States and other key territories that seeks to protect our optimized formulation of bezuclastinib, which could potentially provide exclusivity through at least 2043, as well as a pending U.S. provisional patent application directed to methods of administering bezuclastinib, which could potentially provide exclusivity through at least 2046.

CGT4859 (FGFR2/3)

Fibroblast growth factor receptor ("FGFR") mutations are well-established oncogenic drivers in multiple diseases, but approved medicines fail to capture the full landscape of FGFR altered tumor types, with FGFR1-mediated hyperphosphatemia serving as the most common dose-limiting toxicity for pan-FGFR inhibitors. We are actively enrolling our Phase 1 study of CGT4859 in patients with tumors bearing FGFR2/3 mutations, including advanced cholangiocarcinoma. The trial will explore the safety, tolerability and clinical activity of escalating doses of CGT4859 with a goal of selecting an active and well tolerated dose for further clinical investigation. We expect to share clinical data from our Phase 1 study in 2026.

CGT4255 (ErbB2)

We are also advancing a novel, ErbB2 mutant program, which is focused on actionable and underserved mutations in a variety of solid tumor systemic and CNS involved indications. HER2 alterations such as amplification, overexpression, insertions, and point mutations, are established oncogenic drivers in many solid tumors. Activating HER2 mutations are found in 2-4% of advanced lung cancers and have emerged as mechanisms of acquired resistance to targeted therapies. Patients with HER2 mutant lung tumors develop more brain metastasis during treatment than patients with any other oncogenic drivers in lung cancer. Addressing brain metastasis in this group of patients remains a clinical challenge with limited therapeutic options. Approved HER2 tyrosine kinase inhibitors have inferior potency against key mutations and lack sufficient brain penetration to be an impactful treatment option for patients with brain metastasis. We received clearance from the FDA on our investigational new drug application ("IND") submission for CGT4255 and initiated a Phase 1 dose escalation study in the fourth quarter of 2025.

CGT6297 (PI3Kα)

Our research team is developing a potential best-in-class, wild-type-sparing, PI3Kα inhibitor that provides coverage of both the H1047R mutation as well as E542K and E545K helical mutants, which affects >30,000 cancer patients each year. The phosphoinositide 3-kinase ("PI3K") pathway is a key cell cycle regulating pathway that has an established role in tumor growth and development. PI3Kα mutations are highly prevalent in many solid tumors and are present in 36% of all breast cancer patients. The approved agents for these patients often lead to dose limitations, resulting from activity against wild-type PI3Kα. IND-enabling studies have been completed for CGT6297 and we submitted an IND application for this program in the fourth quarter of 2025. We expect to initiate a Phase 1 dose escalation in the first quarter of 2026.

Research Programs

KRAS

Our research team is developing a potent and selective KRAS inhibitor. Mutations in KRAS are among the most prevalent mutations found in cancer, occurring most often in colorectal cancer, non-small cell lung cancer and pancreatic cancer. We plan submit an IND for this program in 2026.

JAK2

Our research team is developing a novel, wild-type-sparing, JAK2 V617F mutant-selective inhibitor. The JAK2 V617F mutation is the most prevalent molecular abnormality in BCR-ABL-negative myeloproliferative neoplasms, occurring in approximately 95% of patients with polycythemia vera, and 50% of patients with essential thrombocythemia or primary myelofibrosis. We plan to submit an IND for this program in 2026.

Financial Operations Overview

Since our inception in 2014, we have focused significant efforts and financial resources on establishing and protecting our intellectual property portfolio, conducting research and development of our product candidates, manufacturing drug product material for use in preclinical studies and clinical trials, staffing our company, and raising capital. We do not have any products approved for sale and have not generated any revenue from product sales. Our net loss was $328.9 million for the year ended December 31, 2025 compared to net loss of $255.9 million for the year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of $1,188.4 million. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- 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;
- 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;
- maintain, expand, and protect our intellectual property portfolio;
- add operational, financial, and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.
- 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; and
- hire additional research, clinical, scientific, and commercial personnel.

We will not generate revenue from product sales unless and until we 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.

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, 2025, we had cash, cash equivalents and marketable securities of $900.8 million. We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into 2028, including through potential FDA approval of bezuclastinib and commercial launch for SM and GIST.

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;
- the cost of developing and manufacturing material for use in our preclinical studies and clinical trials, including under agreements with consultants and third party contractors and contract manufacturing organizations;
- 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 do not allocate employee costs, laboratory supplies, software 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. 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.

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

- the timing and progress of our preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered, or may enter, into collaboration arrangements;
- our ability to maintain our current research and development programs and to establish new ones;
- the enrollment rates in our clinical trials;
- our ability to establish new licensing or collaboration arrangements;
- the future productivity of the Cogent Research Team in Boulder, CO and its ability to discover new product candidates and build our pipeline;
- the successful completion of clinical trials with safety, tolerability, and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the success in establishing and operating a manufacturing facility, or securing manufacturing supply through relationships with third parties;

- our ability to obtain and maintain patents, trade secret protection, and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved;
- the acceptance of our product candidates, if approved, by patients, the medical community, and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our therapies following approval.

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

General and Administrative Expenses

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

Interest Income

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

Interest Expense

Interest expense consists of interest incurred on the Notes and Credit Facility (as defined below) and associated amortization of issuance costs and the accretion of debt discount.

Loss on Debt Extinguishment

Loss on debt extinguishment consists of loss incurred related to the extinguishment of our Credit Facility.

Other Income (Expense), Net

Other income (expense), net consists of miscellaneous income and expense unrelated to our core operations.

Income Taxes

Since our inception, we have not recorded any current or deferred tax benefit for the net losses we have incurred in each year or for our tax credits generated, as we believe, based upon the weight of available evidence, that it is more likely than not that our net operating loss carryforwards and tax credits will not be realized. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2025. We reevaluate the utilization of net operating loss carryforwards and tax credits at each reporting period. As of December 31, 2025, we had U.S. federal and state net operating loss carryforwards of $428.3 million and $170.8 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, 2025, $425.0 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, 2025, we had U.S. federal and state research and development tax credit carryforwards of $28.8 million and $6.0 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2040 and 2035, respectively. We also had federal orphan drug tax credits of $37.1 million which may be available to offset future income tax liabilities and begin to expire in 2041.

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

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

On July 4, 2025, the President signed the One Big Beautiful Bill Act. Included in this legislation are provisions that allow for the immediate expensing of domestic U.S. research and development expenses, a general requirement to reduce the deduction for research and development expense by any research credit taken, and reinstates 100% bonus depreciation on qualified property placed in service before January 19, 2025. We have evaluated the impact of the enacted legislation and have determined there is no material impact to the consolidated financial statements.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
		(in thousands)	
Operating expenses:			
Research and development	$ 269,780	$ 232,658	$ 37,122
General and administrative	63,583	43,281	20,302
Total operating expenses	333,363	275,939	57,424
Loss from operations	(333,363)	(275,939)	(57,424)
Other income:			
Interest income	14,689	18,088	(3,399)
Interest expense	(3,062)	—	(3,062)
Loss on debt extinguishment	(7,181)	—	(7,181)
Other income (expense), net	(20)	1,992	(2,012)
Total other income, net	4,426	20,080	(15,654)
Net loss	$ (328,937)	$ (255,859)	$ (73,078)

Research and Development Expenses

The following table summarizes our research and development expenses for the year ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
		(in thousands)	
Direct external research and development expenses:			
Bezuclastinib	$ 120,059	$ 120,862	$ (803)
Early-stage, preclinical and discovery programs	40,112	28,141	11,971
Unallocated expenses:			
Personnel related (including stock-based compensation)	87,116	66,009	21,107
Laboratory supplies, facility related and other	22,493	17,646	4,847
Total research and development expenses	$ 269,780	$ 232,658	$ 37,122

Total research and development expense increased by $37.1 million for the year ended December 31, 2025 compared to the year ended December 31, 2024. R&D expense includes activity related to the manufacture and development of bezuclastinib, including costs related to our ongoing SUMMIT, PEAK and APEX clinical trials and costs incurred to support our completed and planned NDA filings for NonAdvSM, AdvSM and GIST. This also includes increased costs associated with the progression of our early stage, preclinical and discovery programs. There was also 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, 2025 compared to the year ended December 31, 2024.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2025 were $63.6 million, compared to $43.3 million for the year ended December 31, 2024. The increase in general and administrative expenses was primarily due to higher personnel and support costs due to the growth of the organization, including costs to support our planned commercial launch.

Interest Income

Interest income for the year ended December 31, 2025 was $14.7 million, compared to $18.1 million for the year ended December 31, 2024. The decrease is due to lower interest rates and lower average invested balances in cash equivalents and marketable securities.

Interest Expense

Interest expense for the year ended December 31, 2025 was $3.1 million related to the Notes and Credit Facility and associated amortization of financing costs and the accretion of debt discount. Interest expense for the year ended December 31, 2024 was nil.

