# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# Form 10-K

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

**For the fiscal year ended December 31, 2024**

**or**

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

**For the transition period from to**

**Commission File Number: 000-29089**

# Agenus Inc.

**(exact name of registrant as specified in its charter)**

| Delaware | 06-1562417 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

**3 Forbes Road, Lexington, Massachusetts 02421**
**(Address of principal executive offices, including zip code)**

**Registrant's telephone number, including area code:**

**(781) 674-4400**

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

| Common Stock, $.01 Par Value | AGEN | The Nasdaq Capital Market |
|---|---|---|
| (Title of each class) | (Trading Symbol) | (Name of each exchange on which registered) |

**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 as of June 28, 2024 (the last trading day of the registrant's second fiscal quarter of 2024) was: $351.6 million. There were 25,308,841 shares of the registrant's Common Stock outstanding as of March 13, 2025.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Definitive Proxy Statement relating to the 2025 Annual Meeting of Stockholders, which the registrant intends to file with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Report.

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**Note Regarding Forward-Looking Statements**

This Annual Report on Form 10-K and other written and oral statements the Company makes from time to time contain forward-looking statements. You can identify these forward-looking statements by the fact they use words such as “could,” “expect,” “anticipate,” “estimate,” “target,” “may,” “project,” “guidance,” “intend,” “plan,” “believe,” “will,” “potential,” “opportunity,” “future” and other words and terms of similar meaning. Forward-looking statements include discussion of future operating or financial performance. You also can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Forward-looking statements involve risks and uncertainties that could delay, divert or change any of them, and could cause actual outcomes to differ materially. These statements relate to, among other things, our business strategy, our research and development, our product development efforts, our ability to commercialize our product candidates, the activities of our licensees, our prospects for initiating partnerships or collaborations, the timing of the introduction of products, the effect of new accounting pronouncements, our future operating results and our potential profitability, availability of additional capital as well as our plans, objectives, expectations, and intentions.

Although we believe we have been prudent in our plans and assumptions, no assurance can be given that any goal or plan set forth in forward-looking statements can be achieved, and readers are cautioned not to place undue reliance on such statements, which speak only as of the date of this report. We undertake no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events or otherwise.

The risks identified in this Annual Report on Form 10-K, including, without limitation, the risks set forth in Part I-Item 1A. “Risk Factors,” could cause actual results to differ materially from forward-looking statements contained in this Annual Report on Form 10-K. We encourage you to read those descriptions carefully. Such statements should be evaluated in light of all the information contained in this document.

## PART I

### Item 1. *Business*

#### Our Business

We are a clinical-stage biotechnology company specializing in discovering and developing therapies to activate the body's immune system against cancer and infections. Our pipeline includes immune-modulatory antibodies, adoptive cell therapies (via MiNK Therapeutics, Inc. ("MiNK")), and vaccine adjuvants (via SaponiQx, Inc. ("SaponiQx")). Our primary focus is immuno-oncology ("I-O"), and our diverse pipeline is supported by our in-house capabilities, including current good manufacturing practice ("cGMP") manufacturing and a clinical operations platform. To succeed in I-O, innovation and speed are paramount. We are a vertically integrated biotechnology company equipped with a suite of technology platforms to advance from novel target identification through manufacturing for clinical trials of antibodies and cell therapies. By understanding each patient's cancer, we aim to substantially expand the population benefiting from current I-O therapies. In addition to a diverse pipeline, we have assembled fully integrated end-to-end capabilities including novel target discovery, antibody generation, cell line development and cGMP manufacturing. Leveraging our science and capabilities, we have established strategic partnerships to advance innovation. We believe the next generation of cancer treatment will build on clinically validated antibodies targeting CTLA-4 and PD-1 combined with novel immunomodulatory agents designed to address underlying tumor escape mechanisms.

Our common stock is currently listed on The Nasdaq Capital Market under the symbol "AGEN."

#### Our Vision

We envision a future where I-O combinations will unlock the full potential of cancer treatment and provide patients with significantly extended and improved lives. We believe our fully integrated, end-to-end capabilities for novel target discovery, antibody generation, and cell line development to our cGMP manufacturing and clinical development and operations capabilities, together with a comprehensive and complementary portfolio will uniquely position us to produce potential novel therapies on accelerated timelines.

#### Our Assets

Our assets encompass a comprehensive array of I-O therapeutics, including antibody-based treatments, monospecific and bispecific antibodies, cell therapy, and vaccine adjuvants. Notable components of our clinical-stage portfolio include botensilimab ("AGEN1181"), a human Fc-enhanced cytotoxic T-lymphocyte antigen 4 ("CTLA-4") blocking antibody, currently in Phase 2 trials in metastatic colorectal cancer ("mCRC"), pancreatic cancer, and melanoma, both as a monotherapy and in combination with balstilimab or chemotherapy; balstilimab ("AGEN2034"), a programmed death receptor-1 ("PD-1") blocking antibody being evaluated in various combinations; AGEN2373, a CD137 antibody in Phase 1b trials; AGEN1423, a CD73/TGFβ TRAP antibody; AGEN1571, an ILT2 antibody. We have also leveraged partnerships to advance our portfolio at speed and finance the business. These include INCAGN1876, INCAGN2390, and INCAGN2385, each targeting different receptors and formerly licensed to Incyte Corporation ("Incyte"); BMS-986442 ("AGEN1777"), a TIGIT bispecific antibody formerly licensed to Bristol Myers Squibb Company ("BMS"); and UGN-301, a zalifrelimab intravesical solution licensed to UroGen Pharma ("UroGen"). Finally, our subsidiary companies are advancing assets through exclusive licenses, including agenT-797, allogeneic invariant natural killer T ("iNKT") cells licensed to MiNK; and QS-21 STIMULON, a cultured plant cell adjuvant used in various vaccines, including those by GlaxoSmithKline Biologicals, S.A. ("GSK").

#### Our Clinical Pipeline Progress

Immunotherapies regulate the body's immune response to cancer and have achieved positive outcomes in a number of cancers that were considered untreatable only a few years ago. Our clinical pipeline consists of various immunotherapy assets targeting complementary mechanisms to fight cancer including:

1. checkpoint inhibitors, which remove the tumor's defenses that evade and suppress the immune system;
2. immune activators, which train and activate a patient's own immune cells for a potent and durable anti-cancer response; and
3. tumor microenvironment ("TME") conditioning agents, which reduce local immune-suppression and attract immune cells to the cancer site.

Our most advanced antibody candidates are botensilimab ("BOT") and balstilimab ("BAL"). BOT is a multifunctional immune cell activator and human CTLA-4 blocking antibody that engages with activating receptors on immune cells. BOT is designed to direct a more effective immune response to cancer through multiple mechanisms by enhancing T cell priming, activation and memory, upregulating antigen presenting cells and myeloid cells and reducing regulatory T cells. BOT also mitigates toxicities associated with first generation anti-CTLA-4 therapy, thus potentially expanding the patient population benefiting from treatment. Balstilimab (BAL)

is a novel, fully human monoclonal immunoglobulin G4 (IgG4) PD-1 (programmed cell death protein 1) inhibitor. It is designed to block PD-1 from interacting with its ligands PD-L1 and PD-L2, enhance T cell activation and effector function BAL is designed to block PD-1 and reactivate exhausted T cells, restoring their ability to fight cancer. When combined with BOT, BAL amplifies and sustains BOT-initiated responses and drives durability of tumor responses. We are investigating BOT as monotherapy and in combination with BAL, along with other mechanisms of action either within our own pipeline or those externally.

To date, BOT and BAL either as monotherapy treatment or as combination treatment have been evaluated in approximately 1,100 patients from more than 60 centers worldwide. The combination has demonstrated clinical responses across nine tumors including those historically considered I-O "cold" tumors resistant to earlier I-O treatments. In April 2023, BOT in combination with BAL received Fast Track designation from the U.S. Food and Drug Administration ("FDA") for the treatment of patients with non-microsatellite instability-high ("MSI-H") and/or deficient mismatch repair ("dMMR") metastatic colorectal cancer without active liver involvement. This designation specifically targets patients who are heavily pretreated and have shown resistance or intolerance to standard chemotherapies, including fluoropyrimidine, oxaliplatin, and irinotecan, as well as those who have received a VEGF inhibitor, an EGFR inhibitor, and/or a BRAF inhibitor, if indicated. We completed enrollment of the Phase 1 study which included patients with refractory MSS mCRC non-active liver metastases ("NLM") in October 2023. Results from the Phase 1 study provided insights to the CRC patient population that may respond better to combination treatment of BOT/BAL, which provided foundation for the Phase 2 study population. The randomized, global Phase 2 trial (n=234) investigated BOT/BAL in refractory MSS mCRC NLM vs standard treatments (regorafenib or trifluridine/tipiracil).

In July 2024, we conducted an End-of-Phase-2 meeting with the FDA for this program. The FDA agreed on a Phase 3 dosing regimen of 75mg BOT every six weeks (up to four doses) combined with 240mg BAL every two weeks (up to two years). However, the FDA advised against pursuing accelerated approval based on the current data, suggesting that objective response rates may not directly translate to a survival benefit.

In January 2025, we presented results from the randomized, global Phase 2 trial in refractory MSS mCRC NLM versus standard treatments (regorafenib or trifluridine/tipiracil) at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium ("ASCO GI") Annual Meeting in San Francisco demonstrating primary endpoints were met. The BOT75mg + BAL regimen demonstrated a 19% ORR and a 55% disease control rate ("DCR") in this heavily pretreated population, while standard treatments showed no objective responses. Notably, 70% of responses were ongoing at data cut-off, indicating durable efficacy of the combination. BOT75mg + BAL exhibited a favorable benefit-risk profile and selected to advance in development. Safety findings were consistent with prior data, with no new safety signals or treatment-related deaths observed. The most common immune-mediated adverse events ("imAEs") at BOT75mg + BAL included diarrhea/colitis and hypothyroidism, all grades, 35% and 13%, respectively.

In addition to the Phase 2 company sponsored study in later line mCRC, data from multiple investigator sponsored trials ("ISTs") were presented, investigating BOT/BAL in combination with FOLFOX and bevacizumab in metastatic CRC, and BOT/BAL in the neoadjuvant setting.

The neoadjuvant data presented at ASCO GI were from two independent studies - UNICORN and NEST. Data from the NEST study demonstrated promising results with no clinical recurrences observed after a median follow-up of 18 months and 9 months for the NEST-1 arm and NEST-2 arm, respectively. The pMR rate improved to 47% in MSS tumors when median time to surgery was extended, indicating a potential benefit of an extended pre-operative window. The combination was well tolerated; no grade 4 events, no unresolved immune-mediated adverse events ("imAEs"), and no surgery delays occurred due to imAEs. The UNICORN Phase 2 study is evaluating pre-operative BOT/BAL combination treatment in resectable colon cancer. Pathological complete responses ("pCR") and major responses ("pMR") were observed in both pMMR/MSS and dMMR/MSI-H tumors, with dMMR/MSI-H patients achieving a 93% pCR and 100% pMR, while patients with pMMR/MSS CRC had a 29% pCR and 36% pMR rate. Serious adverse events ("AEs") were reported in 16% of patients, with treatment-related AEs in 5%, and only one surgery delayed due to an adverse event.. These two studies of BOT/BAL combination suggest a potential to improve outcomes for patients with early-stage colorectal cancer with the potential to improve recurrence free survival and overall survival while de-escalating the need for chemotherapy, radiotherapy, and surgery in selected patients resulting in organ preservation and improved long term quality of life.

The Phase 1/2 trial evaluating BOT/BAL in combination with FOLFOX and bevacizumab ("FOLFOX 3B") in MSS mCRC was also presented at ASCO-GI in January 2025 and demonstrated promising efficacy, regardless of patients having liver metastases or not. Preliminary data show that the combination achieved a 71% ORR, with a 67% ORR specifically in patients with liver metastases. The regimen was well tolerated without dose limiting toxicities.

Based on these data, we have developed designs for registration-enabling trials in MSS CRC across neoadjuvant, first-line, and late-line mCRC. These trial(s) will launch upon completion of strategic transactions. The options being considered are partnerships, licensing, or joint ventures.

Clinical data sets in various tumor types including pancreas, lung, melanoma and sarcoma provide a path for additional expansion opportunities. Patients with advanced sarcomas face poor outcomes and have limited treatment options. In January 2025, data from the Phase 1 open label, multicenter study evaluating BOT/BAL combination across multiple sarcoma subtypes were

published in the Journal of Clinical Oncology. Durable responses were observed across sarcoma types including visceral angiosarcoma, considered immunologically warm, and leiomyosarcoma, which are considered immunologically cold tumors. ORR was 19.2% for the overall study population (n=52). The ORR among angiosarcoma (n=18), visceral and cutaneous subtypes were 27.8%, 33.3% and 22.2% respectively. DCR was 65.4%, with a median PFS rate of 4.4 months. At a median follow-up of 9.1 months, median OS was not reached; the 12-month OS was 69%.

In addition to our lead clinical programs with botensilimab and the botensilimab/balstilimab combination, updated data from a Phase 1 clinical trial of AGEN2373 in combination with botensilimab in patients with advanced solid tumors was presented at the American Society of Clinical Oncology in June 2023. AGEN2373 showed single agent responses with no major toxicity. Responses were reported in patients with prostate cancer, ampullary carcinoma and metastatic vulvar squamous cell carcinoma. No hepatic toxicities, grade ≥3 treatment-related adverse events, or dose-limiting toxicities were observed at doses up to 10 mg/kg.

**Our Strategy**

Our strategy revolves around pioneering optimal combination treatments for cancer patients, with BOT as our cornerstone. Our immediate focus is the development of the BOT/BAL combination for the treatment of patients with CRC. As our data matures we will evaluate our regulatory strategy with the FDA and European Medicines Agency ("EMA") for the registration of the BOT/BAL combination treatment in CRC. We are focusing on externally funded trials for MSS CRC treatment settings.

In December 2024, we announced further detail to our strategic realignment to prioritize and focus resources to accelerate the development, registration, and commercialization of our BOT/BAL program where we have the greatest potential to benefit patients and to drive our future growth. Under this plan, we temporarily postponed all preclinical and clinical programs not related to BOT/BAL and reduced operating expenses across our global organization. We plan to expand combinations with BOT by integrating BAL and other complementary approaches within our clinical portfolio, leveraging targets like LAG-3, ILT2, and our CD137 agonist, AGEN2373. These innovations aim to mitigate disease and modulate the tumor microenvironment with a favorable tolerability profile. We drive portfolio advancement through a blend of independent development and strategic partnerships with industry leaders. Our overarching goal is to introduce innovative combination therapies that substantially enhance the patient population benefiting from current I-O treatments.