Loss on Debt Extinguishment

Loss on debt extinguishment for the December 31, 2025 was $7.2 million related to the extinguishment of our Credit Facility. Loss on debt extinguishment for the year ended December 31, 2024 was nil.

Other Income (Expense), Net

Other income, net for the year ended December 31, 2025 was less than $0.1 million, compared to $2.0 million for the year ended December 31, 2024. For the year ended December 31, 2025, other income represented miscellaneous expense, while for the year ended December 31, 2024, other income represented a milestone payment received related to the 2020 sale of our legacy assets.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates and have generated only limited revenue to date from funding arrangements with our former collaboration partner. While we may generate revenue in the future from the sale of a product candidate, any such revenue would depend on successful regulatory approval and commercial launch. We have historically funded our operations primarily through the public offering and private placement of our securities, issuance of debt, and consideration received from our collaborative agreements.

On May 6, 2022, 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, in an at the market offering ("ATM") registered under a shelf registration statement on Form S-3. On November 7, 2025, we amended the Sales Agreement to increase the aggregate offering price to up to $300.0 million. In 2025 and cumulatively under the Sales Agreement, 7,623,189 shares have been sold for aggregate net proceeds of approximately $159.3 million, after deducting issuances costs of $4.9 million.

On June 11, 2025, we entered into a loan and security agreement (the "Loan and Security Agreement") with SLR Investment Corp. ("SLR") and the other lenders party thereto, which provides for a non-dilutive term loan facility (the "Credit Facility") of up to an aggregate principal amount of $400.0 million, of which a first tranche of $50.0 million was fully funded upon closing of the financing transaction, with future tranches at our election subject to achievement of milestones. No other tranches were drawn under the Credit Facility. The Credit Facility was repaid in full, including accrued interest and associated fees, in November 2025 and the Loan and Security Agreement was terminated.

On July 10, 2025, we completed an underwritten public offering of 25,555,556 shares of our common stock at a public offering price of $9.00 per share (including the exercise in full by the underwriters of their 30-day option to purchase up to 3,333,333 additional shares of common stock). The net proceeds from the offering were approximately $215.8 million, after deducting the underwriting discounts and commissions and offering expenses.

On November 13, 2025, we completed an underwritten public offering of 9,677,420 shares of our common stock at a public offering price of $31.00 per share (including the exercise in full by the underwriters of their 30-day option to purchase up to 1,451,613 additional shares of common stock). The net proceeds from the offering were approximately $324.0 million, after deducting the underwriting discounts and commissions and offering expenses.

On November 18, 2025, we completed an underwritten public offering of $230.0 million aggregate principal amount of our 1.625% convertible senior notes due 2031 ("the Notes") (including the exercise in full of the 30-day option to purchase up to an additional $30.0 million aggregate principal amount of the Notes). The Notes are general, unsecured, senior obligations of the Company. The Notes will accrue interest payable semi-annually in arrears on May 15 and November 15 of each year, beginning on May 15, 2026, at a rate equal to 1.625% per year. The Notes will mature on November 15, 2031, unless earlier converted, redeemed or repurchased by us. Net proceeds from the offering were approximately $222.8 million, after deducting customary underwriting discounts and offering expenses.

As of December 31, 2025, we have 182,955,584 shares outstanding on an as-converted basis, which consists of (i) 160,980,024 shares of common stock outstanding, (ii) pre-funded warrants that are exercisable for 606,060 shares of common stock, (iii) 67,414 shares of Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock") that are convertible into 16,853,500 shares of common stock, and (iv) 4,516 shares of Series B Non-Voting Convertible Preferred Stock ("Series B Preferred Stock") that are convertible into 4,516,000 shares of common stock.

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $900.8 million. We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into 2028, including through potential FDA approval of bezuclastinib and commercial launch for SM and GIST.

Cash Flows

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

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (264,444)	$ (207,791)
Net cash provided by (used in) investing activities	(399,526)	38,276
Net cash provided by financing activities	878,233	214,451
Net increase in cash, cash equivalents and restricted cash	$ 214,263	$ 44,936

Operating Activities

During the year ended December 31, 2025, operating activities used $264.4 million of cash, primarily resulting from our net loss of $328.9 million, partially offset by changes in our operating assets and liabilities of $8.0 million and net non-cash charges of $56.5 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2025 consisted primarily of a $8.2 million increase in accounts payable and accrued expenses and other current liabilities and a $1.6 million decrease in other assets, partially offset by a $1.6 million decrease in operating lease liabilities and a $0.2 million increase in prepaid expenses and other current assets.

During the year ended December 31, 2024, operating activities used $207.8 million of cash, primarily resulting from our net loss of $255.9 million, partially offset by changes in our operating assets and liabilities of $11.6 million and net non-cash charges of $36.5 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2024 consisted primarily of a $17.3 million increase in accounts payable and accrued expenses and other current liabilities, partially offset by a $1.4 million decrease in operating lease liabilities and a $4.3 million increase in prepaid expenses and other current assets.

Investing Activities

During the year ended December 31, 2025, net cash used in investing activities was $399.5 million, which consisted of purchases of marketable securities and property and equipment, partially offset by maturities and sales of marketable securities.

During the year ended December 31, 2024, net cash provided by investing activities was $38.3 million, which consisted of maturities and sales of marketable securities, partially offset by purchases of marketable securities and property and equipment.

Financing Activities

During the year ended December 31, 2025, net cash provided by financing activities was $878.2 million, which consisted of $539.8 million in proceeds from the issuance of common stock in public offerings, net of paid offering costs, $222.8 million in proceeds from the Notes, net of paid issuance costs, $159.3 million in proceeds from the issuance of common stock under the ATM, net of paid issuance costs, $47.0 million in proceeds from the Credit Facility, net of paid issuance costs, proceeds from the issuance of common stock under the ESPP and proceeds from the issuance of common stock upon stock option exercises, partially offset by the repayment of the Credit Facility and taxes paid related to net share settlement of equity awards.

During the year ended December 31, 2024, net cash provided by financing activities was $214.5 million, which consisted of $213.3 million in proceeds from the issuance of common stock and Series B Preferred Stock in a private placement, net of paid offering costs, proceeds from the issuance of common stock under the Employee Stock Purchase Plan, and proceeds from the issuance of common stock upon stock option exercises.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we prepare to commercialize bezuclastinib (if approved), 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:

- 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 regulatory decisions, including failure to receive regulatory approval of our product candidates;
- the initiation, progress, timing, and completion of preclinical studies and clinical trials for our current and future potential product candidates;
- our ability to obtain adequate product supply for any approved product or our inability to do so at acceptable prices;
- our ability to establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain regulatory approval;
- our ability to commercialize our product candidates or gain market acceptance by physicians, patients, third-party payors, and others in the medical community;
- 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;
- 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 ability to establish collaborations, if desired or needed;
- additions or departures of key scientific or management personnel; and
- unanticipated serious safety concerns related to the use of our product candidates.

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $900.8 million. We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into 2028, including through potential FDA approval of bezuclastinib and commercial launch for SM and GIST. 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.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, additional 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, 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.

We estimate the fair value of our stock options granted 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.

We measure the fair value of stock-based awards with market-based vesting conditions on the date of grant using a Monte Carlo simulation model.

For performance-based stock awards, 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. For awards with market conditions, the stock-based compensation expense will be recognized over the derived service period regardless of whether the award achieves the market condition and will only be adjusted to the extent the service condition is not met.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

A description of our material cash requirements, including commitments for capital expenditures, is described above and disclosed in Note 9 and Note 10 to our consolidated financial statements appearing elsewhere in this Annual Report.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2025 and 2024, we had cash, cash equivalents and marketable securities of $900.8 million and $287.1 million, respectively, consisting primarily of money market funds and investments in U.S. government agency securities and treasury obligations.

Interest Rate Risk

We are subject to interest rate risk on our investment portfolio. We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve capital, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of credit exposure. Some of the securities we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate.

Our investment exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our portfolio, changes in the market value due to changes in interest rates and other market factors, as well as the increase or decrease in any realized gains and losses. Our investment portfolio includes only marketable securities and instruments with active secondary or resale markets to help ensure portfolio liquidity. A hypothetical 100 basis point increase or decrease in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest sensitive financial instruments, but may affect our future earnings and cash flows. We generally have the ability to hold our fixed-income investments to maturity and, therefore, do not expect that our operating results, financial position or cash flows will be materially impacted due to a sudden change in interest rates. However, our future investment income may fall short of expectations due to changes in interest rates, or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates or other factors, such as changes in credit risk related to the securities' issuers. To minimize this risk, we schedule our investments to have maturities that coincide with our expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we do not believe that we have material exposure to interest rate risk arising from our investments. Generally, our investments are not collateralized. We have not realized any significant losses from our investments.