**Our Antibody Discovery Platforms and Immunotherapy Programs**

In addition to our clinical programs, our scientists have leveraged our internal discovery and translational platforms and powerful algorithms to develop a pipeline of molecules that are intended to address key aspects of antitumor immunity and tumor resistance mechanisms, by modulating myeloid cell biology, conditioning the tumor microenvironment, and augmenting the activity of immune cells. Some of these novel agents are advancing to the clinic via our pipeline or via partnering relationships. Given the diversity of our pipeline, we are well positioned to advance differentiated combination therapies with our goal to enhance response rates and expand the patient population that could benefit from innovative I-O combination treatments.

We possess end-to-end capabilities in-house – from discovery through to manufacturing – that have enabled us to advance our discoveries at lower costs with efficiency and speed. These product development advantages allow us to manage a large portfolio of discoveries; and have given rise to clinical stage antibody candidates, pre-clinical programs, and partnerships (i.e., with BMS, Gilead Sciences, Inc. (“Gilead”), Incyte and Betta Pharmaceuticals Co., Ltd. (“Betta”)).

**Partnered Programs**

*Bristol Myers Squibb*

In May 2021, we entered into a License, Development and Commercialization Agreement with BMS (the “BMS License Agreement”) pursuant to which we granted BMS an exclusive license to develop, manufacture and commercialize our proprietary TIGIT bispecific antibody program AGEN1777. Pursuant to the BMS License Agreement, we received a non-refundable upfront cash payment of $200.0 million and were eligible to receive development, regulatory and commercial milestone payments plus royalties on worldwide net sales of products containing AGEN1777. In October 2021, we announced that the first patient was dosed in the AGEN1777 Phase 1 clinical trial, triggering the achievement of a $20.0 million milestone and in December 2023, we announced that the first patient was dosed in an AGEN1777 Phase 2 clinical trial, triggering the achievement of a $25.0 million milestone. In July 2024, we received notice from BMS that it was voluntarily terminating the BMS License Agreement, effective as of January 26, 2025. Upon termination, BMS returned AGEN1777 to us.

*Betta*

In June 2020, we entered into a license and collaboration agreement (the “Betta License Agreement”) with Betta, pursuant to which we granted Betta an exclusive license to develop, manufacture and commercialize balstilimab and zalifrelimab in the People’s Republic of China, Hong Kong, Macau and Taiwan (collectively, “Greater China”). Under the terms of the Betta License Agreement,

we received $15.0 million upfront and are eligible to receive up to $100.0 million in milestone payments plus royalties on any future sales in Greater China.

*Gilead*

In December 2018, we entered into a series of agreements with Gilead to collaborate on the development and commercialization of up to five novel I-O therapies. Pursuant to the collaboration agreements, we received an upfront cash payment from Gilead of $120.0 million following the closing in January 2019. At closing, Gilead received worldwide exclusive rights to our bispecific antibody, AGEN1423, as well as a right of first negotiation for two undisclosed programs. Gilead also received the exclusive option to license exclusively AGEN1223, a bispecific antibody, and AGEN2373, a monospecific antibody. In November 2020, Gilead elected to return AGEN1423 to us and to voluntarily terminate the license agreement effective as of February 4, 2021. In the third quarter of 2021, we ceased development of AGEN1223 and in October 2021, the AGEN1223 option and license agreement was formally terminated. In March 2022, we received a $5.0 million clinical milestone under the AGEN2373 option agreement. In August 2024, Gilead elected not to exercise the option to license AGEN2373 and the option and license agreement was formally terminated.

*Incyte*

In January 2015, we entered into a collaboration with Incyte to discover, develop and commercialize novel immuno-therapeutics using our antibody platforms. The collaboration was initially focused on four immunotherapy programs targeting GITR, OX40, TIM-3 and LAG-3, and in November 2015, we expanded the alliance by adding three novel undisclosed immunotherapy targets. Pursuant to the terms of the original agreement, Incyte paid us $25.0 million in upfront cash. Targets under the collaboration were designated as either profit-share programs, where the parties shared all costs and profits equally, or royalty-bearing programs, where Incyte funded all costs, and we were eligible to receive milestones and royalties. Under the original collaboration agreement, programs targeting GITR, OX40 and two of the undisclosed targets were designated as profit-share programs, while the other targets were royalty-bearing programs. For each profit-share product, we were eligible to receive up to $20.0 million in future contingent development milestones. For each royalty-bearing product, we were eligible to receive (i) up to $155.0 million in future contingent development, regulatory, and commercialization milestones and (ii) tiered royalties on global net sales at rates generally ranging from 6%-12%. In February 2017, we and Incyte amended the terms of the original collaboration agreement to, among other things, convert the GITR and OX40 programs from profit-share to royalty-bearing programs with royalties on global net sales at a flat 15% rate for each. In addition, the profit-share programs relating to two undisclosed targets were removed from the collaboration, with one reverting to Incyte and one to Agenus (the latter being our Fc enhanced TIGIT program), each with royalties on global net sales at a flat 15% rate. The remaining three royalty-bearing programs in the collaboration targeting TIM-3, LAG-3 and one undisclosed target remain unchanged, and there are no more profit-share programs under the collaboration. Pursuant to the amended agreement, we received accelerated milestone payments of $20.0 million from Incyte related to the clinical development of INCAGN1876 ("GITR agonist") and INCAGN1949 ("OX40 agonist"). Incyte terminated the OX40 program, effective October 2023, and both the GITR program and undisclosed program, effective May 2024. Upon termination, the rights to the OX40, GITR, and undisclosed programs were returned to us. In July 2024, Incyte announced that it would discontinue further development of the LAG-3 and TIM-3 monoclonal antibodies, and in February 2025, we received notice from Incyte formally terminating the collaboration effective February 2026, at which time Incyte will return to us all rights to LAG-3 and TIM-3.

*Merck & Co.*

In April 2014, we entered into a collaboration and license agreement with Merck to discover and optimize fully-human antibodies against two undisclosed immunotherapy targets. In 2016, Merck selected a lead product candidate against ILT4, a monospecific antibody targeting ILT4 ("MK-4830"), to advance into preclinical studies, and subsequently initiated a Phase 1 clinical trial in August 2018. In November 2020, Merck initiated a Phase 2 clinical trial with MK-4830, triggering a $10.0 million milestone payment to us. Under the terms of the agreement, Merck is responsible for all future product development expenses for MK-4830, and we are eligible to receive potential milestone payments plus royalties on any future sales. In 2024 Merck notified us that the further clinical development of MK-4830 will be limited to a neoadjuvant ovarian study of MK-4830 in combination with pembrolizumab and chemotherapy with or without bevacizumab that is ongoing.

*XOMA*

On September 20, 2018, we, through our wholly-owned subsidiary, Agenus Royalty Fund, LLC, entered into a Royalty Purchase Agreement (the "XOMA Royalty Purchase Agreement") with XOMA (US) LLC ("XOMA US"). Pursuant to the terms of the XOMA Royalty Purchase Agreement, XOMA US paid us $15.0 million at closing in exchange for the right to receive 33% of the future royalties and 10% of the future milestones that we were then entitled to receive from Incyte and Merck, net of certain of our obligations to a third party.

*Ligand*

In May 2024, we, and certain of our wholly-owned subsidiaries, entered into a Purchase and Sale Agreement (the "Ligand Purchase Agreement") with Ligand Pharmaceuticals Incorporated ("Ligand") for the sale to Ligand of (i) 31.875% of the

development, regulatory and commercial milestone payments we were then eligible to receive under our agreements with BMS, UroGen, Gilead, Merck and Incyte (the "Covered License Agreements"); (ii) 18.75% of the royalties we receive under the Covered License Agreements; and (iii) a 2.625% synthetic royalty on worldwide net sales of BOT and BAL (collectively the "Purchased Assets"). The total amounts payable to Ligand are subject to a 50% reduction in the event total payments to Ligand exceed a specified return hurdle. The synthetic royalty is subject to a reduction if annual worldwide net sales exceed a specified level, and a cap on annual worldwide net sales if annual worldwide net sales exceed a higher specified level. The synthetic royalty can increase by 1% based on the occurrence of certain future events. After taking into account our obligations under the Ligand Purchase Agreement, XOMA Royalty Purchase Agreement and the recent status of our collaboration agreements, we remain eligible to receive up to approximately $136.3 million and $49.4 million and in potential development, regulatory, and commercial milestones from UroGen and Merck, respectively.

**Our Subsidiary Companies**

In October 2021, we completed the initial public offering ("IPO") of MiNK, which trades on the Nasdaq Capital Market under the ticker symbol "INKT." MiNK is a clinical stage biopharmaceutical company focused on developing allogeneic iNKT cell therapies to treat cancer and other life-threatening immune diseases. MiNK's most advanced product candidate, agenT-797, is an off-the-shelf, allogeneic, native iNKT cell therapy. Expansion of clinical programs is currently underway, notably a Phase 2 clinical trial in 2L gastric cancer at Memorial Sloan Kettering Cancer Center. MiNK is also evaluating agenT-797 as a variant-agnostic therapy for patients with viral acute respiratory distress syndrome ("ARDS"). In addition to our lead clinical program, MiNK announced a collaboration with ImmunoScape, Inc. ("ImmunoScape") to discover and develop next-generation T-cell receptor therapies against novel targets in solid tumors. MiNK will combine its unique, proprietary library of T cell antigens with ImmunoScape's platform for rapid discovery of novel T cell receptors.

Founded in 2021, our subsidiary, SaponiQx, stands at the forefront of saponin-based adjuvant discovery and manufacturing. Its mission is to provide scalable and affordable vaccine adjuvants to enhance global health. SaponiQx is building an innovative adjuvant platform to deliver both sustainable manufacturing approaches and a secure supply of known adjuvants, as well as discover novel adjuvants and develop new, more effective vaccines utilizing optimized antigen-adjuvant pairings.

**SaponiQx & QS-21 STIMULON Adjuvant**

SaponiQx is our subsidiary that is building an integrated vaccine platform based on scalable and secure manufacturing of QS-21 STIMULON and other saponin-based adjuvants. QS-21 STIMULON is an adjuvant, which is a substance added to a vaccine or other immunotherapy that is intended to enhance an immune response to the target antigens. QS-21 is a natural product, a triterpene glycoside, or saponin, purified from the bark of the Chilean soapbark tree, Quillaja, and has the ability to stimulate an antibody-mediated immune response and has also been shown to activate cellular immunity. It has become a key component in the development of investigational preventive vaccine adjuvants across a wide variety of diseases. These studies have been carried out by academic institutions and pharmaceutical companies in the United States and internationally. A number of these studies have shown QS-21 to be significantly more effective in stimulating immune responses than aluminum hydroxide or aluminum phosphate, the adjuvants most commonly used in approved vaccines in the United States today.

In February 2024, SaponiQx and Ginkgo Bioworks, Inc. ("Ginkgo") announced a 5-year contract totaling up to $31.0 million from the Department of Defense's Defense Threat Reduction Agency ("DTRA") to discover and develop next-generation vaccine adjuvants. The need for vaccines offering long-lasting efficacy and efficient production was amplified in the COVID-19 pandemic. The durability offered by QS-21 STIMULON has been validated by Shingrix, with protection exceeding nine years, but the supply is limited due to reliance on a complicated and expensive extraction process from a Chilean soap bark tree. To this end, SaponiQx is working with Phyton Biotech and Ginkgo to optimize the plant cell culture process which we have developed for the purposes of scalable manufacturing cpcQS-21 and next-generation saponin-based adjuvants. In January 2019, we announced that the Bill & Melinda Gates Foundation awarded us a grant to develop the plant cell culture process for cpcQS-21 STIMULON. Our goal is to establish a platform for optimized and scalable vaccine adjuvant formulations to address pandemic threats and other disease settings. In 2023, SaponiQx announced a pivotal advancement in vaccine research and production with the availability of cGMP STIMULON cultured plant cell ("cpc") QS-21. STIMULON cpcQS-21 is a sustainable and cost-efficient alternative to conventionally extracted QS-21 from bark extract, used in high-performance vaccines such as SHINGRIX and AREXVY.

In January 2025, SaponiQx entered into a strategic collaboration with Probius, a pioneer in quantum molecular spectroscopy for AI-driven discovery, and Ginkgo Bioworks. This partnership, fully funded by the DTRA Joint Science and Technology Office for the Chemical and Biological Defense Program, aims to accelerate the discovery and development of next-generation vaccine adjuvants to combat emerging viral, bacterial, and fungal threats. In August 2024, SaponiQx announced the availability of STIMULON cpcQS-21 on InvivoGen's international retail infrastructure. SaponiQx's STIMULON QS-21 is a key adjuvant component in market-leading vaccines for shingles, malaria, and respiratory syncytial virus. cpcQS-21 is derived from a cultured plant cell source, offering a sustainable alternative to conventional QS-21 extracted from a limited supply of tree bark. The latest preclinical data from cpcQS-21

was published in the journal Vaccines, in December 2024. The study highlights SaponiQx's innovative cpcQS-21 adjuvant technology.

***Partnered QS-21 STIMULON Programs***

In 2006, we entered into a license agreement and a supply agreement with GSK for the use of QS-21 STIMULON (the "GSK License Agreement" and the "GSK Supply Agreement," respectively). In 2009, we entered into an Amended and Restated Manufacturing Technology Transfer and Supply Agreement (the "Amended GSK Supply Agreement") under which GSK has the right to manufacture all of its requirements of commercial grade QS-21 STIMULON. GSK is obligated to supply us, or our affiliates, licensees, or customers, certain quantities of commercial grade QS-21 STIMULON for a stated period of time. In March 2012, we entered into a First Right to Negotiate and Amendment Agreement amending the GSK License Agreement and the Amended GSK Supply Agreement to clarify and include additional rights for the use of QS-21 STIMULON (the "GSK First Right to Negotiate Agreement"). As consideration for entering into the GSK First Right to Negotiate Agreement, GSK paid us an upfront cash payment of $9.0 million, $2.5 million of which was creditable toward future royalty payments. We refer to the GSK License Agreement, the Amended GSK Supply Agreement and the GSK First Right to Negotiate Agreement collectively as the GSK Agreements. We are no longer entitled to any additional milestone payments under the GSK Agreements. Under the terms of the Agreement, we are generally entitled to receive a 2% royalty on net sales of prophylactic vaccines for a period of 10 years after the first commercial sale of a resulting GSK product, which was triggered with GSK's first commercial sale of Shingrix in 2017. Notably, we have already monetized and sold this entire royalty stream as discussed in more detail below. The GSK License and Amended GSK Supply Agreements may be terminated by either party upon a material breach if the breach is not cured within the time specified in the respective agreement. The termination or expiration of the GSK License Agreement does not relieve either party from any obligation which accrued prior to the termination or expiration. Among other provisions, the license rights granted to GSK survive expiration of the GSK License Agreement. The license rights and payment obligations of GSK under the Amended GSK Supply Agreement survive termination or expiration, except that GSK's license rights and future royalty obligations do not survive if we terminate due to GSK's material breach unless we elect otherwise. We do not incur clinical development costs for products partnered with GSK.