We do not use interest rate derivative instruments to manage exposure to interest rate changes. We seek to ensure the safety and preservation of invested principal funds by limiting default risk, market risk and reinvestment risk. Our policy is to reduce default risk by investing in investment grade securities.

Inflation Risk

Inflation generally impacts us by potentially increasing our operating expenses, including clinical trial costs. We do not believe that inflation has had a material impact on our business or results of operations during the periods for which the consolidated financial statements are presented in this report. Significant adverse changes in inflation could negatively impact our future results of operations.

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.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Cogent Biosciences, Inc. and its subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2025, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued External Research and Development Expenses

As described in Notes 2 and 5 to the consolidated financial statements, the Company has entered into various research and development contracts with companies both inside and outside of the United States. Management records accruals for estimated ongoing external research and development costs. When billing terms under these contracts do not coincide with the timing of when the work is performed, management is required to make estimates of outstanding liabilities to the third parties as of the end of the reporting period. When evaluating the adequacy of the accrued liabilities, management analyzes progress of the studies or trials, including the phase or completion of events, communication from the contract research organizations or other companies of any actual costs incurred during the period that have not yet been invoiced, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Within accrued expenses and other current liabilities, total accrued external research and development expense is $20.1 million as of December 31, 2025.

The principal considerations for our determination that performing procedures relating to accrued external research and development expenses is a critical audit matter are (i) the significant judgment by management in developing the estimate of accrued external research and development expenses and (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures related to management's development of the estimate of accrued external research and development expenses.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's estimate of accrued external research and development expenses. These procedures also included, among others, (i) testing management's process for developing the estimate of accrued external research and development expenses; (ii) evaluating the appropriateness of the method used by management to develop the estimate; (iii) testing the completeness and accuracy of the underlying data used in the estimate; and (iv) evaluating the reasonableness of management's estimate of accrued external research and development expenses by (a) testing the completeness and accuracy of costs incurred, on a sample basis, by tracing information to the underlying contracts, purchase orders, invoices and information received from contract research organizations or other companies, as applicable, and (b) evaluating the reasonableness of the estimated costs incurred for the services that have not been invoiced, on a sample basis, by tracing to underlying supporting documentation, such as underlying contracts, purchase orders and information received from contract research organizations or other companies, as applicable.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
February 17, 2026

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,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 312,012	$ 98,165
Short-term marketable securities	588,753	188,912
Prepaid expenses and other current assets	9,590	9,395
Total current assets	910,355	296,472
Operating lease, right-of-use assets	18,078	20,097
Property and equipment, net	5,457	6,467
Restricted cash	416	—
Other assets	3,301	4,862
Total assets	$ 937,607	$ 327,898
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,504	$ 12,013
Accrued expenses and other current liabilities	52,902	42,132
Operating lease liabilities	1,547	1,565
Total current liabilities	63,953	55,710
Convertible senior notes, net	222,895	—
Operating lease liabilities, net of current portion	14,355	15,902
Other liabilities	33	—
Total liabilities	301,236	71,612
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 8,979,420 shares authorized; no shares issued or outstanding	—	—
Series A non-voting convertible preferred stock, $0.001 par value; 1,000,000 shares authorized; 67,414 and 70,465 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	53,830	56,515
Series B non-voting convertible preferred stock, $0.001 par value; 20,580 shares authorized; 4,516 and 6,868 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	35,563	54,085
Common stock, $0.001 par value; 300,000,000 shares authorized; 160,980,024 shares and 110,461,729 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	161	110
Additional paid-in capital	1,734,882	1,004,612
Accumulated other comprehensive income	355	447
Accumulated deficit	(1,188,420)	(859,483)
Total stockholders' equity	636,371	256,286
Total liabilities and stockholders' equity	$ 937,607	$ 327,898

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,		
	2025	2024	2023
Operating expenses:			
Research and development	$ 269,780	$ 232,658	$ 173,755
General and administrative	63,583	43,281	34,375
Total operating expenses	333,363	275,939	208,130
Loss from operations	(333,363)	(275,939)	(208,130)
Other income:			
Interest income	14,689	18,088	13,077
Interest expense	(3,062)	—	—
Loss on debt extinguishment	(7,181)	—	—
Change in fair value of CVR liability	—	—	1,700
Other income (expense), net	(20)	1,992	943
Total other income, net	4,426	20,080	15,720
Net loss	$ (328,937)	$ (255,859)	$ (192,410)
Net loss per share, basic and diluted, Series A non-voting convertible preferred stock	$ (538.96)	$ (484.85)	$ (486.23)
Weighted average Series A non-voting convertible preferred stock outstanding, basic and diluted	67,600	73,350	77,085
Net loss per share, basic and diluted, Series B non-voting convertible preferred stock	$ (2,155.80)	$ (1,939.47)	$ —
Weighted average Series B non-voting convertible preferred stock outstanding, basic and diluted	6,778	9,731	—
Net loss per share, basic and diluted, common stock	$ (2.16)	$ (1.94)	$ (1.94)
Weighted average common stock outstanding, basic and diluted	128,899,408	103,856,611	79,657,942
Comprehensive loss:			
Net loss	$ (328,937)	$ (255,859)	$ (192,410)
Other comprehensive income (loss):			
Net unrealized gains (losses) on marketable securities	(92)	201	350
Total other comprehensive income (loss)	(92)	201	350
Comprehensive loss	$ (329,029)	$ (255,658)	$ (192,060)

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		Series B Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Income) Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2022	81,050	$ 65,830	—	$ —	69,893,434	$ 70	$ 601,153	$ (104)	$ (411,214)	$ 255,735
Issuance of common stock in underwritten public offering, net of offering costs of $10.7 million	—	—	—	—	14,375,000	14	161,775	—	—	161,789
Conversion of Series A non-voting convertible preferred stock into common stock	(6,585)	(5,795)	—	—	1,646,250	2	5,793	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	85,878	—	752	—	—	752
Issuance of common stock from exercises	—	—	—	—	123,687	—	965	—	—	965
Unrealized gains on marketable securities	—	—	—	—	—	—	—	350	—	350
Stock-based compensation expense	—	—	—	—	—	—	30,621	—	—	30,621
Net loss	—	—	—	—	—	—	—	—	(192,410)	(192,410)
Balances at December 31, 2023	74,465	$ 60,035	—	$ —	86,124,249	$ 86	$ 801,059	$ 246	$ (603,624)	$ 257,802
Issuance of Series B non-voting convertible preferred stock and common stock, net of issuance costs of $11.7 million, in connection with the Private Placement	—	—	12,280	87,311	17,717,997	18	125,958	—	—	213,287
Exchange of common stock for Series B non-voting convertible preferred stock	—	—	8,300	74,754	(8,300,000)	(8)	(74,746)	—	—	—
Conversion of Series B non-voting convertible preferred stock into common stock	—	—	(13,712)	(107,980)	13,712,000	13	107,967	—	—	—
Conversion of Series A non-voting convertible preferred stock into common stock	(4,000)	(3,520)	—	—	1,000,000	1	3,519	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	176,893	—	916	—	—	916
Issuance of common stock from exercises	—	—	—	—	30,590	—	199	—	—	199
Unrealized gains on marketable securities	—	—	—	—	—	—	—	201	—	201
Stock-based compensation expense	—	—	—	—	—	—	39,740	—	—	39,740
Net loss	—	—	—	—	—	—	—	—	(255,859)	(255,859)
Balances at December 31, 2024	70,465	$ 56,515	6,868	$ 54,085	110,461,729	$ 110	$ 1,004,612	$ 447	$ (859,483)	$ 256,286
Issuance of common stock in underwritten public offerings, net of offering costs of $35.3 million	—	—	—	—	36,684,589	37	539,675	—	—	539,712
Issuance of common stock under ATM, net of issuance costs of $4.9 million	—	—	—	—	7,623,189	8	159,315	—	—	159,323
Conversion of Series A non-voting preferred stock into common stock	(3,051)	(2,685)	—	—	762,750	1	2,684	—	—	—
Conversion of Series B non-voting preferred stock into common stock	—	—	(2,352)	(18,522)	2,352,000	2	18,520	—	—	—
Restricted stock units vesting	—	—	—	—	2,794,000	—	—			—
Shares withheld related to net share settlement of equity awards	—	—	—	—	(1,239,443)	—	(48,896)			(48,896)
Issuance of common stock from exercises	—	—	—	—	1,327,446	2	11,544	—	—	11,546
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	213,764	1	1,349	—	—	1,350
Stock-based compensation expense	—	—	—	—	—	—	46,079	—	—	46,079
Unrealized losses on marketable securities	—	—	—	—	—	—	—	(92)	—	(92)
Net loss	—	—	—	—	—	—	—	—	(328,937)	(328,937)
Balances at December 31, 2025	67,414	$ 53,830	4,516	$ 35,563	160,980,024	$ 161	$ 1,734,882	$ 355	$ (1,188,420)	$ 636,371