In September 2015, we monetized a portion of the royalties associated with the GSK License Agreement to an investor group led by Oberland Capital Management for up to $115.0 million in the form of a non-dilutive royalty transaction. Under the terms of a note purchase agreement with the investor group (the "Note Purchase Agreement"), we received $100.0 million at closing for which the investors had the right to receive 100% of our worldwide royalties under the GSK License Agreement on sales of GSK's Shingrix and malaria ("RTS,S") prophylactic vaccine products that contain our QS-21 STIMULON adjuvant to pay down principle and interest. In November 2017, and pursuant to the Note Purchase Agreement, we received an additional $15.0 million in cash from the investors based on the approval of Shingrix by the FDA. Pursuant to the terms of this transaction, we retained the right to receive all royalties from GSK after all principal, interest and other obligations were satisfied under the Note Purchase Agreement. The Note Purchase Agreement also allowed us to buy back the loan and extinguish the notes early under pre-specified terms, which we did in January 2018.

In January 2018, we sold 100% of all royalties we were entitled to receive from GSK to Healthcare Royalty Partners III, L.P. and certain of its affiliates ("HCR") and used the proceeds to extinguish the debt under the Note Purchase Agreement. HCR paid approximately $190.0 million at closing for the royalty rights, of which approximately $161.9 million was used to extinguish the prior notes, yielding us approximately $28.0 million in net proceeds. We were also entitled to receive up to $40.35 million in milestone payments from HCR based on sales of GSK's vaccines as follows: (i) $15.1 million upon reaching $2.0 billion last-twelve-months net sales any time prior to 2024 (the "First HCR Milestone") and (ii) $25.25 million upon reaching $2.75 billion last-twelve-months net sales any time prior to 2026 (the "Second HCR Milestone"). GSK's net sales of Shingrix for the twelve months ended December 31, 2019, exceeded $2.0 billion. As a result, we received the First HCR Milestone of $15.1 million in 2020 after GSK's net sales of Shingrix in 2019 exceeded $2.0 billion. GSK's net sales of Shingrix for the twelve months ended June 30, 2022, exceeded $2.75 billion. As a result, we received the Second HCR Milestone of $25.25 million in 2022.

**Manufacturing**

***Antibody Manufacturing***

In December 2015, we acquired an antibody manufacturing pilot plant in Berkeley, California from XOMA Corporation ("XOMA"), which we refer to as "Agenus West." A team of former XOMA employees with valuable chemistry, manufacturing and controls experience joined us and continue to operate the facility. Since the acquisition of Agenus West, we have made significant improvements in the plant, and added additional headcount increasing both scale and capacity. Agenus West is currently producing antibody drug substance for certain of our proprietary antibody programs (monospecific and bispecific). In some cases, we have been able to deliver clinical grade material from research cell banks in approximately six to nine months, which is significantly faster than the industry average of 12-18 months. Agenus West utilizes cutting-edge technology platforms, enabling us to be self-reliant and giving us the advantage of drug substance manufacturing speed, cost efficiency, operational flexibility and manufacturing technology transfer to commercial scale partners—all with desired product quality, and with the goal of benefiting patients. In November 2020,

we entered into a long-term lease in Emeryville, CA for cGMP commercial manufacturing space. Construction of this end-to-end 83,000 square foot GMP clinical and commercial biologics manufacturing facility (from cell line development through Drug Product fill & finish, packaging and labeling) is complete and the facility is being commissioned for GMP manufacturing.

The quality control organization for all of our product candidates in Berkeley and Lexington, Massachusetts performs a series of release assays designed to ensure that our antibody drug substance meets all applicable specifications. Our quality assurance staff also reviews manufacturing and quality control records prior to batch release in an effort to assure conformance with cGMP as mandated by the FDA and foreign regulatory agencies. Our manufacturing staff is trained and routinely evaluated for conformance to rigorous manufacturing procedures and quality standards. This oversight is intended to ensure compliance with FDA and foreign regulations and to provide consistent drug substance output. Our quality control and quality assurance staff are similarly trained and evaluated as part of our effort to ensure consistency in the testing and release of the product, as well as consistency in materials, equipment and facilities.

***QS-21 STIMULON Manufacturing***

Except in the case of GSK, we have retained worldwide manufacturing rights for QS-21 STIMULON, and we have the right to subcontract manufacturing for QS-21 STIMULON.

**Intellectual Property Portfolio**

We seek to protect our technologies through a combination of patents, trade secrets and know-how, and we currently own, co-own or have exclusive rights to at least 39 issued United States patents and at least 150 issued foreign patents. We also own, co-own or have exclusive rights to at least 35 pending United States patent applications and at least 180 pending foreign patent applications.

Through various acquisitions, we own, co-own, or have exclusive rights to a number of patents and patent applications directed to various methods and compositions, including methods for identifying therapeutic antibodies and product candidates arising out of such entities' technology platforms. In particular, we own patents and patent applications relating to our Retrocyte Display technology platform, a high throughput antibody expression platform for the identification of fully-human and humanized monoclonal antibodies.

In addition, as we advance our research and development efforts with our institutional and corporate collaborators, we are seeking patent protection for certain newly identified therapeutic antibodies and product candidates. We can provide no assurance that any of our patents, including the patents that we acquired or in-licensed, will have commercial value, or that any of our existing or future patent applications, including the patent applications that were acquired or in-licensed, will result in the issuance of valid and enforceable patents.

The patent rights for each of our clinical candidates, together with the year in which the basic product patent expires are those for the programs set forth in the table below. Unless otherwise indicated, the years set forth in the table below pertain to the basic product patent expiration for the respective products. Patent term extensions, supplementary protection certificates, and regulatory exclusivity periods, including pediatric exclusivity periods are not reflected in the expiration dates listed in the table below. In some instances, we may obtain later-expiring patents relating to our products directed to particular forms or compositions, to methods of manufacturing, or to use of the drug in the treatment of particular diseases or conditions. However, in some cases, such patents may not protect our drug from generic or, as applicable, biosimilar competition after the expiration of the basic patent.

*Projected Patent Expiration Year on a Candidate by Candidate Basis*

| Candidate | U.S. Basic Product Patent Expiration Year (Earliest Estimated Year) | E.U. Basic Product Patent Expiration Year (Earliest Estimated Year) |
|---|---|---|
| Botensilimab | 2037 | 2037 |
| Balstilimab | 2037 | 2036 |
| Zalifrelimab | 2037 | 2036 |
| AGEN2373 | 2038 | 2038 |
| AGEN1777 | 2042 | 2042 |
| INCAGN2390 | 2037 | 2037 |
| INCAGN2385 | 2037 | 2037 |
| INCAGN1876 | 2035 | 2035 |

| | | |
|---|---|---|
| AGEN1949 | 2037 | To be determined |
| AGEN1423 | 2041 | To be determined |
| AGEN1571 | 2043 | 2043 |

Various patents and patent applications have been exclusively licensed to us by the following entity:

***Ludwig Institute for Cancer Research***

On December 5, 2014, we entered into a license agreement with the Ludwig Institute for Cancer Research Ltd., or Ludwig, which replaced and superseded a prior agreement entered into between the parties in May 2011. Pursuant to the terms of the license agreement, Ludwig granted us an exclusive, worldwide license under certain intellectual property rights of Ludwig and Memorial Sloan Kettering Cancer Center arising from the prior agreement to further develop and commercialize GITR, OX40 and TIM-3 antibodies. On January 25, 2016, we entered into a second license agreement with Ludwig, on substantially similar terms, to develop CTLA-4 and PD-1 antibodies. Pursuant to the December 2014 license agreement, we made an upfront payment of $1.0 million to Ludwig. The December 2014 license agreement also obligates us to make potential milestone payments of up to $20.0 million for events prior to regulatory approval of licensed GITR, OX40 and TIM-3 products, and potential milestone payments in excess of $80.0 million if such licensed products are approved in multiple jurisdictions, in more than one indication, and certain sales milestones are achieved. Under the January 2016 license agreement, we are obligated to make potential milestone payments of up to $12.0 million for events prior to regulatory approval of CTLA-4 and PD-1 licensed products, and potential milestone payments of up to $32.0 million if certain sales milestones are achieved. Under each of these license agreements, we will also be obligated to pay low to mid-single digit royalties on all net sales of licensed products during the royalty period, and to pay Ludwig a percentage of any sublicensing income, ranging from a low to mid-double digit percentage depending on various factors. The license agreements may each be terminated as follows: (i) by either party if the other party commits a material, uncured breach; (ii) by either party if the other party initiates bankruptcy, liquidation or similar proceedings; or (iii) by us for convenience upon 90 days' prior written notice. The license agreements also contain customary representations and warranties, mutual indemnification, confidentiality and arbitration provisions.

**Regulatory Compliance**

Governmental authorities in the United States and other countries extensively regulate the pre-clinical and clinical testing, manufacturing, labeling, storage, record keeping, advertising, promotion, export, marketing and distribution, among other things, of our investigational product candidates. In the United States, the FDA under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations, subject pharmaceutical products to rigorous review.

In order to obtain approval of a new product from the FDA, we must, among other requirements, submit proof of safety and efficacy as well as detailed information on the manufacture and composition of the product. In most cases, this proof entails extensive pre-clinical, clinical, and laboratory tests. Before approving a new drug or marketing application, the FDA may also conduct pre-licensing inspections of the company, its contract research organizations and/or its clinical trial sites to ensure that clinical, safety, quality control, and other regulated activities are compliant with Good Clinical Practices ("GCP"), or Good Laboratory Practices ("GLP"), for specific non-clinical toxicology studies. The FDA may also require confirmatory trials, post-marketing testing, and extra surveillance to monitor the effects of approved products, or place conditions on any approvals that could restrict the commercial applications of these products. Once approved, the labeling, advertising, promotion, marketing, and distribution of a drug or biologic product must be in compliance with FDA regulatory requirements.

In Phase 1 clinical trials, the sponsor tests the product in a small number of patients or healthy volunteers, primarily for safety at one or more doses. Phase 1 trials in cancer are often conducted with patients who have end-stage or metastatic cancer. In Phase 2, in addition to safety, the sponsor evaluates the efficacy of the product in a patient population somewhat larger than Phase 1 trials. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at geographically dispersed test sites. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time.

The sponsor must submit to the FDA the results of pre-clinical and clinical testing, together with, among other things, detailed information on the manufacture and composition of the product, in the form of a new drug application ("NDA"), or in the case of biologics, a BLA. In a process that can take a year or more, the FDA reviews this application and, when and if it decides that adequate data are available to show that the new compound is both safe and effective for a particular indication and that other applicable requirements have been met, approves the drug or biologic for marketing.

Whether or not we have obtained FDA approval, we must generally obtain approval of a product by comparable regulatory authorities of international jurisdictions prior to the commencement of marketing the product in those jurisdictions. We are also subject to cGMP, GCP, and GLP compliance obligations and are subject to inspection by international regulatory authorities.

International requirements may in some circumstances be more rigorous than U.S. requirements and may require additional investment in manufacturing process development, non-clinical studies, clinical studies, and record-keeping that are not required for U.S. regulatory compliance or approval. The time required to obtain this approval may be longer or shorter than that required for FDA approval and can also require significant resources in time, money and labor.

Under the laws of the United States, the countries of the European Union and other nations, we and the institutions where we sponsor research are subject to obligations to ensure the protection of personal information of human subjects participating in our clinical trials. We have instituted procedures that we believe will enable us to comply with these requirements and the contractual requirements of our data sources. The laws and regulations in this area are evolving, and further regulation, if adopted, could affect the timing and the cost of future clinical development activities.

We are also subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other current and potential future federal, state, or local regulations. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials, various radioactive compounds, and for some experiments we use recombinant DNA. We believe that our procedures comply with the standards prescribed by local, state, and federal regulations; however, the risk of injury or accidental contamination cannot be completely eliminated. We conduct our activities in compliance with the National Institutes of Health Guidelines for Recombinant DNA Research.

Additionally, the U.S. Foreign Corrupt Practices Act ("FCPA"), prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

**Competition**

Competition in the pharmaceutical and biotechnology industries is intense. Many pharmaceutical or biotechnology companies have products on the market and are actively engaged in the research and development of products for the treatment of cancer.

Many competitors have substantially greater financial, manufacturing, marketing, sales, distribution, and technical resources, and more experience in research and development, clinical trials, and regulatory matters, than we do. Competing companies developing or acquiring rights to more efficacious therapeutic products for the same diseases we are targeting, or which offer significantly lower costs of treatment, could render our products noncompetitive or obsolete. See Part I-Item 1A. "Risk Factors-Risks Related to the Commercialization of Our Product Candidates-Our competitors may have superior products, manufacturing capability, selling and marketing expertise and/or financial and other resources."

Academic institutions, governmental agencies, and other public and private research institutions conduct significant amounts of research in biotechnology, medicinal chemistry and pharmacology. These entities have become increasingly active in seeking patent protection and licensing revenues for their research results. They also compete with us in recruiting and retaining skilled scientific talent.