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,		
	2025	**2024**	**2023**
Cash flows from operating activities:			
Net loss	$ (328,937)	$ (255,859)	$ (192,410)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	2,564	2,450	2,270
Stock-based compensation expense	46,079	39,740	30,621
Amortization of right-of-use operating lease assets	2,019	1,901	1,318
Change in fair value of CVR liability	—	—	(1,700)
Net amortization (accretion) of premiums (discounts) on marketable securities	(1,962)	(7,619)	(5,173)
Loss on disposal of property and equipment	—	—	8
Amortization of debt discount and issuance costs	601	—	—
Loss on debt extinguishment	7,181	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(195)	(4,334)	(626)
Other assets	1,561	2	(119)
Accounts payable	(2,509)	1,358	4,813
Accrued expenses and other current liabilities	10,686	15,956	8,170
Operating lease liability	(1,565)	(1,386)	(796)
Other liabilities	33	—	—
Net cash used in operating activities	(264,444)	(207,791)	(153,624)
Cash flows from investing activities:			
Purchases of property and equipment	(1,554)	(573)	(2,796)
Purchases of marketable securities	(687,171)	(255,603)	(348,803)
Maturities and sales of marketable securities	289,199	294,452	253,775
Net cash provided by (used in) investing activities	(399,526)	38,276	(97,824)
Cash flows from financing activities:			
Proceeds from long-term debt	49,291	—	—
Repayment of long-term debt	(54,635)	—	—
Proceeds from convertible senior notes	223,100	—	—
Payment of debt issuance costs	(2,622)	—	—
Proceeds from issuance of common stock in public offerings, net of offering costs of $35.3 million	539,776	—	—
Proceeds from issuance of common stock in public offering, net of offering costs of $10.7 million	—	—	161,819
Proceeds from issuance of common stock under ATM, net of issuance costs of $4.9 million	159,323	—	—
Proceeds from issuance of common stock and Series B non-voting convertible preferred stock in connection with the Private Placement, net of offering costs $11.7 million	—	213,336	—
Taxes paid related to net share settlement of equity awards	(48,896)	—	—
Proceeds from issuance of common stock upon stock option exercises	11,546	199	965
Proceeds from issuance of stock from employee stock purchase plan	1,350	916	752
Net cash provided by financing activities	878,233	214,451	163,536
Net increase (decrease) in cash, cash equivalents and restricted cash	214,263	44,936	(87,912)
Cash, cash equivalents and restricted cash at beginning of period	98,165	53,229	141,141
Cash, cash equivalents and restricted cash at end of period	$ 312,428	$ 98,165	$ 53,229
Supplemental disclosure of cash flow information:			
Cash paid for interest	2,015	—	—
Supplemental disclosure of noncash investing and financing information:			
Debt discount included in accrued expenses and other liabilities	20	—	—
Offering costs included in accounts payable and accrued expenses	64	49	30
Property & equipment included in accounts payable and accrued expenses	—	—	43
Conversion of Series A Preferred Stock into common stock	2,685	3,520	5,795
Conversion of Series B Preferred Stock into common stock	18,522	107,980	—

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 clinical-stage biotechnology company focused on developing precision therapies for genetically defined diseases. Cogent's approach is to design rational precision therapies that treat the underlying cause of disease and improve the lives of patients. Cogent's most advanced program is bezuclastinib, also known as CGT9486, a highly selective tyrosine kinase inhibitor that is designed to potently inhibit the KIT D816V mutation as well as other mutations in KIT exon 17. In the vast majority of cases, KIT D816V is responsible for driving Systemic Mastocytosis ("SM"), a serious and rare disease caused by unchecked proliferation of mast cells. Exon 17 mutations are also found in patients with advanced gastrointestinal stromal tumors ("GIST"), a type of cancer with strong dependence on oncogenic KIT signaling. Bezuclastinib is a highly selective and potent KIT inhibitor with the potential to provide a new treatment option for these patient populations. The Company is developing bezuclastinib to treat patients living with Non-Advanced Systemic Mastocytosis ("NonAdvSM"), Advanced Systemic Mastocytosis ("AdvSM") and GIST. The Company is building an internal commercial organization and expects to launch bezuclastinib commercially in the United State in the second half of 2026, pending regulatory approval. The Company also has an ongoing Phase 1 study of its novel internally developed FGFR2/3 inhibitor and has initiated a Phase 1 study of its CNS-penetrant, selective mutant ErbB2 inhibitor. In addition, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases targeting mutations in PI3Kα, KRAS and JAK2.

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 $328.9 million for the year ended December 31, 2025. As of December 31, 2025, the Company had an accumulated deficit of $1,188.4 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 or other marketing and distribution arrangements, partnerships, joint ventures, combinations or divestitures of one or more of its assets or businesses. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborative arrangements or divest its assets. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. Arrangements with collaborators or others may require the Company to relinquish rights to certain of its technologies or product candidates. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate its research and development programs or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations.

The Company's 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 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 generally three months or less at the date of purchase to be cash equivalents.

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 and operating lease right-of-use assets. 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.

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.

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 external research and development costs. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding liabilities to those third parties as of the end of the reporting period. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, communication from the contract research organizations or other companies of any actual costs incurred during the period that have not yet been invoiced, 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.

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.

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.

The Company estimates the fair value of stock-based options granted 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. The Company based its estimate of expected volatility on a blended volatility of the volatility of the Company's stock price and 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.

The Company measures the fair value of stock-based awards with market-based vesting conditions on the date of grant using a Monte Carlo simulation model.

For performance-based stock awards, 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. For awards with market conditions, the stock-based compensation expense will be recognized over the derived service period regardless of whether the award achieves the market condition and will only be adjusted to the extent the service condition is not met.

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 years ended December 31, 2025, 2024 and 2023, the Company's only element of other comprehensive loss was unrealized gains (losses) on marketable securities.

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 December 2023, the FASB issued ASU 2023-09 Income Taxes (Topic 740): Improvements to Income Tax Disclosures related to income tax disclosure requirements. The pronouncement enhances the transparency and decision usefulness of income tax disclosures. The pronouncement is effective for annual periods beginning after December 15, 2024. The Company adopted ASU 2023-09 effective January 1, 2025, with no material impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. The new standard requires additional disclosure of the nature of expenses included in the income statement as well as disclosures about specific types of expenses included in the expense captions presented in the income statement. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The Company is currently evaluating the impact of the ASU on its consolidated financial statements.

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

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

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury bills and notes (due within one year)	$ 588,397	$ 363	$ (7)	$ 588,753
	$ 588,397	$ 363	$ (7)	$ 588,753

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury bills and notes (due within one year)	$ 188,465	$ 451	$ (4)	$ 188,912
	$ 188,465	$ 451	$ (4)	$ 188,912

As of December 31, 2025, the Company held one security that was 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, 2025 was $40.0 million and there were no securities held by the Company in an unrealized loss position for more than twelve months. As of December 31, 2024, the Company held three 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, 2024 was $8.9 million and there were no securities held by the Company in an unrealized loss position for more than twelve months. The Company has the intent and ability to hold such securities until recovery. As a result, the Company did not record any charges for impairments for its marketable debt securities for the years ended December 31, 2025, 2024 or 2023.

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

	Fair Value Measurements at December 31, 2025 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 213,102	$ —	$ —	$ 213,102
Marketable securities:				
U.S. Treasury bills and notes	$ —	$ 588,753	$ —	$ 588,753
Total Assets	$ 213,102	$ 588,753	$ —	$ 801,855

	Fair Value Measurements at December 31, 2024 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 85,946	$ —	$ —	$ 85,946
Marketable securities:				
U.S. Treasury bills and notes	$ —	$ 188,912	$ —	$ 188,912
Total Assets	$ 85,946	$ 188,912	$ —	$ 274,858

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

During the years ended December 31, 2025, 2024, and 2023, 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,	
	2025	2024
Laboratory equipment	$ 8,847	$ 8,083
Computer equipment and software	887	819
Furniture and fixtures	1,176	1,176
Leasehold improvements	2,463	2,463
Construction-in-progress	763	41
Total property and equipment	14,136	12,582
Accumulated depreciation	(8,679)	(6,115)
Property and equipment, net	$ 5,457	$ 6,467

Depreciation and amortization expense was $2.6 million, $2.5 million and $2.3 million for the years ended December 31, 2025, 2024 and 2023, respectively.

5. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2025	2024
Accrued employee compensation and benefits	$ 15,740	$ 12,259
Accrued external research and development expense	20,052	19,957
Accrued external manufacturing costs	3,805	6,548
Accrued professional and consulting services	6,560	2,995
Other	6,745	373
	$ 52,902	$ 42,132

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

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

Series A Non-Voting Convertible Preferred Stock

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

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

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

Series B Non-Voting Convertible Preferred Stock

On February 13, 2024, the Company entered into a Securities Purchase Agreement for a private placement (the "Private Placement") with certain institutional and accredited investors (each, a "Purchaser" and collectively, the "Purchasers"), pursuant to which the Purchasers purchased (i) an aggregate of 17,717,997 shares of the Company's common stock at a price per share of $7.50, and (ii) 12,280 shares of the Company's Series B Preferred Stock, at a price per share of $7,500.00. Net proceeds were approximately $213.3 million after deducting placement fees and offering costs. On February 14, 2024, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of the Series B Non-Voting Convertible Preferred Stock with the Secretary of State of the State of Delaware (the "Series B Certificate of Designation") in connection with the Private Placement. The Series B Certificate of Designation provided for the issuance of up to 12,280 shares of Series B Preferred Stock, par value $0.001 per share. Subsequently, on March 21, 2024, the Company entered into exchange agreements with certain of the Purchasers (the "Exchange Stockholders"), pursuant to which the Exchange Stockholders agreed to exchange an aggregate of 8,300,000 shares of the Company's common stock, for an aggregate of 8,300 shares of the Company's Series B Preferred Stock (the "Exchange"). On March 21, 2024, in connection with the Exchange, the Company filed a Certificate of Amendment to the Series B Certificate of Designation to increase the number of authorized shares of Series B Preferred Stock from 12,280 to 20,580.

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

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

Cumulatively, through December 31, 2025, 95,911 shares of Series A Preferred Stock, or 58.7% of the previously issued Series A Preferred Stock, have been converted into 23,977,750 shares of common stock. The 67,414 shares of Series A Preferred Stock outstanding as of December 31, 2025 are convertible into 16,853,500 shares of common stock. Cumulatively, through December 31, 2025, 16,064 shares of the Series B Preferred Stock, or 78.1% of the previously issued Series B Preferred Stock, have been converted into 16,064,000 shares of common stock. The 4,516 shares of Series B Preferred Stock outstanding as of December 31, 2025 are convertible into 4,516,000 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, 2025.

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.

On May 6, 2022, 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, in an at the market offering ("ATM") registered under a shelf registration statement on Form S-3. On November 7, 2025, the Company amended the Sales Agreement to increase the aggregate offering price to up to $300.0 million. As of December 31, 2025, 7,623,189 shares have been sold under the Sales Agreement for net proceeds of approximately $159.3 million.

The Company issued certain pre-funded warrants in 2022. Each pre-funded warrant entitles the holder to purchase shares of common stock at an exercise price of $0.01 per share and is exercisable at any time beginning on the date of issuance. These warrants were recorded as a component of stockholders' equity within additional paid-in capital. Per the terms of the warrant agreement, a holder of the outstanding warrant is not entitled to exercise any portion of the pre-funded warrant if, upon giving effect to such exercise, would cause the aggregate number of shares of common stock beneficially owned by such holder (together with its affiliates and any other person whose beneficial ownership of common stock would be aggregated with the holder) to exceed 9.99% of the total number of then issued and outstanding shares of common stock, as such percentage ownership is determined in accordance with the terms of the pre-funded warrant and subject to such holder's rights under the pre-funded warrant to increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from such holder. As of December 31, 2025, 2,424,242 pre-funded warrants have been exercised and 606,060 pre-funded warrants remain outstanding. In January 2026, the remaining 606,060 pre-funded warrants were exercised.

On July 10, 2025, the Company completed an underwritten public offering of 25,555,556 shares of the Company's common stock at a public offering price of $9.00 per share (including the exercise in full by the underwriters of their 30-day option to purchase up to 3,333,333 additional shares of common stock). The net proceeds from the offering were approximately $215.8 million, after deducting the underwriting discounts and commissions of $13.8 million and offering expenses of $0.4 million.

On November 11, 2025, the Company completed an underwritten public offering of 9,677,420 shares of the Company's common stock at a public offering price of $31.00 per share (including the exercise in full by the underwriters of their 30-day option to purchase up to 1,451,613 additional shares of common stock). The net proceeds from the offering were approximately $324.0 million, after deducting the underwriting discounts and commissions of $20.7 million and offering expenses of $0.3 million.

At the Company's 2024 annual meeting of stockholders on June 5, 2024, the Company's stockholders approved an amendment to the Company's Third Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") (the "Amendment"), to increase the number of authorized shares of common stock from 150,000,000 to 300,000,000 and the Company filed a Certificate of Amendment to the Certificate of Incorporation with the Secretary of State of the State of Delaware to effect the Amendment, which became effective immediately upon such filing. Pursuant to the terms of the Series B Certificate of Designation, on June 10, 2024, 13,712 shares of Series B Preferred Stock automatically converted to 13,712,000 shares of common stock, and 4,516 shares of Series B Preferred Stock remain outstanding as of December 31, 2025.

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. At the Company's 2021 annual stockholder meeting, the Company's stockholders approved the amendment and restatement of the 2018 Plan to increase the number of shares of common stock issuable under the 2018 Plan by 6,000,000 shares. At the Company's 2023 annual stockholder meeting, the Company's stockholders approved the amendment and restatement of the 2018 Plan to increase the number of shares of common stock issuable under the 2018 Plan by an additional 6,000,000 shares.

The shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by the Company under the 2018 Plan or the 2015 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan.

As of December 31, 2025, 527,142 shares of common stock remain available for issuance under the 2018 Plan, excluding the 2025 Executive PSUs (as defined below) granted in October 2025 which were subject to forfeiture in the event sufficient shares were not added to the equity pool under the Company's 2018 Plan on January 1, 2026 via the evergreen refresh provision. The number of authorized shares reserved for issuance under the 2018 Plan was increased by 6,439,201 shares effective as of January 1, 2026.

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. The number of shares initially reserved for issuance under the Inducement Plan was 3,750,000, subject to adjustment for stock dividends, stock splits, or other changes in Cogent's common stock or capital structure. As of December 31, 2025, 1,353,095 shares of common stock remain available for issuance under the Inducement Plan.

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

2018 Employee Stock Purchase Plan

The Company's 2018 Employee Stock Purchase Plan (the "ESPP") became effective on March 28, 2018, at which time a total of 78,500 shares of common stock were reserved for issuance. In addition, the number of shares of common stock that may be issued under the ESPP automatically increases on each January 1 through January 1, 2027, by the least of (i) 125,000 shares of common stock, (ii) 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or (iii) such lesser number of shares as determined by the ESPP administrator. As of December 31, 2025, 302,733 shares remain available for issuance under the ESPP. In January 2026, 173,128 shares were issued to employees 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, 2026.

Performance-based restricted stock units

In February 2023, the board of directors approved grants to executives in aggregate of up to 2,500,000 PSUs ("2023 Executive PSUs") under the 2018 Plan, which grants were subject to forfeiture in the event that the Company's stockholders did not approve an increase to the number of shares reserved for issuance under the 2018 Plan (the "2023 Pool Increase"). On June 7, 2023, stockholders approved the 2023 Pool Increase and a grant date was established for accounting purposes for these PSUs in accordance with *ASC 718 Compensation- Stock Compensation*. An award holder can generally receive between 0% and 200% of the target award based on achievement of specified stock price hurdles and/or research and development milestones over a three-year performance period ending in February 2026. Any PSUs earned will vest, if at all, in a single tranche in February 2026 subject to a condition of continuing employment through the end of the performance period. The Company granted an additional 214,000 2023 Executive PSUs to the Chief Commercial Officer upon his start date with the same terms and conditions as the awards granted in 2023. The fair value of the market-based awards was estimated on the date of grant for accounting purposes using a Monte Carlo simulation model. The fair value of the performance-based awards was based on the closing share price of the Company's common stock on the accounting grant date. On December 17, 2025, after achievement of 200% of the target awards, the Company's Board of Directors approved the acceleration of vesting on the 2023 Executive PSUs and the Company recognized the remaining expense of $1.1 million in the fourth quarter of 2025.

In October 2025, the Board of Directors approved grants to executives in aggregate of up to 3,650,000 PSUs ("2025 Executive PSUs") under the 2018 Plan. An award holder can generally receive between 0% and 200% of the target award based on achievement of specified stock price hurdles or research and commercial milestones over a three-year performance period ending in December 2028. Any 2025 Executive PSUs earned will vest, if at all, in a single tranche in December 2028 subject to a condition of continuing employment through the end of the performance period. The fair value of the market-based awards was estimated on the date of grant for accounting purposes using a Monte Carlo simulation model. The fair value of the performance-based awards was based on the closing share price of the Company's common stock on the accounting grant date. As of December 31, 2025, the maximum number awards were earned as a result of the achievement of the maximum stock price target.

During the year ended December 31, 2025, the Company granted 340,000 performance-based restricted stock units to certain non-executives ("Non-executive PSUs") under the 2018 Plan. These awards are subject to the holders' continuous service to the Company through each applicable vesting event. As of December 31, 2025, one of the performance milestones was determined to be probable of achievement.

Stock Options

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,		
	2025	2024	2023
Risk-free interest rate	4.3%	4.1%	3.9%
Expected volatility	85.4%	84.7%	76.7%
Expected dividend yield	—	—	—
Expected life (in years)	6.06	6.06	6.01

The following table summarizes activity under the 2018 Plan and the Inducement Plan, excluding performance-based and time-based restricted stock units:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	21,497,158	$ 8.83		
Granted	7,538,879	12.67		
Exercised	(1,327,446)	8.70		
Forfeited	(349,024)	8.89		
Outstanding as of December 31, 2025	27,359,567	$ 9.90	7.21	$ 747,167
Vested and expected to vest as of December 31, 2025	27,358,567	$ 9.90	7.21	$ 747,167
Options exercisable as of December 31, 2025	16,783,067	$ 9.13	6.25	$ 469,808

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, 2025, 2024 and 2023 was $28.0 million, $0.1 million and $0.6 million, respectively. The weighted average grant-date fair value of awards granted during the years ended December 31, 2025, 2024 and 2023 was $9.52 per share, $4.40 per share and $9.12 per share, respectively.

Performance-based restricted stock units

The following table summarizes the activity of performance-based restricted stock units:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Unvested as of December 31, 2024	2,714,000	$ 7.63
Granted	3,990,000	10.39
Vested	(2,714,000)	7.63
Forfeited	—	—
Unvested as of December 31, 2025	3,990,000	$ 10.39

The 2023 Executive PSUs that vested in the year ended December 31, 2025, were net-share settled and the Company withheld shares with value equivalent to the employees' minimum statutory obligation for the applicable income and other employment taxes and remitted the cash to the appropriate taxing authorities. The total shares withheld were 1,239,443, based on the value of the awards on the issuance date as determined by the Company's closing stock price. Total payments for the employees' tax obligations to taxing authorities were $48.9 million in the year ended December 31, 2025, and are reflected as a financing activity within the accompanying Consolidated Statements of Cash Flows.

Time-based restricted stock units

During the year ended December 31, 2025, the Company granted time-based restricted stock units to employees with service-based vesting conditions. The time-based restricted stock units vest over the 2 year service period. The following table summarizes the activity of time-based restricted stock units:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Unvested as of December 31, 2024	80,000	$ 4.54
Granted	539,000	39.45
Vested	(80,000)	4.54
Forfeited	—	—
Unvested as of December 31, 2025	539,000	$ 39.45

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,		
	2025	2024	2023
Risk-free interest rate	4.3%	5.2%	4.0%
Expected volatility	68.2%	112.1%	75.7%
Expected dividend yield	—	—	—
Expected life (in years)	0.50	0.50	0.50

Stock-Based Compensation

The following table summarizes stock-based compensation expense during the years ended December 31, 2025, 2024, 2023 *(in thousands)*:

	Year Ended December 31,		
	2025	2024	2023
Stock-based compensation expense by type of award:			
Time-based stock options	$ 30,847	$ 30,222	$ 26,012
Performance-based restricted stock units	14,087	8,665	4,196
Time-based restricted stock units	367	211	—
Employee stock purchase plan	778	642	413
Total	$ 46,079	$ 39,740	$ 30,621

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,		
	2025	2024	2023
Research and development expenses	$ 23,081	$ 18,965	$ 14,595
General and administrative expenses	22,998	20,775	16,026
Total	$ 46,079	$ 39,740	$ 30,621

As of December 31, 2025, total unrecognized compensation cost related to the unvested time-based stock options and time-based restricted stock units was $83.6 million and $21.1 million, respectively, which is expected to be recognized over a weighted average period of 2.62 years and 3.96 years, respectively.

As of December 31, 2025, total unrecognized compensation cost related to the unvested 2025 Executive PSUs was $35.8 million based on the maximum achievement of 200% of the target award, which is expected to be recognized ratably over a weighted average period of 3.0 years.

8. Income Taxes

During the years ended December 31, 2025, 2024 and 2023, the Company recorded no current or deferred income tax benefits due to its full valuation allowance. The Company had no foreign operations.

As further described in Note 2, Summary of Significant Accounting Policies, we have elected to prospectively adopt the guidance in *ASU 2023-09*. The following table is a reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate for the year ended December 31, 2025 in accordance with *ASU 2023-09 (in thousands, except percent)*:

	Year Ended December 31, 2025	
	Amount	*Percent*
U.S. federal statutory income tax rate	$ (69,077)	21.0%
State and local income taxes, net of federal income tax effect[(1)]	—	—
Tax credits:		
Research and development tax credits	(9,050)	2.8
Orphan Drug tax credits	(11,321)	3.4
Changes in the valuation allowance	88,129	(26.8)
Nontaxable or nondeductible items:		
Stock-based compensation	(20,089)	6.1
Non-deductible executive compensation	21,355	(6.5)
Other	53	—
Effective income tax rate	$ —	0.0%

[(1)] State tax in Massachusetts accounted for the majority (greater than 50%) of the tax effect in this category, offset with a valuation allowance.

The following table is a reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate for the years ended December 31, 2024 and 2023, in accordance with the guidance prior to the adoption of *ASU 2023-09*:

	Year Ended December 31,	
	2024	2023
Federal statutory income tax rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(1.9)	(4.8)
Federal and state tax credits	(7.9)	(7.9)
Rate change	4.4	(2.3)
Nondeductible stock compensation	2.4	1.8
Other items	—	(0.9)
Change in valuation allowance	24.0	35.1
Effective income tax rate	0.0%	0.0%

The Company's net deferred tax assets as of December 31, 2025 and 2024 consisted of the following *(in thousands)*:

	December 31,	
	2025	2024
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 100,592	$ 64,299
Tax credits	70,591	48,961
Accrued expenses	3,636	2,901
Capitalized research and development expense	122,334	90,525
Operating lease right-of-use assets	(4,118)	(4,688)
Operating lease liabilities	4,678	5,271
Stock compensation	10,885	9,992
Other	2,432	1,291
Total deferred tax assets	311,030	218,552
Valuation allowance	(311,030)	(218,552)
Net deferred tax assets	$ —	$ —

As of December 31, 2025, the Company had U.S. federal and state net operating loss carryforwards of $428.3 million and $170.8 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, 2025, $425.0 million is available to be carried forward indefinitely but can only offset 80% of taxable income per year. As of December 31, 2025, the Company had U.S. federal and state research and development tax credit carryforwards of $28.8 million and $6.0 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2040 and 2035, respectively. The Company also had federal orphan drug tax credits of $37.1 million which may be available to offset future income tax liabilities and begin to expire in 2041.

Utilization of the U.S. federal and state net operating loss carryforwards and tax credit carryforwards may be subject to 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. As of December 31, 2025, approximately $73.0 million and $1.5 million of federal and state net operating losses, respectively, were subject to the July 2020 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. Subsequent ownership changes, as defined by Section 382, may potentially further limit the amount of net operating loss and tax credit carryforwards that could be utilized to offset future taxable income and tax.

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, 2025, 2024, and 2023. Management reevaluates the positive and negative evidence at each reporting period.

The changes in the valuation allowance during the years ended December 31, 2025, 2024 and 2023 primarily related to net operating loss carryforwards, tax credits generated and capitalized research and development expenses. Changes were as follows *(in thousands)*:

	Year Ended December 31,		
	2025	2024	2023
Valuation allowance as of beginning of year	$ 218,552	$ 157,070	$ 89,544
Decreases recorded to income tax provision	—	—	—
Increases recorded to income tax provision	92,478	61,482	67,526
Valuation allowance as of end of year	$ 311,030	$ 218,552	$ 157,070

As of December 31, 2025, 2024, and 2023, 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 from 2022 to the present, with certain states open from 2021 to the present. The Company's tax attributes related to years prior to 2022 can still be adjusted under audit.

For the period ended December 31, 2025, the Company had no provision for income taxes and made no income tax payments. The only tax payments during the period related to excise taxes.

9. Commitments and Contingencies

Operating Leases

Corporate Headquarters - Waltham, MA

On March 19, 2022, the Company and Cimpress USA Incorporated ("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, 2025 and 2024.

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.

Future Corporate Headquarters - Waltham, MA

On September 5, 2025, the Company and BP THIRD AVENUE LLC ("BP") entered into a lease agreement (the "Waltham Lease") pursuant to which the Company will lease approximately 31,518 square feet of office space in Waltham, Massachusetts, which will serve as its corporate headquarters and replace its existing headquarters in Waltham, Massachusetts.

The term of the Waltham Lease will commence when BP has substantially completed all construction and the office space is ready for occupancy, which is expected to be in May 2026 (the "Commencement Date"). The Waltham Lease will have a term of 7 years and 10 months from the Commencement Date, and the Company has an option to extend the term of the Waltham Lease for an additional five-year period. The Company's obligation to pay base rent begins 5 months after the Commencement Date at an initial rate of $32.00 per square foot. Rent will be payable in equal monthly installments and subject to annual increases of $1.00 per square foot over the term. Additionally, the Company is required to pay its share of operating expenses and property taxes as additional rent. In connection with the Waltham Lease, the Company deposited with BP a letter of credit in the amount of approximately $0.3 million as a security deposit which is recorded in Restricted Cash in the consolidated balance sheet as of December 31, 2025.