The I-O drug landscape is crowded with several competitors developing assets against a number of targets. Our development plans are spread across various indications and lines of therapy, either alone or in combination with other assets. Our competitors range from small cap to large cap companies, with assets in pre-clinical or clinical stages of development. Therefore, the landscape is dynamic and constantly evolving. We and our partners have I-O antibody programs currently in clinical stage development targeting various pathways including PD-1, CTLA-4, TIM-3, LAG-3, CD73, TGFb, CD137, ILT2, and TIGIT. We are aware of many companies that have antibody-based products on the market or in clinical development that are directed to the same biological targets as these programs, including, without limitation, the following: (1) BMS markets ipilimumab, an anti-CTLA-4 antibody, nivolumab, an anti-PD-1 antibody, and relatlimab, an anti-LAG-3 antibody, and is currently developing agents targeting TIGIT, TIM-3, CD137 and TGFb, (2) Merck has an approved anti-PD-1 antibody, pembrolizumab, and has an anti-CTLA-4, anti-TIGIT and LAG-3 antagonists recruiting in clinical trials, (3) Regeneron has an approved anti-PD-1 antibody, cemiplimab, and an antibody targeting LAG-3 in the clinic, (4) Roche/Genentech has an approved anti-PD-L1 antibody, atezolizumab, a late-stage anti-TIGIT antibody, an anti-TGFb antibody as well as bispecific antibodies targeting CD137 and LAG-3 in clinical development, (5) AstraZeneca has an approved anti PD-L1 antibody, durvalumab, an approved anti-CTLA-4 antibody, tremelimumab, and has monoclonal antibodies targeting CD73, as well as bispecific antibodies targeting CTLA-4, TIGIT, TIM-3 in clinical development, (6) Merck KGaA has an approved anti-PD-L1 antibody, avelumab, as well as clinical assets including an anti-TIGIT antibody and bispecific antibodies targeting LAG-3 and TGFβ, (7) GSK has an approved anti PD-1 antibody, dostarlimab, as well as antibodies targeting TIM-3, LAG-3 and TIGIT in the clinic (8) Coherus Biosciences has an approved anti-PD-1 antibody, toripalimab, (9) Incyte has an approved anti-PD-1 antibody, retifanlimab, and clinical assets targeting LAG-3 and CD73, (10) Beigene Ltd has an approved anti-PD1 antibody, tislelizumab, and has clinical assets targeting LAG-3 and TIGIT, (11) Checkpoint Therapeutics has an approved anti-PD-L1 antibody, cosibelimab. Besides these PD-1 and PD-L1 antibodies that are approved in the U.S., we are also aware of competitors with approved PD-1 and PD-L1 agents in ex-U.S. geographies such as China. These include Akeso Biopharma, CStone Pharmaceuticals, Harbin

Gloria Pharmaceuticals (Arcus Bioscience has rights in North America, Europe, Japan and certain other territories), Harbor Biomed, Innovent Biologics, Jiangsu Alphamab/3D Medicines, Jiangsu HengRui Pharmaceuticals, Lee's Pharmaceuticals, Lepu Biopharma (previously Taizhou Houdeaoke Technology), Qilu Pharmaceutical Co Ltd, Shanghai Henlius Biotech Co Ltd, Shanghai Junshi Biosciences (Coherus BioSciences has rights to co-develop in U.S. and Canada), Shanghai Pharmaceuticals, Shenzhou Cell Engineering, Sichuan Kelun Botail Biomedicine and Sino Biopharmaceuticals.

In addition to the companies noted above, we are also aware of additional competitors with clinical-stage PD-1/PD-L1 agents, both as monospecific and bispecific antibodies, including but not limited to AbbVie, Amgen, Arcus Biosciences/Gilead, Biocad Ltd., Boehringer Ingelheim, Eli Lilly, Janssen Pharmaceuticals, Novartis, Ono, Pfizer, and Sanofi. In addition, we are also aware of pre-clinical monospecific or bispecific antibodies targeting PD-1 or PD-L1.

We are aware of companies developing "next-generation" anti-CTLA-4 assets, which may be competitive to our next-generation AGEN1181. These next-generation monospecific antibodies targeting CTLA-4 include but are not limited to Adagene, BioAtla, Harbour BioMed, OncoC4/BioNTech and Xilio Therapeutics. We are also aware of companies advancing preclinical or clinical stage CTLA-4 targeting bispecific antibodies or oncolytic viruses as a next-generation approach including but not limited to Biocad, Jiangsu Alphamab, Macrogenics, Replimune, Sichuan Baili Pharmaceuticals and Xencor.

There are additional competitors with clinical stage drug candidates against LAG-3, TIM-3, CD73, TGFb, CD137, and TIGIT. Some of these competitors include but are not limited to AbbVie, Arcus Biosciences/Gilead, Alligator Biosciences, Anaptsys Bio, Astellas, Beigene, Bicara Therapeutics, Boehringer Ingelheim, Compass Therapeutics, Compugen, Galapagos NV, Genmab, Innovent Biologics, iTeos Therapeutics, Jacobio Pharmaceuticals, Lokon Pharma, Lyvgen Biopharma, Macrogenics, Mereo Biopharma, Novartis, Oncotellic Therapeutics, Palvella Therapeutics, Pfizer, Replimune, Sanofi, Scholar Rock, Servier, Sirnaomics and Spine Therapeutics. There is no guarantee that our antibody product candidates will be able to successfully compete with our competitors' antibody products and product candidates.

There are many therapies that are approved to treat colorectal cancer. This includes but is not limited to chemotherapy agents such as fluorouracil injection ("5FU"), irinotecan hydrochloride, leucovorin, oxaliplatin, capecitabine and trifluridine/tipiracil hydrochloride; infused anti-VEGF agents such as bevacizumab, ramucirumab, and ziv-aflibercept; immuno-oncology agents such as nivolumab, pembrolizumab and ipilimumab; anti-EGFR agents such as cetuximab and panitumumab; KRAS G12C inhibitors such as adagrasib and sotorasib; tucatinib, a HER2 antagonist; fruquintinib, an oral VEGFR antagonist; regorafenib, a tyrosine kinase inhibitor; and encorafenib, a BRAF V600E inhibitor.

There is significant competition to develop therapies to treat patients with refractory colorectal cancer ("CRC"). Companies that have clinical stage agents to treat refractory CRC include but are not limited to Abbvie, which is evaluating a c-Met inhibitor as a monotherapy; Adagene, which is evaluating a CTLA-4 inhibitor in combination with pembrolizumab; Exelixis, which is evaluating a tyrosine kinase inhibitor in combination with atezolizumab; Jiangsu Alphamab, which is evaluating a PD-L1xCTLA-4 bispecific antibody in combination with regorafenib; Merck, which is evaluating a CD47 inhibitor in combination with cetuximab and pembrolizumab; Replimune, which is evaluating its oncoloytic virus candidates in combination with bevacizumab and atezolizumab; Xilio Therapeutics, which is evaluating its CTLA-4 inhibitor in combination with atezolizumab.

Additionally, AGEN1571, our ILT2 antibody is now in clinical development. We are aware of other clinical stage anti-ILT2, both monospecific and bispecific antibodies, and anti-HLA-G antibodies that could compete with this program. These include but are not limited to, Bond Biologics/Sanofi, ImmuneOs Therapeutics, Invectys, Janssen, LG Chem, NGM Biopharmaceuticals, Pfizer and Tizona Therapeutics. We are also aware of competitor programs that are in preclinical development against this target. There is no guarantee that our antibody product candidates will be able to successfully compete with our competitors' antibody products and product candidates.

In addition, and prior to regulatory approval, if ever, our other product candidates may compete for access to patients with other products in clinical development, with products approved for use in the indications we are studying, or with off-label use of products in the indications we are studying. We anticipate that we will face increased competition in the future as new companies enter markets we seek to address and scientific developments surrounding immunotherapy and other traditional cancer therapies continue to accelerate.

SaponiQx is developing QS-21 STIMULON. Several other vaccine adjuvants are in development or in use and could compete with QS-21 STIMULON for inclusion in vaccines. These adjuvants may include but are not limited to: (1) oligonucleotides, under development by Dynavax, (2) MF59, under development by Novartis, (3) IC31, under development by Intercell (now part of Valneva), (4) MPL, under development by GSK, (5) Matrix-MTM, under development by Novavax, (6) AS03 and additional AS portfolio members, under development by GSK, and (7) TQL 1055, under development by Adjuvance Technologies. In the past, we have provided QS-21 STIMULON to other entities under materials transfer arrangements. There is a risk that material provided pursuant to an MTA is used without our permission to develop synthetic formulations and/or derivatives of QS-21. In addition, other companies and academic institutions are developing saponin adjuvants, including derivatives and synthetic formulations. These sources may be competitive to our ability to execute future partnering and licensing arrangements involving QS-21 STIMULON. We

are also aware of other manufacturers of QS-21. The existence of products developed by these and other competitors, or other products of which we are not aware, or which other companies may develop in the future, may adversely affect the marketability of products developed or sold using QS-21 STIMULON.

Even if we obtain regulatory approval to market our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

**Human Capital Resources and Employees**

As of February 28, 2025, we had 316 employees, of whom 68 were PhDs and 17 were MDs. None of our employees are subject to a collective bargaining agreement. We believe that we have good relations with our employees.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and additional employees. We provide compensation and benefit programs to attract and retain employees. In addition to salaries, these programs include potential annual discretionary bonuses, various stock awards under our equity incentive plans, a 401(k) Plan, healthcare and insurance benefits, flexible spending accounts, paid time off, family leave, and flexible work schedules, among others.

**Corporate History**

Antigenics L.L.C. was formed as a Delaware limited liability company in 1994 and was converted to Antigenics Inc., a Delaware corporation, in February 2000 in conjunction with our initial public offering of common stock. On January 6, 2011, we changed our name from Antigenics Inc. to Agenus Inc.

**Availability of Periodic SEC Reports**

Our Internet website address is *www.agenusbio.com*. We make available free of charge through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended ("Exchange Act"), as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission (the "SEC"). In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the sections entitled "Publications", "Investors" and "Media," as sources of information about us.

The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

The contents of the websites referred to above are not incorporated into this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

## Item 1A. Risk Factors

**Summary of Risk Factors**

Our business is subject to a number of risks and uncertainties. The following is a summary of the principal risk factors described in this section:

*Risks Related to our Financial Position and Need for Additional Capital*

- We have historically incurred net losses and anticipate that we will continue to incur net losses in the future.
- If we fail to obtain additional financing, we will not be able to complete development and commercialization of our product candidates.
- 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.
- Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and its financial condition and results of operations.
- Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements.

*Risks Related to the Development of Our Product Candidates*

- Our business is highly dependent on the success of botensilimab and our combination therapy programs.
- Preliminary or interim data that we report on our clinical trials could change materially by the time the data is finalized.
- Our clinical trials or those of our current and future collaborators may reveal significant adverse events or a lack of therapeutic efficacy or durability of treatment-related effect.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We have limited resources, and the number of product candidates that we are attempting to simultaneously advance creates a significant strain on these resources and could prevent us from successfully advancing any candidates.

*Risks Related to the Commercialization of Our Product Candidates*

- We may not be able to commercialize, or may be delayed in commercializing, our product candidates.
- Our product candidates are new molecular entities that could face challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval may be significantly impacted.
- Our product candidates may cause unacceptable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- Our competitors may have superior products, manufacturing capability, expertise and/or resources.
- Even if our product candidates receive marketing approval, such products may not achieve market acceptance or coverage, or may become subject to unfavorable pricing regulations or third-party reimbursement practices.
- The market opportunities for our product candidates may be small, and our estimates of the prevalence of our target patient populations may be inaccurate.
- We have no prior experience as a company in marketing, selling and distributing products or performing commercial compliance.

*Risks Related to Manufacturing and Supply*

- Manufacturing challenges could result in having insufficient quantities of our drug candidates or drugs or such quantities at an acceptable cost.
- We own and operate our own clinical scale manufacturing infrastructure, which is costly and time-consuming.
- We have built and are in the process of qualifying our own commercial scale manufacturing facility, which is costly and time-consuming and will require regulatory approvals before the facility can begin manufacturing.

*Risks Related to Our Reliance on Third Parties*

- We are dependent upon third parties to further develop and commercialize certain of our antibody programs.
- Failure to enter into and/or maintain clinical trial, licensing, distribution and/or collaboration agreements may adversely affect our business.
- If third parties do not carry out their contractual duties, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

*Risks Related to Government Regulation*

- The regulatory approval process for our product candidates is uncertain and will be lengthy, and may evolve even after we have engaged with relevant regulatory authorities and selected a regulatory pathway.
- We may fail to obtain regulatory approval of our product candidates.
- Our business operations and relationships with third parties are subject to extensive healthcare laws and regulations.
- If we receive regulatory approval of any product candidates or therapies, we will be subject to ongoing regulatory obligations and continued regulatory review to maintain the approval.
- Healthcare reform initiatives may have an adverse effect on our business.
- Laws and regulations governing any international operations may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.
- Risks associated with doing business internationally could negatively affect our business.
- Our ability to use net operating losses and tax credits to offset future income may be subject to limitations.

*Risks Related to Our Intellectual Property*

- We may be unable to obtain and enforce patent protection for our product candidates and related technology.
- If we fail to comply with our intellectual property licenses, we could lose important license rights.
- We may not be able to protect our intellectual property rights throughout the world.
- Changes in U.S. patent law could diminish the value of patents.

- We may be unable to protect the confidentiality of our proprietary information.
- Our employees, consultants or independent contractors could wrongfully use or disclose confidential information.
- We may infringe the patents and other proprietary rights of third parties.
- We may become involved in lawsuits to protect or enforce our patents.

*Risks Related to Business Operations, Employee Matters and Managing Growth*

- We may encounter difficulties in managing our recent growth.
- Legal claims against us may create distraction for our management team, adversely impact our ability to develop and gain approval for our products and/or result in substantial damages.
- Information technology security breaches could result in a material disruption in our business and subject us to sanctions and penalties.
- Our subsidiaries MiNK Therapeutics may be unsuccessful at advancing its cell therapy business, and SaponiQx, Inc. may be unsuccessful in advancing its vaccine adjuvant business. Our subsidiary, Atlant Clinical, may be unsuccessful in maintaining and growing its clinical research organization ("CRO") businesses.

*Risks Related to Our Common Stock*

- Our stock's trading volume and public trading price has been volatile.
- We do not intend to pay cash dividends on our common stock.
- Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control.

Our future operating results could differ materially from the results described in this Annual Report on Form 10-K due to the risks and uncertainties described herein. You should consider carefully all information about risks in evaluating our business. If any of the described risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

We cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See "Note Regarding Forward-Looking Statements" in this Annual Report on Form 10-K. Factors that could cause or contribute to such differences include those factors discussed below.