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").

The Boulder Lease has an initial term of 12 years with the option to extend for three successive five-year terms. Boulder Lease payments began in June 2023 after an initial free rent period. Rent is 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, 2025 and 2024.

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.

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

	2025	2024	2023
Lease cost			
Operating lease cost	$ 3,295	$ 3,295	$ 3,796
Variable lease cost[1]	714	807	687
Sublease income	—	—	(950)
Total lease cost	$ 4,009	$ 4,102	$ 3,533
Other information			
Cash paid for amounts included in the measurement of lease liabilities	$ 2,841	$ 3,663	$ 3,537
Weighted average remaining lease term	9.17	9.84	10.58
Weighted average discount rate	8.26%	8.00%	8.00%

[1] The variable lease costs for the years ended December 31, 2025, 2024 and 2023 include common area maintenance and other operating charges.

Future minimum lease payments under the Company's operating leases as of December 31, 2025 are as follows *(in thousands)*:

Year Ending December 31,	
2026	2,950
2027	3,148
2028	3,227
2029	3,307
2030	3,388
Thereafter	14,096
Total future minimum lease payments	30,116
Less: imputed interest	14,214
Total operating lease liability	$ 15,902
Included in the consolidated balance sheet:	
Current operating lease liability	$ 1,547
Operating lease liability, net of current portion	14,355
Total operating lease liability	$ 15,902

License Agreements

Plexxikon License Agreement

In July 2020, the Company obtained an exclusive, sublicensable, worldwide license (the "License Agreement") to certain patents and other intellectual property rights to research, develop and commercialize bezuclastinib. Under the terms of the License Agreement, the Company is required to pay Plexxikon Inc., a member of the Daiichi Sankyo Group ("Plexxikon"), aggregate payments of up to $7.5 million upon the satisfaction of certain clinical milestones and up to $25.0 million upon the satisfaction of certain regulatory milestones. During the second quarter of 2022, as a result of the progression of the PEAK study, the first clinical milestone was achieved, resulting in payment of $2.5 million to Plexxikon in June 2022. In the fourth quarter of 2025, $5.0 million became payable upon the achievement of certain regulatory milestones and additional $15.0 million may become payable in the next twelve months as a result of the achievement of additional regulatory milestones.

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

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

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2025 or 2024.

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. Debt

Convertible Senior Notes Due 2031

On November 18, 2025, the Company completed a public offering of $230.0 million aggregate principal amount of its 1.625% Convertible Senior Notes due 2031 (the "Notes"), including the exercise in full of the underwriters' over-allotment option to purchase up to an additional $30.0 million aggregate principal amount of the Notes. The Notes were issued pursuant to, and are governed by, an indenture (the "Base Indenture"), dated as of November 18, 2025, between the Company and U.S. Bank Trust Company, National Association, as trustee (the "Trustee"), as supplemented by a first supplemental indenture (the "Supplemental Indenture," and the Base Indenture, as supplemented by the Supplemental Indenture, the "Indenture"), dated as of November 18, 2025, between the Company and the Trustee.

The Notes are general, unsecured, senior obligations of the Company. The Notes accrue interest payable semiannually in arrears on May 15 and November 15 of each year, beginning on May 15, 2026, at a rate equal to 1.625% per year. In addition, special interest will accrue on the Notes upon the occurrence of certain events relating to the Company's failure to file certain reports with the U.S. Securities and Exchange Commission as provided in the Indenture and as described below. The Notes will mature on November 15, 2031 (the "Maturity Date"), unless earlier converted, redeemed or repurchased by the Company.

Noteholders may convert their Notes at their option only in the following circumstances: (i) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending on March 31, 2026, if the last reported sale price per share of the Company's common stock, exceeds 130% of the conversion price for each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter; (ii) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the "Measurement Period") in which the trading price per $1,000 principal amount of Notes for each trading day of the Measurement Period was less than 98% of the product of the last reported sale price per share of the common stock on such trading day and the conversion rate on such trading day; (iii) upon the occurrence of certain corporate events or distributions on the common stock, as described in the Indenture; (iv) if the Company calls such Notes for redemption; and (v) at any time from, and including, August 15, 2031 until the close of business on the scheduled trading day immediately before the Maturity Date. The Company will settle conversions by paying or delivering, as applicable, cash, shares of common stock or a combination of cash and shares of common stock, at the Company's election, based on the applicable conversion rate(s). The initial conversion rate is 22.2469 shares of Common Stock per $1,000 principal amount of Notes, which represents an initial conversion price of approximately $44.95 per share, and is subject to adjustment as described in the Indenture. If certain corporate events that constitute a "Make-Whole Fundamental Change" occur, then the Company will in certain circumstances increase the conversion rate for a specified period of time.

The Notes will be redeemable, in whole or in part (subject to certain limitations described below), at the Company's option at any time, and from time to time, on a redemption date on or after November 20, 2029 and on or before the 26th scheduled trading day immediately before the Maturity Date, at a cash redemption price equal to the principal amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, but only if the last reported sale price per share of the common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and (ii) the trading day immediately before the date the Company sends such notice. However, the Company may not redeem less than all of the outstanding Notes unless at least $75.0 million aggregate principal amount of Notes are outstanding and not called for redemption as of the time the Company sends the related redemption notice. In addition, calling any Note for redemption will constitute a "Make-Whole Fundamental Change" with respect to that Note, in which case the conversion rate applicable to the conversion of that Note will be increased in certain circumstances if it is converted after it is called for redemption.

As of December 31, 2025, the Notes are classified as a long-term liability on the consolidated balance sheets and presented net of unamortized issuance costs of $7.1 million. The issuance costs are amortized to interest expense over the contractual term of the Notes. As of December 31, 2025, the effective interest rate of the Notes is 2.2%.

The outstanding balance of the Notes as of December 31, 2025 consisted of the following *(in thousands):*

	December 31, 2025
Principal amount	$ 230,000
Unamortized debt discount and issuance costs	(7,105)
Convertible senior notes, net	$ 222,895

As of December 31, 2025, the estimated fair value of the Notes was approximately $270.3 million. The fair value was determined based on the quoted price of the Notes in an inactive market on the last trading day of the reporting period and has been classified as Level 2 in the fair value hierarchy.

Credit Facility

On June 11, 2025 (the "Closing Date"), the Company entered into a loan and security agreement (the "Loan and Security Agreement") as a borrower with its subsidiaries (each a "Guarantor," collectively, the "Guarantors"), the lenders party thereto (the "Lenders"), and SLR Investment Corp., as the administrative agent and collateral agent for itself and the Lenders ("SLR"). The Loan and Security Agreement provides for a non-dilutive term loan facility (the "Credit Facility") of up to an aggregate principal amount of $400.0 million, of which a first tranche of $50.0 million was fully funded on the Closing Date, with future tranches at the Company's election subject to achievement of milestones consisting of (i) a second tranche of $25.0 million subject to the Company announcing positive data from its Phase 2 SUMMIT clinical trial, (ii) a third tranche of $75.0 million subject to the Company announcing positive data from its Phase 3 PEAK clinical trial, (iii) a fourth tranche of $50.0 million subject to the Company achieving at least $85.0 million in net product revenue on a trailing six month basis on or prior to June 30, 2027, and (iv) a fifth tranche of $200.0 million subject to mutual agreement of the Company and SLR.

On November 18, 2025, using proceeds received from the issuance of the Notes described above, the Company prepaid in full all of its amounts outstanding with respect to the Credit Facility and repaid in full all obligations due. The aggregate payoff amount was approximately $54.8 million, which includes $50.0 million of principal, additional loan consideration and premiums of $4.6 million, and accrued interest of $0.2 million through the repayment date. The loss on debt extinguishment was $7.2 million, and was included in the loss on debt extinguishment in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2025.

Interest expense related to the Notes and Credit Facility for the year ended December 31, 2025 was $3.1 million. This consisted of amortization of debt discount and issuance costs of $0.6 million and the contractual coupon interest expense of $2.5 million. The Company did not recognize any interest expense during the year ended December 31, 2024.

11. Net Loss per Share

The Company computes net loss per share of common stock, Series A Preferred Stock and Series B Preferred Stock using the two-class method required for multiple classes of common stock and other participating securities. The two-class method is an earnings (loss) allocation method that requires income (loss) available to common stockholders be allocated to all such classes of common stock and other participating securities in accordance with the contractual terms of each class of stock. The Company has determined that the Series A Preferred Stock and Series B Preferred Stock represent other classes of common stock for purposes of calculating net loss per share.