**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.***

Investment in I-O 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. Our net losses for the years ended December 31, 2024, 2023, and 2022, were $232.3 million, $257.4 million and $230.7 million, respectively. We expect to incur significant losses for the foreseeable future as we continue our research and development efforts, seek regulatory approvals, and begin commercial readiness efforts for our product candidates. We anticipate that our expenses will increase substantially if, and as, we:

- conduct clinical trials for our pipeline of product candidates;
- further develop our antibody programs and platforms, MiNK's cell therapy programs, and our saponin-based vaccine adjuvants (through SaponiQx);
- continue to discover and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific, manufacturing, commercial and related personnel;
- expand in-house clinical and commercial manufacturing capabilities;
- 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;

- acquire or in-license other product candidates and technologies;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval; and
- add operational, regulatory, financial and management information systems and personnel, including personnel to support our product development and planned commercialization efforts.

To become profitable, we or any current or potential future licensees and collaboration partners must develop, gain approval and eventually commercialize products with significant market potential at an adequate profit margin after cost of goods sold and other expenses. This will require us to be successful in a range of challenging activities, including completing clinical trials, obtaining marketing approval for product candidates, obtaining adequate reimbursement for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause our stockholders to lose all or part of their investment.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development costs and other expenditures to develop and market additional product candidates in our pipeline. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Furthermore, our ability to generate cash from operations is dependent in part on the success of our licensees and collaboration partners, as well as the likelihood and timing of new strategic licensing and partnering relationships and/or successful development, approval and commercialization of product candidates, including through our antibody programs and platforms, MiNK's adoptive cell therapy programs, and our saponin-based vaccine adjuvants (through SaponiQx).

***We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we will not be able 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 conduct further research and development and preclinical or nonclinical testing and studies and clinical trials of our current and future programs, to build a supply chain, to seek regulatory approvals for our product candidates and to launch and commercialize any products for which we receive regulatory approval, including building our own commercial organization. To date, we have financed our operations primarily through the sale of equity, assets, notes, corporate partnerships and interest income. In order to finance future operations and pay our obligations, we will be required to raise additional funds in the capital markets, through arrangements with collaboration partners or from other sources.

As of December 31, 2024, we had $40.4 million of cash and cash equivalents. Based on our current plans and projections, we believe that our cash resources as of December 31, 2024, plus anticipated funding will be sufficient to satisfy our critical liquidity requirements through the second quarter of 2025. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical or nonclinical testing and studies and clinical trials for our product candidates;
- the clinical development plans we establish for our product candidates;
- the number and characteristics of future product candidates that we develop or may in-license;

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such arrangements;
- the timing, receipt and amount of sales of, or royalties on, our future products and those of our partners, if any;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the costs of establishing and maintaining a clinical and commercial supply chain for the development and manufacture of our product candidates;
- the cost and timing of establishing, expanding and scaling commercial manufacturing capabilities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, other marketing or distribution arrangements and sale of non-strategic assets. 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 one or more of our products or product candidates or one or more of our other research and development initiatives as we did in August 2023 and December 2024 when we streamlined our operations to focus on our lead program. 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 and we may become insolvent.

From time to time we have issued, and in the future may issue, projections regarding our future cash position. Such projections include the expectation that we will be able to raise additional funds from the aforementioned sources and our ability to do so is subject to the risks described herein.

General economic conditions in the United States and abroad, including the impacts of public health crises, the policies of the current administration or otherwise, and geopolitical disputes and wars such the invasion of Ukraine by Russia or conflicts in the Middle East, may have a material adverse effect on the financial markets and our liquidity and financial condition, particularly if our ability to raise additional funds is impaired.

***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.***

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships, alliances and licensing arrangements and the sale of non-strategic assets. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect their rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves.

***The nature and length of our operating history may make it difficult to evaluate our technology and product development capabilities and predict our future performance.***

We have no products approved for commercial sale and have not generated any revenue from product sales. Our ability to generate product revenue or profits will depend on the successful development, regulatory approval and eventual commercialization of our product candidates, which may never occur. We may never be able to develop or commercialize a marketable product.

All of our programs require additional pre-clinical or clinical research and development, clinical and commercial manufacturing supply, capacity and/or expertise, building of a commercial organization, substantial investment and/or significant marketing efforts before we generate any revenue from potential product sales. Other programs of ours require additional discovery research and then preclinical development. In addition, our product candidates must be approved for marketing by the FDA or certain other health regulatory agencies, including the EMA, before we may commercialize any product.

Our operating history, particularly in light of the rapidly evolving and competitive I-O field, may make it difficult to evaluate our technology and industry and predict our future performance. We will encounter risks and difficulties frequently experienced by clinical stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer. Similarly, we expect that our financial condition and operating results will fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our stockholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance.

In addition, as a clinical stage company, we have encountered unforeseen expenses, difficulties, complications, delays and other known and unknown circumstances. As we advance our product candidates, we will need to transition from a company with a research and clinical focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.***

Global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including increased inflation, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, and the volatility of such market and economic conditions have increased as a result of the conflicts in the Middle East and the Russian invasion of Ukraine, and may increase as a result of other geopolitical actions, including newly imposed tariffs and other actions that directly or indirectly impact the global economy. The scope, duration and long-term impact of conflicts in the Middle East and the Russian invasion are unknown at this time, so there can be no assurance how significant any deterioration in credit and financial markets and confidence in economic conditions will be and how long it may continue. Our general business strategy may be adversely affected by any such economic downturn, volatile geopolitical and business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans for some or all of our pipeline candidates. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

As of December 31, 2024, we had cash, cash equivalents and short-term investments of $40.4 million. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents and investments since December 31, 2024, no assurance can be given that deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

***Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements, and it is possible that such report on our financial statements may include such an explanation again in the future.***

We believe we have sufficient capital to fund our critical expenses through the second quarter of 2025. Going forward, if we are unable to obtain sufficient funding to support our operations or pay our obligations, we could be forced to delay, reduce or eliminate all of our research and development programs, product portfolio expansion or commercialization efforts, our financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. In the future, reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, if at all.

***Our obligations to the holders of our promissory notes and certain finance leases could materially and adversely affect our liquidity and operations.***

In February 2015, we issued subordinated promissory notes in the aggregate principal amount of $14.0 million, of which $10.5 million remains outstanding (the "2015 Subordinated Notes"). The 2015 Subordinated Notes have been amended to extend the maturity date to July 2026 and increase the interest rate to 9%. The 2015 Subordinated Notes include default provisions that allow for the acceleration of the principal payment of the 2015 Subordinated Notes in the event we become involved in certain bankruptcy proceedings, become insolvent, fail to make a payment of principal or (after a grace period) interest on the 2015 Subordinated Notes, default on other indebtedness with an aggregate principal balance of $13.0 million or more if such default has the effect of accelerating the maturity of such indebtedness, or become subject to a legal judgment or similar order for the payment of money in an amount greater than $13.0 million if such amount will not be covered by third-party insurance. If we default on the 2015 Subordinated Notes and the repayment of such indebtedness is accelerated, our liquidity could be materially and adversely affected.

In 2021, we entered into a finance lease arrangement for the purchase of equipment installed in our Emeryville, CA facility. Under the terms of this agreement failure to maintain a minimum cash balance is an event of default as defined in the agreement. During 2024 we notified the lessor our balance fell below this minimum cash balance. If this default is not cured or waived by the lessor, the lessor may take possession of the equipment which will significantly impact our manufacturing process.

In 2024, we entered into a promissory note for a loan in the aggregate principal amount of $22.0 million (the "Loan"). The Loan has a two-year term and is principally secured by our manufacturing facility in Berkeley, CA and parcels of land located in Vacaville, CA and bears interest at an annual rate of 12% through November 30, 2025 and 13% from December 1, 2025 through November 30, 2026. Interest under the Note is payable monthly, one half in cash and one half of the Company's common stock. Additionally, $1.8 million of the Loan funds were held back to serve as an interest payment reserve for the Loan. The Note contains customary representations, warranties and covenants, including customary events of default, including failure to repay the Loan when due. Any event of default, if not cured or waived in a timely manner, could result in the acceleration of the Loan.

If we do not have sufficient cash on hand to service or repay our obligations, or to maintain our required minimum cash balance, we may be required to raise additional capital which entails the risks described herein.

***Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.***

We regularly maintain cash balances at third-party financial institutions, such as Silicon Valley Bank ("SVB"), in excess of the Federal Deposit Insurance Corporation ("FDIC") insurance limit. In March 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. If another depository institution is subject to other adverse conditions in the financial or credit markets, it could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance. In addition, if any parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

**Risks Related to the Development of Our Product Candidates**

***Our business is highly dependent on the success of our clinical stage programs, including botensilimab and related combination therapy programs, which still require significant additional clinical development.***

Our business and future success depends in large part on our ability to obtain regulatory approval of, and then successfully launch and commercialize, our product candidates. Our timelines are aggressive and subject to various factors outside of our control, including regulatory review and approval. Although we have engaged with the FDA on our regulatory programs and protocols, there is no guarantee that our product candidates will be approved, or that we will be able to successfully commercialize these assets. If the botensilimab programs (including combination therapies with botensilimab) encounter safety, efficacy, supply or manufacturing problems, developmental delays, regulatory or commercialization issues or other problems, our development plans and business may be significantly harmed.

Even though we have observed preliminary positive results based on an assessment of overall response rate and disease control rate to date in certain colorectal cancer settings, they may not necessarily be predictive of the final results of the trials or future clinical

trials or otherwise be sufficient to support an approval. Many companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results, and we cannot be certain that we will not face similar setbacks.

The FDA may disagree that our data and development program are sufficient to support BLA filing or approval. For example, the FDA discouraged submission of our Phase 2 results evaluating botensilimab and balstilimab in adult patients with r/r MSS CRC with NLM in support of an accelerated approval based on the observed magnitude of effect, remaining questions about contributions of the components of the combination product, and their view that objective response rates may not translate to survival benefit, and they recommended the inclusion of a botensilimab monotherapy arm in the planned Phase 3 study. Furthermore, because botensilimab and balstilimab are both novel agents, and are being used in combination, any BLA submission for the combination will require significant information on each agent as well as the combination.

All of our other product candidates are in earlier stages of development and will require additional nonclinical and/or clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing and commercial efforts before we can generate any revenue from product sales.

***Clinical drug development involves a risky, lengthy and expensive process, with an uncertain outcome. We may encounter substantial delays in completing our clinical trials which in turn will require additional costs, or we may fail to demonstrate adequate safety and efficacy to the satisfaction of FDA and other foreign regulatory authorities.***

It is impossible to predict if or when any of our product candidates will prove safe or effective in humans or will receive regulatory approval and the risk of failure throughout the clinical development process is high. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate our product candidates are safe, pure and potent in humans and have a favorable risk-benefit profile. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development or prevent our ability to receive marketing approval for our product candidates include:

- the FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies or impose additional requirements before permitting us to initiate a clinical trial;
- the FDA or comparable foreign regulatory authorities, Institutional Review Boards ("IRBs") or ethics committees ("ECs") may disagree with our study design, may require that we modify or amend our clinical trial protocols, or may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;
- clinical investigators or clinical trial sites may deviate from trial protocols or GCP requirements or drop out of a trial, and we may need to add new investigators or sites;
- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, if at all;
- the number of participants required for clinical trials may be larger than expected, enrollment in clinical trials may be slower than expected or participants may drop out or fail to return for post-treatment follow-up at a higher rate than expected;
- the cost of clinical trials and preclinical studies may be greater than we anticipate, or we may have insufficient funds to conduct such trial or study or to pay the substantial user fees required by the FDA upon the submission of a BLA;
- the supply or quality of our product candidates or other materials necessary to conduct our clinical trials or preclinical studies may be insufficient or inadequate to initiate or complete a given clinical trial;
- our product candidates may have undesirable side effects or other unexpected characteristics that are viewed to outweigh their potential benefits;
- reports from clinical testing of other similar therapies may raise safety, tolerability or efficacy concerns about our product candidates; and
- clinical trials of our product candidates may fail to show appropriate safety, purity or potency of our product candidates, may produce negative or inconclusive results or may otherwise fail to improve on the existing standard of care, and we may

decide, or regulators may require us, to conduct additional clinical trials or preclinical studies or we may decide to abandon product candidate development.

We could encounter significant delays if a clinical trial is suspended or terminated by us, by the IRBs or ECs of the institutions in which such trials are being conducted, by an independent Safety Review Board for such trial or by the FDA or other foreign regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Product development costs for any of our product candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA, comparable foreign regulatory authorities, and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. Further, the FDA or other foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials. For example, we are conducting and may in the future conduct "open-label" clinical trials where both the patient and investigator know whether the patient is receiving the investigational product candidate or another product, such as standard of care therapy. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, including "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment and "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Moreover, patients selected for early clinical trials often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment.

If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB or other reviewing entities, or any of our clinical trial sites suspend or terminate any clinical trials of our product candidates, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. In addition, clinical trial delays could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates.

***The successful development of immune modulating antibodies, including botensilimab, alone and in combination with other therapeutic candidates, is highly uncertain.***

Successful development of immune modulating antibodies, such as botensilimab, is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Immune modulating antibodies that appear promising in the early phases of development may fail to reach, or remain in, the market for several reasons, including:

- clinical trial results may show our candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects, toxicities or other negative consequences;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical trials, patients dropping out of trials, length of time to achieve trial endpoints, additional time requirements for data analysis, or BLA preparation, disagreement with the FDA regarding clinical trial design or our interpretation of data,, an FDA request for additional nonclinical or clinical data that may be deemed necessary to meet evolving regulatory standards and pathways, other discussions with FDA, or unexpected safety or manufacturing issues;
- clinical and commercial manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the candidates uneconomical;
- proprietary rights of others and their competing products and technologies that may prevent our candidates from being commercialized or profitable;

- failure to initiate or successfully complete confirmation trials for candidates that receive accelerated approval; and
- the length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority may be difficult to predict for immune modulating antibodies, including for CTLA-4 antibody and related combination therapies.

Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of insurance coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, and private health insurers, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors may limit coverage to a population smaller than that implied in the label granted by regulatory authorities, and could require us to conduct additional studies, including post-marketing studies related to the cost-effectiveness or comparative benefit of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide adequate insurance coverage and reimbursement levels for any one of our products once approved, market acceptance and commercial success would be reduced.

In addition, if any of our products are approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and will need to continue to comply (or ensure that our third-party providers comply) with cGMPs and GCPs, for any clinical trials that we conduct post-approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly and any failure to comply or other issues with our product candidates' post-approval could have a material adverse effect on our business, financial condition and results of operations.

***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 and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publish interim top-line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available and mature over time. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Preliminary or top-line results may not be indicative of the final results from the relevant study, and the final results may not support a marketing approval for any of our product candidates. Furthermore, third parties, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could delay or prevent regulatory approval of, or limit commercial prospects for, the particular product candidate. Additionally, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to disclose. There is no guarantee that botensilimab, balstilimab, zalifrelimab, or AGEN2373 (or any of our other earlier stage or partnered programs) will receive marketing approval in any jurisdiction, and failure to achieve marketing approval for any of these programs as a monotherapy or combination could have a material adverse impact on our business. Any adverse differences between preliminary or interim data and final data could significantly harm our business and partnership prospects.

***Preclinical development is uncertain. Some of our antibody programs are in early stage development that may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, and which would have an adverse effect on our business.***

Several of our proprietary antibody programs are currently in early stage development, and many of our antibody programs are pre-clinical. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

***Our clinical trials or those of our current and future collaborators may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.***

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through potentially lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe, pure, and potent in humans and have a favorable risk-benefit profile in each target indication. Failure can occur at any time during the clinical trial process.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities, or an institutional review board may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of any approved product due to its tolerability versus other therapies.

In addition, some patients who have serious or life-threatening illnesses and have exhausted all other available therapies may receive access to our product candidates prior to their commercial approval through compassionate use, expanded access programs, or named patient programs, collectively referred to as compassionate use programs. The risk for serious adverse events in these patient populations is high, and any adverse events that are determined to be drug-related could have a negative impact on the safety profile of our product candidates, which could impact our ability to obtain regulatory approval for and successfully commercialize our product candidates.

Any of these developments could materially harm our business, financial condition and prospects.

***We intend to develop our existing antibody candidates, and may develop future product candidates, alone and in combination with one or more additional cancer therapies. The uncertainty resulting from the use of our product candidates in combination with other cancer therapies may make it difficult to accurately predict side effects in future clinical trials.***

The development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For example, we are currently developing botensilimab and balstilimab in combination for the treatment of certain cancers. The FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. Additionally, developments related to one product or product candidate may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include, among other things, changes to an assessment of the other product's safety or efficacy profile, changes to the availability of the product, and quality, manufacturing and supply issues. Any of these developments could materially harm our business, financial condition and prospects.

***Positive results from preclinical and preliminary findings from the earlier clinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any future clinical trials of our product candidates. If we cannot replicate the positive results from our earlier studies of our product candidates in our later studies and future clinical trials, we may be unable to successfully develop, obtain regulatory for and commercialize our product candidates.***

Any positive results from our preclinical studies of our product candidates may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any future clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results. Moreover, positive results observed in interim data may not necessarily be predictive of the results from final, more mature data.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive preliminary results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported

adverse events. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval or EMA positive assessment for EC approval.

***If we encounter difficulties enrolling patients in our clinical trials or if our clinical trial sites encounter staffing shortages that impact their operations, our clinical development activities could be delayed or otherwise adversely affected.***

We may experience difficulties in patient enrollment and in and timely completion of 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, or the ability of our CROs to enroll a sufficient number of patients who remain in the study until its conclusion and the sites being able to operate as needed to adhere to the clinical requirements as set forth in the protocol. The enrollment of patients depends on many factors, including:

- the severity of the disease under investigation;
- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability, and that of our CROs, to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be in clinical development or approved for the indications we are investigating;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability of our CROs and our ability to oversee and/or the monitoring of patients adequately during and after treatment;
- the ability of our CROs and our ability to oversee and/or to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for our targeted therapeutic areas, potential patients and their doctors may be inclined to use conventional or newly launched competitive therapies, rather than enroll patients in any future clinical trial.

Staffing shortages at clinical trial sites and delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

***The number of product candidates that we are attempting to simultaneously advance creates a significant strain on our resources and may prevent us from successfully advancing any product candidates. If, due to our limited resources and access to capital, we prioritize development of certain product candidates, such decisions may prove to be wrong and may adversely affect our business.***

We or our affiliates are currently advancing multiple immune modulating antibodies, adoptive cell therapies (MiNK subsidiary) and vaccine adjuvants (SaponiQx subsidiary). Simultaneously advancing so many product candidates may create a significant strain on our limited human and financial resources. As a result, we may not be able to provide sufficient resources to any single product candidate to permit the successful development, approval and commercialization of such product candidate, causing material harm to our business.

If, as we announced in December 2024, due to our limited resources and access to capital, we prioritize development of certain product candidates such as botensilimab/balstilimab in refractory MSS CRC that ultimately proves to be unsuccessful, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

**Risks Related to the Commercialization of Our Product Candidates**

***If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.***

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Except for Prophage in Russia, we have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Although FDA accepted for filing our BLA for balstilimab in 2021, we subsequently voluntarily withdrew such application in response to a request from FDA due to FDA granting full approval for a competing agent. We, as a company, have limited experience in filing and supporting the applications necessary to gain regulatory approvals and rely in part on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have unacceptable side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved as well as evolving regulatory standards for products like ours. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, BLA or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Additionally, the FDA or other foreign regulatory authorities may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe , pure and potent and has a favorable risk-benefit profile for its proposed indication;
- the FDA or comparable foreign regulatory authorities may require us to obtain clearance or approval of a companion diagnostic;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- The FDA or comparable foreign regulatory authorities may disagree with our selected dosing regimen or regimens or determine that additional data are needed to support dose selection;
- the regulatory pathway being pursued is eliminated due to the unexpected or early full approval of a competing agent, as occurred with balstilimab;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities or those of our third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval standard policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

As part of the BLA review, the FDA may require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, authorities may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could reduce the size of the potential market for our product candidates and materially harm the commercial prospects for our product candidates.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy development and approval process as well as the unpredictability of future clinical trial outcomes may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. To the extent that we seek regulatory approval of two novel candidates at the same time, the risks and challenges associated with the regulatory review and approval process may be even more significant. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

***We may seek accelerated approval for some of our product candidates but may not be able to obtain it as the sufficiency of our clinical trial results for accelerated approval are subject to the FDA's discretion.***

The general approach for FDA approval of a new biologic or drug is for sponsors to seek licensure or approval based on dispositive data from adequate and well-controlled, Phase 2 or 3 clinical trials of the relevant product candidate in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients dosed in well-controlled trials that have significant costs and may take years to complete. We may seek to utilize, among other strategies, FDA's accelerated approval program for our product candidates given the limited alternatives for treatments for certain rare diseases, cancer and autoimmune diseases, but the FDA may not agree with our plans. The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. For drugs granted accelerated approval, FDA generally requires sponsors to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. The Food and Drug Omnibus Reform Act of 2022 gave FDA the authority to require, as appropriate, a post-approval study to be underway prior to granting accelerated approval. Failure to conduct required post-approval studies with due diligence, failure to confirm a clinical benefit during the post-approval studies, or dissemination of false or misleading promotional materials would allow the FDA to withdraw the product approval on an expedited basis.

If we choose to pursue accelerated approval, there can be no assurance that the FDA will agree that our proposed primary endpoint is an appropriate surrogate endpoint. Similarly, there can be no assurance that after subsequent FDA feedback that we will continue to pursue accelerated approval, even if we initially decide to do so. For example, although we planned to seek accelerated approval for BOT/BAL based on our Phase 2 results in adult patients with r/r MSS CRC with NLM, FDA advised against the submission based on the observed magnitude of effect, remaining questions about contributions of the components of the combination product, and their view that objective response rates may not translate to survival benefit, and they recommended the inclusion of a BOT monotherapy arm in the planned Phase 3 study. If we submit an application for accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. The FDA also could require us to conduct further studies or trials prior to considering our application or granting approval of any type. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. Even if we receive accelerated approval from the FDA for one or more of our product candidates,

there is no guarantee that we will be able to successfully complete one or more confirmatory trials needed to obtain full approval. We also will be subject to rigorous post-approval requirements, including submission to the FDA of all promotional materials prior to their dissemination. The FDA could withdraw accelerated approval for multiple reasons, including our failure to conduct any required post-approval study with due diligence, or the inability of such study to confirm the predicted clinical benefit. A failure to obtain accelerated approval or any other form of expedited review or approval for a product candidate could result in a longer time period prior to commercializing such product candidate, increase the cost of development of such product candidate, and harm our competitive position in the marketplace.

***The FDA or comparable foreign regulatory authorities could require the clearance or approval of a companion diagnostic device as a condition of approval of our product candidates, which may require substantial financial resources and could delay regulatory approval.***

Approval of genetic or biomarker diagnostic tests may be necessary in order to advance some of our product candidates to clinical trials or potential commercialization. If the safe and effective use of any of our product candidates depends on an in vitro diagnostic that is not otherwise commercially available, then the FDA may require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves such product candidate. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities, and the FDA has generally required premarket approval, or PMA approval, for genetically targeted therapies. The approval of a companion diagnostic as part of an approved product's labeling limits the use of the product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect.

If FDA or comparable foreign regulatory authorities requires the use of a companion diagnostic for our product candidates, we may be dependent on the cooperation and effort of third-party collaborators to develop such companion diagnostic. We and our third-party collaborators may encounter difficulties in developing, validating, and obtaining FDA clearance or approval of such companion diagnostic. The process of obtaining or creating such diagnostics is time consuming and costly, and the outcome uncertain. Any delay or failure by us or our potential future collaborators to develop or obtain regulatory clearance or approval of such companion diagnostics, if necessary, could delay or prevent approval of our product candidate.

***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. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those jurisdictions. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be deemed to have representative patients enrolled or be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for pricing and reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to negotiation or approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. 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.

***Our product candidates may cause unacceptable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.***

Unacceptable side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. As is the case with many treatments for cancer and autoimmune diseases, it is likely that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product

candidates for any or all targeted indications. The treatment-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may delay and/or increase the costs of our development programs and harm our business, financial condition and prospects significantly.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify unacceptable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates which could cause delay and/or increase costs;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy ("REMS"), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions which may cause delay and/or increase costs;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates on our projected timelines and generate revenues.

***Our competitors may have superior products, manufacturing capability, selling and marketing expertise and/or financial and other resources.***

Our product candidates and the product candidates in development by our collaboration partners may fail because of competition from major pharmaceutical companies and specialized biotechnology companies that market products, or that are engaged in the development of product candidates and for the treatment cancer. Many of our competitors, including large pharmaceutical companies, have substantially greater financial, technical and other resources than we do, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Our competitors may:

- develop safer or more effective therapeutic drugs or vaccine adjuvants and other products;
- establish superior intellectual property positions;
- discover technologies that may result in medical insights or breakthroughs, which render our drugs or vaccine adjuvants obsolete, possibly before they generate any revenue, if ever;
- adversely affect our ability to recruit patients for our clinical trials;
- solidify partnerships or strategic acquisitions that may increase the competitive landscape;
- develop or commercialize their product candidates sooner than we commercialize our own, if ever; or
- implement more effective approaches to sales, marketing and patient assistance programs and capture some of our potential market share.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Established pharmaceutical companies may also invest heavily to accelerate discovery and

development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

There is no guarantee that our product candidates will be able to compete with potential future products being developed by our competitors including those described under "Item 1. Business – Competition."

Even if we obtain regulatory approval to market our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

***Even if our product candidates receive marketing approval, we, or others, may subsequently discover that such product is less effective than previously believed or causes undesirable side effects that were not previously identified and our ability to market such product will be compromised.***

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into such clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a "black box" warning or contraindication;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive additional safety studies prior to approval or post-marketing studies required by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition and results of operations.

***Even if our product candidates receive marketing approval, such products may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.***

If any of our product candidates receive marketing approval, whether as single agents or in combination with other therapies, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and physicians could continue to rely on these therapies. If any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any future products, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of the disease;
- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the perceived ratio of risk and benefit of these therapies by physicians;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement, including of combination therapies;
- adoption of a companion diagnostic and/or complementary diagnostic; and
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling.

***Even if we are able to commercialize any product candidates, such products may not receive coverage or may become subject to unfavorable pricing regulations, inadequate coverage and reimbursement by third party payors, or healthcare reform initiatives that otherwise adversely affect demand for and access to such products,, all of which would harm our business.***

The legislation and regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or drug licensing approval is granted and, in some countries, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate in that country. In the United States, there is increasing scrutiny from the Congress and regulatory authorities of the pricing of pharmaceutical products. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

The success of our product candidates, if approved, depends significantly on the availability of adequate coverage and reimbursement from third-party payors. Patients who are provided medical treatment for their conditions 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, private health insurers and other payors therefore are critical to new product acceptance. Because our product candidates represent new approaches to the treatment of the diseases they target, we cannot be sure that adequate coverage and reimbursement will be available for our product candidates.

Significant uncertainty exists as to the coverage and reimbursement status of our product candidates for which we seek regulatory approval. Government authorities and private third-party payors decide which medications they will pay for and establish reimbursement levels. Obtaining and maintaining adequate reimbursement for our product candidates, if approved, may be difficult. Moreover, the process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Further, one payor's determination to provide coverage for a product or decision regarding reimbursement does not assure that other payors will also provide coverage and reimbursement for our products, if they are approved.

A primary trend in the healthcare industry in the United States and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. There may be significant delays in obtaining reimbursement for newly-approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable regulatory authorities outside the United States. Third-party payors may also seek, with respect to an approved product, additional clinical and health economic evidence, including comparative effectiveness evidence, that goes beyond the data required to obtain marketing approval in order to demonstrate clinical benefits and value relative to other therapies before covering our products. If so, we may be required to conduct additional pharmacoeconomic studies beyond what is required for marketing approval. Third party payors providing coverage may nonetheless manage utilization, including by implementing a drug formulary, coverage or access restrictions, establishing different copays for different drugs or requiring a prescriber to obtain prior authorization from the relevant third-party payor before a drug will be covered for a particular patient.

We expect to experience pricing pressures in connection with the sale of our product candidates. Eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, regulatory approval, sale and distribution. Reimbursement for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used; may be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services. The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense and new products face increasing challenges in entering the market successfully. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or requested by private payors in exchange for favorable coverage and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold. Our ability to commercialize our product candidates successfully may be adversely affected by discounts or rebates that we are required to provide in order to ensure coverage of our products and compete in the marketplace. Accordingly, we cannot be sure that reimbursement will be available for any drug that we commercialize and, if reimbursement is available, we cannot be sure as to the level of reimbursement and whether it will be adequate. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

***The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our estimates of the prevalence of our target patient populations may be inaccurate.***

Cancer and autoimmune therapies are sometimes characterized as first-line, second-line, third-line and even fourth-line, and the FDA often approves new therapies initially only for last-line use. Initial approvals for new cancer and autoimmune therapies are often restricted to later lines of therapy, and in the case of cancer specifically, for patients with advanced or metastatic disease.