Basic and diluted net loss per common share is computed by dividing the net loss by the weighted-average number of shares and pre-funded warrants outstanding during the period, without consideration of potential dilutive securities. The pre-funded warrants are included in the computation of basic net loss per common share as the exercise price is negligible and they are fully vested and exercisable. For periods in which the Company generated a net loss, the Company does not include potential shares of common stock in diluted net loss per share when the impact of these items is anti-dilutive. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potential shares of common stock would be anti-dilutive.

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.

The following tables set forth the computation of basic and diluted net loss per share of Common Stock, Series A Preferred Stock, and Series B Preferred Stock *(in thousands, except share and per share amounts)*:

	Year Ended December 31, 2025		
	Series A Preferred Stock	Series B Preferred Stock	Common Stock
Numerator:			
Allocated net loss	$ (36,434)	$ (14,612)	$ (277,890)
Denominator:			
Weighted average shares outstanding, basic and diluted	67,600	6,778	128,899,408
Net loss per share, basic and diluted	$ (538.96)	$ (2,155.80)	$ (2.16)

	Year Ended December 31, 2024		
	Series A Preferred Stock	Series B Preferred Stock	Common Stock
Numerator:			
Allocated net loss	$ (35,564)	$ (18,873)	$ (201,422)
Denominator:			
Weighted average shares outstanding, basic and diluted	73,350	9,731	103,856,611
Net loss per share, basic and diluted	$ (484.85)	$ (1,939.47)	$ (1.94)

	Year Ended December 31, 2023		
	Series A Preferred Stock	Series B Preferred Stock	Common Stock
Numerator:			
Allocated net loss	$ (37,481)	$ —	$ (154,929)
Denominator:			
Weighted average shares outstanding, basic and diluted	77,085	—	79,657,942
Net loss per share, basic and diluted	$ (486.23)	$ —	$ (1.94)

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 shares of common stock, 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,		
	2025	2024	2023
Stock options to purchase common stock	27,358,567	21,497,158	15,502,746
Shares issuable upon conversion of convertible notes	5,116,787	—	—
Performance-based restricted stock units subject to vesting	3,990,000	2,714,000	2,500,000
Time-based restricted stock units subject to vesting	539,000	80,000	—
	37,004,354	24,291,158	18,002,746

12. 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 $2.0 million, $1.5 million and $1.2 million for the years ended December 31, 2025, 2024 and 2023, respectively.

13. Segment Information

The Company manages its operations as a single operating 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. Cogent's chief operating decision maker ("CODM") is the Chief Executive Officer. The CODM manages and allocates resources to the operations of the Company on a total company basis and segment performance is evaluated based on consolidated net loss. The Company's CEO uses consolidated financial information for purposes of evaluating performance, understanding future forecasted results and allocating resources. The measure of segment assets is reported on the balance sheet as total consolidated assets. All of the Company's tangible assets are held in the United States.

The accounting policies for each operating segment are consistent with the Company's policies for the consolidated financial statements.

The following table is a summary of segment information for the years ended December 31, 2025, 2024, 2023 *(in thousands)*:

	Year Ended December 31,		
	2025	2024	2023
Operating Expenses			
Late-stage development	$ 120,059	$ 120,862	$ 85,484
Early-stage, preclinical and discovery programs	40,112	28,141	19,171
R&D personnel related	64,035	47,048	38,206
Research and development software, facilities and other strategic support	20,085	10,812	9,374
Other operational infrastructure and advisory support	40,429	26,886	23,010
Stock-based compensation expense	46,079	39,740	30,621
Depreciation expense	2,564	2,450	2,264
Interest income	(14,689)	(18,088)	(13,077)
Interest expense	3,062	—	—
Loss on debt extinguishment	7,181	—	—
Change in fair value of CVR liability	—	—	(1,700)
Other expense (income), net	20	(1,992)	(943)
Segment net loss and consolidated net loss	$ 328,937	$ 255,859	$ 192,410

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, 2025. 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, 2025, 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 our internal control over financial reporting as of December 31, 2025. 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 our internal control over financial reporting was effective as of December 31, 2025.

The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears in this Annual Report on Form 10-K.

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, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the quarter ended December 31, 2025, as such terms are defined under Item 408(a) of Regulation S-K.

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 is incorporated herein by reference to information in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders, including under the headings "Corporate Governance," "Executive Officers," "Insider Trading Policies and Prohibitions on Derivatives, Hedging Monetization and Other Transactions," and, if applicable, "Delinquent Section 16(a) Reports."

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated herein by reference to information in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders, including under headings "Corporate Governance" and "Executive Compensation."

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

The information required by this Item 12 is incorporated herein by reference to information in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders, including under the heading "Certain Information about our Common Stock."

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

The information required by this Item 13 is incorporated herein by reference to information in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders, including under the headings "Corporate Governance" and "Certain Relationships and Related Party Transactions."

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 2026 Annual Meeting of Stockholders, including under the "Ratification of Independent Registered Public Accounting Firm."

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 77 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	Fourth Restated Certificate of Incorporation of Cogent Biosciences, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K (File No. 001-38443) filed on June 5, 2025)
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 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)
3.4	Certificate of Designations of Preferences, Rights and Limitations of Series B Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K (File No. 001-38443) filed on February 14, 2024)
3.5	Certificate of Amendment to the Certificate of Designations of Preferences, Rights and Limitations of Series B Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K (File No. 001-38443) filed on March 22, 2024)
4.1*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
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)
4.3	Indenture by and between Cogent Biosciences, Inc. and U.S. Bank Trust Company, National Association, as trustee dated November 18, 2025 (incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-K (File No. 001-38443) filed on November 18, 2025)
4.4	First Supplemental Indenture by and between Cogent Biosciences, Inc. and U.S. Bank Trust Company, National Association, as trustee dated November 18, 2025 (incorporated by reference to Exhibit 4.2 to the Registrant's Form 8-K (File No. 001-38443) filed on November 18, 2025)
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
10.3#*	Cogent Biosciences, Inc. 2020 Inducement Plan and form of option award agreement thereunder and forms of award agreements thereunder
10.4#	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)
10.5#	Cogent Biosciences, Inc. Form of Inducement Award Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-281291) filed August 6, 2024)
10.6#	Cogent Biosciences, Inc. Form of Inducement Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-281291) filed August 6, 2024)
10.7#	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)
10.8(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)
10.9	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)
10.10	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)
10.11	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)
10.12	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)
10.13	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)
10.14#	Employment Agreement dated as of October 23, 2020, between Cogent Biosciences, Inc. and Andrew Robbins (incorporated by reference to Exhibit 10.7 to the Registrant's Form 10-Q (File No. 001-38443) filed on November 9, 2020)
10.15#	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)
10.16#	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)
10.17#	Amended and Restated Employment Agreement entered into on December 20, 2021 by and between Cogent Biosciences, Inc. and John Robinson (incorporated by reference to Exhibit 10.15 to the Registrant's Form 10-K (File No. 001-38443) filed on February 26, 2024)
10.18#	Amended and Restated Employment Agreement entered into on December 20, 2021 by and between Cogent Biosciences, Inc. and Evan Kearns (incorporated by reference to Exhibit 10.16 to the Registrant's Form 10-K (File No. 001-38443) filed on February 26, 2024)
10.19	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)

10.20	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 14, 2022)
10.21(1)	Securities Purchase Agreement, dated as of February 13, 2024, by and among Cogent Biosciences, Inc. and each purchaser identified on Annex A thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38443) filed on February 14, 2024)
10.22(1)	Registration Rights Agreement, dated as of February 13, 2024, by and among Cogent Biosciences, Inc. and the purchasers party thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K (File No. 001-38443) filed on February 14, 2024)
10.23	Form of Exchange Agreement, dated March 21, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38443) filed on March 22, 2024)
10.24#	Employment Agreement dated as of May 25, 2024, between Cogent Biosciences, Inc. and Cole Pinnow (incorporated by reference to Exhibit 10.22 to the Registrant's Form 10-K (File No. 001-38443) filed on February 25, 2025)
10.25(1)(2)	Loan and Security Agreement, dated as of June 11, 2025, by and between the Company, SLR Investment Corp., and the lenders party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q (File No. 001-38443) filed on August 5, 2025)
10.26(1)	Lease by and between Cogent Biosciences, Inc. and BP THIRD AVENUE LLC dated September 5, 2025 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38443) filed on September 11, 2025)
19.1	Insider Trading Policies and Procedures (incorporated by reference to Exhibit 19.1 to the Registrant's Form 10-K (File No. 001-38443) filed on February 25, 2025)
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.
97.1	Incentive Compensation Clawback Policy (incorporated by reference to Exhibit 97.1 to the Registrant's Form 10-K (File No. 001-38443) filed on February 26, 2024)
101INS*	Inline XBRL Instance Document.
101SCH*	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Document.
104*	Coverage Page Interactive 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.
(2) Certain portions of this exhibit (indicated by "[***]") have been omitted because they are both (i) not material and (ii) customarily and actually treated as private or confidential.
† 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: February 17, 2026

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 February 17, 2026:

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