Our projections of both the number of people who have the diseases we are targeting, as well as the subset of people with these diseases in a position to receive our therapies, if approved, are based on our current beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, input from key opinion leaders, patient foundations, or secondary market research databases, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Furthermore, regulators and payors may further narrow the therapy-accessible treatment population. Even if we obtain significant market share for our product candidates, because certain of the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

***Prior to a product approval, we would need to build marketing, sales and commercial compliance functions, and as a company, we have no experience in marketing, selling and distributing products or adhering to commercial compliance standards and regulations. If we are unable to establish such capabilities or enter into agreements with third parties to perform such functions, we may not be able to generate product revenue.***

We currently have a small number of individuals who have capabilities to build our marketing, sales and commercial compliance functions, and we currently have no experience as a company performing such tasks. Developing an in-house marketing team, sales force and commercial compliance function will require significant capital expenditures, management resources and time and may ultimately prove to be unsuccessful. In the event we develop and deploy these capabilities, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain personnel qualified to perform these tasks. If we fail to market and sell our approved products in compliance with applicable laws and regulations, we may be subject to investigations and/or legal review and challenges which may result in fines or other penalties as well as causing distraction and reputational harm.

In addition to establishing internal sales, marketing and distribution and commercial compliance capabilities, we may pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to ensure compliance and support successful commercialization of any product in the United States or overseas.

**Risks Related to Manufacturing and Supply**

***Our product candidates are uniquely manufactured. If we or any of our third-party manufacturers encounter difficulties in manufacturing our product candidates, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***

The manufacturing process used to produce certain of our product candidates is complex and novel and has not yet been validated for commercial production. As a result of these complexities, the cost to manufacture certain of our product candidates is potentially higher than traditional antibodies and the manufacturing process is less reliable and is more difficult to reproduce. Furthermore, our manufacturing process for certain of our product candidates has not been scaled up to commercial production. The actual cost to manufacture and process certain of our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of such product candidates.

Our manufacturing process may be susceptible to logistical issues associated with the collection of materials sourced from various suppliers as well as shipment of the final product to clinical centers, manufacturing issues associated with interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in production batches, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in our manufacturing facilities in which our product candidates are made, production at such manufacturing facilities may be interrupted for an extended period of time to investigate and remedy the contamination. Further, as we transition from late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

Although we continue to optimize our manufacturing process for our antibody product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of reagents and/or raw materials. We ultimately may not be successful in transferring our in-house clinical scale production system to any commercial scale manufacturing facilities that we establish ourselves or establish at a contract manufacturing organization ("CMO"). If we are unable to adequately validate or scale-up the manufacturing process for our product candidates with our contracted CMO, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us for all product candidates. As a result, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

In November 2020, we entered into a long-term lease in Emeryville, CA for cGMP commercial manufacturing space. Construction of this end-to-end 83,000 square foot GMP clinical and commercial biologics manufacturing facility (from cell line development through Drug Product fill & finish, packaging and labeling) is complete. It is being commissioned for GMP manufacturing but may take longer or be more costly than we anticipated. We have never built, owned or operated a commercial manufacturing building, and there is no guarantee that we will be successful doing so.

The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority regulation and approval process. In complying with the manufacturing regulations of the FDA and comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money, and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. If we or our CMOs are unable to reliably produce products in compliance with cGMPs and to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product in compliance with cGMPs and to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Additionally, failure to comply with FDA or foreign regulatory authority requirements could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition, and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design, or build and install unanticipated equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

***We own and operate our own clinical scale manufacturing facility and infrastructure in addition to or in lieu of relying on CMOs for the manufacture of clinical supplies of our product candidates. This is costly and time-consuming.***

We own and operate the manufacturing pilot plant that supplies our antibody drug substance requirements for clinical proof-of-concept and other clinical studies.

Any performance failure on the part of our existing facility could delay clinical development or marketing approval of our antibody programs.

We have given our corporate QS-21 STIMULON licensee, GSK, manufacturing rights for QS-21 STIMULON for use in their product programs. We have retained the right to manufacture QS-21 for ourselves and third parties, although no other such programs are anticipated to bring us substantial revenues in the near future, if ever. We have some internal supply in-house and from a third-party supplier(s) and manufacturer(s), we have also contracted with a new third party to become an alternative long-term supply partner for some aspects of manufacturing this adjuvant. In January 2019, we announced that the Bill & Melinda Gates Foundation awarded us a grant to develop an alternative, plant cell culture-based manufacturing process with the goal of ensuring the continuous future supply of QS-21 STIMULON adjuvant. While we are pursuing this in partnership with Phyton Biotech and Ginkgo, there is no guarantee that we will be successful in developing a scalable process. In February 2024, SaponiQx and Ginkgo announced a 5-year contract totaling up to $31 million from the DTRA to discover and develop next-generation vaccine adjuvants, but we cannot be certain that we will be successful with this contract in developing promising new adjuvants.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our clinical and commercial manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing process or facilities, or that of our licensees and suppliers, could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

The FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing process could restrict our ability to meet our clinical and regulatory timelines, and market demand for our products.

***We are dependent on suppliers for some of our components and materials used to manufacture our product candidates.***

We currently depend on suppliers for some of the components necessary for our product candidates. We cannot be sure that these suppliers will remain in business, that they will be able to meet our supply needs, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. There are, in general, relatively few alternative sources of supply for these components. These suppliers may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from a supplier or manufacturing location could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects. If we are able to find a replacement supplier, the replacement

supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay and additional costs. While we seek to maintain adequate inventory of the materials used to manufacture our products, any interruption or delay in the supply of materials, or our inability to obtain materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders. In addition, as part of the FDA's approval of our product candidates, we will also require FDA approval of the individual components of our process, which include the manufacturing processes and facilities of our suppliers. Our reliance on these suppliers subjects us to a number of risks that could harm our business, and financial condition, including, among other things: interruption of product candidate or commercial supply resulting from modifications to or discontinuation of a supplier's operations; delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component; a lack of long-term supply arrangements for key components with our suppliers; inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms; difficulty and cost associated with locating and qualifying alternative suppliers for our components and precursor cells in a timely manner; production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications; delay in delivery due to our suppliers prioritizing other customer orders over ours; and fluctuation in delivery by our suppliers due to changes in demand from us or their other customers. If any of these risks materialize, our manufacturing costs could significantly increase and our ability to meet clinical and commercial demand for our products could be impacted.

***We rely on third parties for the manufacture of clinical supplies of certain of our product candidates and expect to rely on third parties for commercial supplies of any approved product candidates until our new commercial manufacturing facility is fully commissioned and qualified. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We expect to rely on third-party manufacturers for the manufacture of commercial supplies of our drug candidates until our own commercial manufacturing facility is fully commissioned and qualified. At present, we do not have long-term supply agreements with all of the vendors needed to produce our product candidates for commercial sale and we may be unable to establish such agreements with third-party manufacturers or do so on acceptable terms.

The agreements that we do have in place with our third-party manufacturers obligate us to make significant non-refundable deposits to reserve manufacturing slots prior to the receipt of marketing approval for our product candidates. Additionally, if our product candidates are approved, we will be required to make minimum purchases and will have limited ability to purchase product in excess of our forecasted needs. As a result, if product sales fall below our minimum purchase obligations, we will be obligated to purchase more product than we can successfully sell, and if product demand exceeds the amount that we can purchase from our manufacturers, we will have to forgo some product sales unless and until we are able to manufacture commercial supplies at our own facility. Either of these events may materially harm our financial prospects. Finally, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible failure of the third party to manufacture our drug candidate according to our schedule, or at all, including if the third-party manufacturer gives greater priority to the supply of other drugs over our drug candidates, or otherwise does not satisfactorily perform according to the terms of the manufacturing agreement;
- staffing shortages, equipment malfunctions, power outages, natural or man-made calamities, geopolitical disputes, or other general disruptions experienced by our third-party manufacturers to their respective operations and other general problems with a multi-step manufacturing process;
- the possible misappropriation or disclosure by the third party or others of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

As is common in the industry, the agreements that we have in place with our third-party suppliers and manufacturers significantly limit the liability of such suppliers and manufacturers for failing to supply or manufacture, as applicable, our product candidates pursuant to the terms of our agreements, or as required by applicable regulation or law. As a result, if we suffer losses due to our suppliers or manufacturers failure to perform, we will have limited remedies available against such suppliers and manufacturers and are unlikely to be able to recover such losses from them.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. Facilities used by our third-party manufacturers must be inspected by the FDA before potential approval of the drug candidate. Similar regulations apply to manufacturers of our drug candidates for use or sale in foreign countries. Until our own commercial manufacturing facility is completed and validated, we will not control the manufacturing process and will be completely dependent on our third-party manufacturers for compliance with the applicable regulatory requirements for the commercial manufacture of our drug candidates. If our manufacturers cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they will not be able to secure the applicable approval for their manufacturing facilities. If these facilities are not approved for commercial manufacture, we may need to find alternative manufacturing facilities, which could result in delays in obtaining approval for the applicable drug candidate as alternative qualified manufacturing facilities may not be available on a timely basis or at all. In addition, our manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMPs or other regulatory requirements could result in sanctions being imposed on us or the contract manufacturer, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect supplies of our drug candidates and have a material adverse impact on our business, financial condition and results of operations as well as cause reputational damage. Any drugs that we may develop may compete with other drug candidates and drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Our current and future dependence upon others for the commercial manufacture of our drug candidates or drugs until our own facility is completed and qualified may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis.

**Risks Related to Our Reliance on Third Parties**

***We are dependent upon our collaboration with Betta to further develop and commercialize certain antibody programs. If we or Betta Pharmaceuticals fail to perform as expected, the potential for us to generate future revenues under such collaboration could be significantly reduced, the development and/or commercialization of these antibodies may be terminated or substantially delayed, and our business could be adversely affected.***

We may need to raise additional capital and may need to identify and come to agreement with another collaboration partner to advance certain of our antibody programs. Even if we are able to find another partner, this effort could cause delays in our timelines and/or additional expenses, which could adversely affect our business prospects and the future of our antibody product candidates under the collaboration.

In June 2020, we entered into a license and collaboration agreement with Betta Pharmaceuticals to collaborate on the development and commercialization of balstilimab and zalifrelimab in greater China. Pursuant to the license and collaboration agreement, Betta Pharmaceuticals received an exclusive license to develop, manufacture and commercialize zalifrelimab and balstilimab in all fields (other than intravesical delivery) in greater China. Under the agreement, Betta Pharmaceuticals is responsible for all of the development, regulatory approval, manufacturing and commercialization costs in greater China. As part of the collaboration, Betta Pharma made an upfront cash payment of $15.0 million and agreed to make up to $100.0 million in aggregate milestone payments plus tiered royalties on net sales of zalifrelimab and balstilimab. Royalties range from mid-single digit to low-twenties percent, subject to certain reductions under certain circumstances. Accordingly, the timely and successful completion by Betta Pharmaceuticals of development, regulatory approval, manufacturing and commercialization activities will significantly affect the timing and amount of any milestones or royalties we may receive from Betta Pharmaceuticals. Betta Pharmaceuticals' activities will be influenced by, among other things, the efforts and allocation of resources by Betta Pharmaceuticals, which we cannot control.

In addition, our collaboration with Betta Pharmaceuticals may be unsuccessful due to other factors, including, without limitation, that Betta Pharmaceuticals:

- may terminate any of the license and collaboration agreement for convenience upon 90 days' notice;
- has control over the development, regulatory approval, manufacturing and commercialization of balstilimab and zalifrelimab in greater China;
- may change the focus of its business efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to balstilimab and zalifrelimab; and

- may choose not to develop and commercialize balstilimab and zalifrelimab in all markets within greater China or for one or more indications, if at all.

Additionally, the US-China relationship has deteriorated in recent years and, further deterioration may impact the ability of Agenus and Betta Pharmaceuticals to successfully collaborate.

***Failure to enter into and/or maintain additional significant licensing, distribution and/or collaboration agreements in a timely manner and on favorable terms to us may hinder or cause us to cease our efforts to develop and commercialize our product candidates, increase our development timelines, and/or increase our need to rely on partnering or financing mechanisms, such as sales of debt or equity securities, to fund our operations and continue our current and anticipated programs. Even if we enter into and maintain such agreements, they may not prove successful, and/or we may not receive significant payments from agreements.***

Part of our strategy is to develop and commercialize many of our product candidates by continuing or entering into arrangements with academic, government, or corporate collaborators and licensees. Our success depends on our ability to negotiate such agreements on favorable terms and on the success of the other parties in performing research, pre-clinical and clinical testing, completing regulatory applications, and commercializing product candidates. Our research, development, regulatory and commercialization efforts with respect to antibody candidates from our technology platforms are, in part, contingent upon the participation of institutional and corporate collaborators. For example, in February 2015, we began a broad collaboration with Incyte to pursue the discovery and development of antibodies, in December 2018 we entered into a partnership with Gilead relating to five of our antibody programs and in May 2021 we entered into a license agreement with BMS relating to our anti-TIGIT bispecific antibody program. Disagreements, the failure of either party to perform satisfactorily, or the termination of the arrangements by either party, which has occurred to our collaborations with Incyte, Gilead and BMS, could have an adverse impact on these programs.

Our ability to advance our antibody programs depends in part on such collaborations. In addition, from time to time we engage in efforts to enter into licensing, distribution and/or collaboration agreements with one or more pharmaceutical or biotechnology companies to assist us with development and/or commercialization of our other product candidates. Any licensing, distribution and/or collaborations agreements, we enter into, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our current or future collaborations do not result in the successful discovery, development, approval and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our technology and product candidates could be delayed and we may need additional resources to develop product candidates and our technology. All of the risks relating to product development, regulatory approval and commercialization described herein also apply to the activities of our therapeutic collaborators.

Additionally, since BMS, Incyte and Gilead, terminated their agreements with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

Collaborations are complex and time-consuming to negotiate, document and execute. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected.

***We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.***

We depend upon third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. Such reliance obligates us to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We rely heavily on third parties over the course of our clinical trials, and, as a result, have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials or at a particular site may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or sites, or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials

comply with the GCP requirements. In addition, our clinical trials must be conducted with biologic product produced under cGMP requirements and may require a large number of patients.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process and increase the costs of such trials. 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.

The persons engaged by third parties conducting our clinical trials are not our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not such persons devote sufficient time and resources to our ongoing pre-clinical and clinical programs. 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 product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs as we are required to do as part of our sponsor oversight, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

**Risks Related to Government Regulations**

***The regulatory approval process for our product candidates in the United States, European Union and other jurisdictions is currently uncertain and will be lengthy, time-consuming and inherently unpredictable and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.***

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics, are subject to extensive regulation by the FDA in the United States and regulatory authorities in other jurisdictions. We are not permitted to market any biological product in the United States for commercial use until we receive a biologics license from the FDA. Although FDA accepted for filing the BLA for balsilimab in 2021, we subsequently voluntarily withdrew such application in response to a request from FDA due to FDA granting full approval to a competing agent. As a result, we have not submitted a BLA for any product candidate that was approved by the FDA. Even after submission of a BLA for one or more of our product candidates, we expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and we may never obtain regulatory approval for our product candidates.

***The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of our product candidates, which may be difficult to predict.***

The FDA, the EMA and regulatory authorities in other countries may implement further regulations or restrictions on biotechnology products, such as antibodies, adjuvants and adoptive cell therapies. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of antibodies, vaccine adjuvants or adoptive cell therapies products may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. Similarly, the EMA has the responsibility for regulating antibodies, vaccine adjuvants and adoptive cell therapies in the European Union and may issue new guidelines concerning evidential requirements for the development to support marketing authorization for such products and that we are expected to take account of these new guidelines in our product development program. We may be required to perform additional studies or trials in order to satisfy the new regulatory standards and evidential requirements which can be subject to divergent interpretations. The additional studies can be costly and considerably lengthen the initially projected timeline for completing the clinical development for our product candidates. As a result, product approval and commercialization can be delayed. The new regulatory requirements may impose

restrictions or post-approval commitments to monitor the safety and efficacy of our product candidates on an ongoing basis. In order for us to advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates.

While many of the current administration's proposed policies appear to be focused on deregulation, the new administration and federal government could adopt legislation, regulation, or policy that adversely affects our business or creates a more challenging and costly environment to pursue the development and commercialization of our product candidates. For example, the federal government, including the FDA, may implement legislative, regulatory, or policy changes regarding the standards for approving biologic products that we may be unable to satisfy. It is difficult to predict how executive actions that may be taken under the current administration may affect the FDA's ability to exercise its regulatory authority. If such executive actions impose constraints on the FDA's ability to engage in routine oversight and product review activities in the normal course, our business may be negatively impacted.

***Breakthrough Therapy Designation or Fast Track Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.***

We may seek a Breakthrough Therapy Designation ("BTD") for some of our product candidates. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a BTD for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may withdraw Fast Track or Breakthrough Therapy designation if it believes that the designation is no longer supported by data from our clinical development program.

If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation ("FTD"). The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure our stockholders that the FDA would decide to grant it. We may not experience a faster development process, review or approval compared to conventional FDA procedures for the product candidate for which we have received, or may receive in the future, FTD. The FDA may withdraw FTD if it believes that the designation is no longer supported by data from our clinical development program. FTD alone does not guarantee qualification for the FDA's priority review procedures. Neither FTD nor BTD changes the scientific or medical standards for approval or the quality of evidence necessary to support approval.

In April 2023, we received FTD for investigation of botensilimab in combination with balstilimab for the treatment of patients with relapsed or refractory metastatic MSS CRC in patients with non-active liver metastases.

***We may seek priority review designation for one or more of our other product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a 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 over available therapies, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA is to take action on the marketing application within six months of the 60-day filing date, rather than the standard review period of ten months from filing. We may request priority review for our product candidates. 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. A priority review does not change the scientific or medical standards for approval or the quality of evidence necessary to support approval. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

***We may not be able to obtain or maintain orphan drug designations from the FDA for our current and future product candidates, as applicable.***

Our strategy includes filing for orphan drug designation where available for our product candidates, but thus far, our applications for orphan drug designation with respect to balstilimab and zalifrelimab have been rejected.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full new drug application, or NDA, or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the orphan- designated disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may receive and be approved for the same condition. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may again seek orphan drug designation for our product candidates, we may never receive such designations.

***If approved, our product candidates that are regulated as biological products, or biologics, may face competition from biosimilars approved through an abbreviated regulatory pathway.***

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established an abbreviated pathway for the approval of biosimilar and interchangeable biologics with an FDA-licensed reference biologic product. Under the BPCIA, a reference biological product is granted 12 years of non-patent data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as their BLA does not rely on the reference product or sponsor's data and is not submitted as a biosimilar application. Certain changes and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period. The law is complex and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our product candidates that receive FDA approval, if any, will qualify for the current 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidate to be a reference product for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure. It is also possible that payors will give reimbursement preference to biosimilars over reference biological products, even absent a determination of interchangeability.

Laws and regulations outside the United States differ, including the length and extent of patent and exclusivity protection and pathways for competition to enter the market. Other countries may have significantly shorter or longer periods of exclusivity. In addition, other countries may have different standards in determining similarity to a reference product. Any market entry of competing products to our product candidates in these other regions could adversely affect our business in those regions.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates it could adversely affect our business, financial condition, results of operations and prospects.

***Our business operations and current and future arrangements with third parties such as investigators, healthcare professionals and other healthcare providers, third-party payors, patients, patient organizations and purchasers of our products, may expose us to investigations, litigation, criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Our business operations and current and future arrangements with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, if approved. Such laws, some of which may apply only after our products are approved for marketing, include:

- the federal healthcare anti-kickback statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made, under federal and state healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the anti-kickback statute or specific intent to violate it in order to have committed a violation;
- the federal False Claims Act ("FCA"), which imposes criminal and civil penalties on individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government and actions under the FCA may be brought by private whistleblowers as well as the government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for the purposes of the FCA;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by a Medicare or a state healthcare program;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, including private health plans, and also establishes requirements related to the privacy security, and transmission or individually identifiable health information which apply to many healthcare providers, physicians and third-party payors with whom we interact;
- the federal false statement statute prohibits knowingly and willfully 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 anti-kickback prohibition known as Eliminating Kickbacks in Recovery Act, or EKRA, which prohibits certain payments related to referrals of patients to certain providers (recovery homes, clinical treatment facilities, and laboratories) and applies to services reimbursed by private health plans as well as government health care programs;
- the FDCA, which, among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws, such as the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to calculate, report and certify certain complex product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under governmental healthcare programs;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the so-called federal "sunshine law" or Open Payments which requires manufacturers of drugs, devices, biologics and medical supplies to report to the Centers for Medicare & Medicaid Services information related to payments and other "transfers of value" to teaching hospitals, physicians and other healthcare practitioners, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private health plans, and state laws which regulate interaction between pharmaceutical companies and healthcare providers, require pharmaceutical companies to comply with specific compliance standards, require

pharmaceutical companies to report information on transfers of value to other healthcare providers, marketing expenditures; or pricing information and/or require licensing of sales representatives. State laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, amount other foreign laws.

We have adopted and revised our code of business conduct and ethics, which we review and update on a periodic basis, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare and other laws and regulations will involve substantial costs. Given the breadth of the laws and regulations and narrowness of any exceptions, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, regulatory authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations, including our consulting agreements and other relationships with healthcare providers.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to actions including the imposition of civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements, or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***Even if we receive regulatory approval of any product candidates or therapies, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, limit how we market and manufacture our products, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, export, import, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, 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 product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw 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 our product candidates, 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 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 restrictions or other restrictions under a REMS program. Other potential consequences include, 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;
- fines, warning 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 license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are in development, as well as those placed on the market. Products 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 liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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 lose any marketing approval that we may have obtained which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If any such actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.***

Changes in statutes, regulations or the interpretation of the same could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of initiatives to reform delivery of, or payment, for healthcare, which include initiatives to reduce the cost of healthcare generally and drugs specifically. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act ("ACA"), which expanded healthcare coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included a number of changes to the coverage and reimbursement of drug products under government healthcare programs as well as the imposition of annual fees on manufacturers of branded pharmaceuticals.

Beyond the ACA, there have been and are ongoing and widespread health care reform efforts, a number of which have focused on regulation of prices or payment for drug products. Drug pricing and payment reform has been an ongoing focus. For example, federal legislation eliminated a statutory cap on Medicaid drug rebate program rebates effective January 1, 2024. As another example, the Inflation Reduction Act ("IRA") of 2022 includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D, with varying implementation dates. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the Medicare Part D coverage gap discount program implemented under ACA) and a drug price negotiation program for certain high spend Medicare Part B and D drugs (with negotiated prices for the first set of drugs scheduled to take effect in 2026). Subsequent to the enactment of the IRA, in 2022, the Biden Administration announced its commitment to expanding certain IRA reforms. There have been significant and wide-ranging reforms to federal policy and the federal government under the new presidential administration, including reductions in the federal workforce at key federal healthcare agencies. Drug pricing and payment reform was

a focus of the prior Trump administration and that focus is likely to continue under the current administration. Other potential healthcare reform efforts under the current administration may affect access to healthcare coverage or the funding of health care benefits. There is significant uncertainty regarding the nature or impact of any such reform implemented by the current administration through executive action or by Congress.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, with respect to the ACA, tax reform legislation was enacted that eliminated the tax penalty established for individuals who do not maintain mandated health insurance coverage beginning in 2019 and, in 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed and subsequent legislation imposed a moratorium on implementation of the rule until January 2032. As another example, the IRA drug price negotiation program has been challenged in litigation filed by various pharmaceutical manufacturers and industry groups.

Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect to experience pricing pressures in connection with the sale of any of our product candidates, if and when approved for marketing, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

In addition, other legislative changes have been adopted that could have an adverse effect upon, and could prevent, our product candidates' commercial success. For example, the Budget Control Act of 2011, as amended, or the Budget Control Act, includes provisions intended to reduce the federal deficit, including reductions in Medicare payments to providers through 2032. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs, or any significant taxes or fees imposed as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, or otherwise, could have an adverse impact on our anticipated product revenues.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our product candidates if approved for sale. We cannot predict the ultimate content, timing or effect of any federal and state reform efforts. There is no assurance that federal or state healthcare reform will not adversely affect our future business and financial results.

***European Union drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.***

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of pharmaceutical products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States. Infringement of these laws could result in substantial fines and imprisonment.

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

In addition, in most foreign countries, including the European Economic Area, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement 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. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. 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. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates 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, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

***European data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.***

The collection and use of personal health data in the European Union ("EU"), was previously governed by the provisions of the Data Protection Directive, which has been replaced by the General Data Protection Regulation 2016/679 ("GDPR") as of May 2018.

The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, such as us, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area, ("EEA"), including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR substantially increases the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10 million Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20 million Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the new law, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EU. Also, in the field of handling genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty.

With respect to our clinical trials in the EEA, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States in compliance with European data protection laws including the GDPR. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

***Laws and regulations governing any international operations may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.***

Because we have operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. individual or business from paying,

offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. We, directly or through our CROs, are conducting clinical trials in countries that Transparency International has identified as "perceived as more corrupt", including, Brazil, Chile, Georgia, Russia and Ukraine. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we expand our presence outside of the United States, we must dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

***We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions (including sanctions against Russia following their invasion of Ukraine), and other trade laws and regulations. We can face serious consequences for violations.***

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. The Russian invasion of Ukraine has resulted in new and expanded U.S. and EU sanctions against Russia which have impacted the conduct of business with Russian entities, has and may continue to impact existing sales of services within Russia by our wholly-owned, independently-operated subsidiary, Atlant Clinical, a CRO based in Moscow, Russia, which we acquired in 2020.

***Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes and the impact of crises that hinder its operations. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, the current administration appears to be to focused on decreasing spending in the federal government, including through significant staff reductions. Any significant staff reductions at FDA could impact the agency's ability to engage in routine regulatory and oversight activities and result in delays or limitations on our ability to proceed with clinical development programs and obtain regulatory approvals. Additionally, over the last

several years , the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If significant staff reductions or a prolonged government shutdown occur, 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 business.

***If we do not comply with environmental laws and regulations, we may incur significant costs and potential disruption to our business.***

We use or may use hazardous, infectious, and radioactive materials, and recombinant DNA in our operations, which have the potential of being harmful to human health and safety or the environment. We store these hazardous (flammable, corrosive, toxic), infectious, and radioactive materials, and various wastes resulting from their use, at our facilities pending use and ultimate disposal. We are subject to a variety of federal, state, and local laws and regulations governing use, generation, storage, handling, and disposal of these materials. We may incur significant costs complying with both current and future environmental health and safety laws and regulations. In particular, we are subject to regulation by the Occupational Safety and Health Administration, the Environmental Protection Agency, the Drug Enforcement Agency, the Department of Transportation, the Centers for Disease Control and Prevention, the National Institutes of Health, the International Air Transportation Association, and various state and local agencies. At any time, one or more of the aforementioned agencies could adopt regulations that may affect our operations. We are also subject to regulation under the Toxic Substances Control Act and the Resource Conservation Development programs.

Although we believe that our current procedures and programs for handling, storage, and disposal of these materials comply with federal, state, and local laws and regulations, we cannot eliminate the risk of accidents involving contamination from these materials. Although we have a workers' compensation liability policy, we could be held liable for resulting damages in the event of an accident or accidental release, and such damages could be substantially in excess of any available insurance coverage and could substantially disrupt our business.

***If we or our employees, independent contractors, consultants, commercial partners and vendors fail to comply with laws or regulations, it could adversely impact our reputation, business and stock price.***

We are exposed to the risk of employee fraud or other misconduct our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by employees could include intentional and/or negligent failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health care fraud and abuse, transparency, and/or data privacy laws and regulations (including the California Consumer Privacy Act) and security laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices; to promote transparency; and to protect the privacy and security of patient data. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs.

While we have adopted a corporate compliance program, we may not be able to protect against all potential issues of noncompliance. Efforts to ensure that our business complies with all applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable laws and regulations.

Employee misconduct could also involve the improper use or disclosure of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. We may not be able to prevent a director, executive or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert the attention of our management team.

***Risks associated with doing business internationally could negatively affect our business.***

We currently have research and development operations in the United Kingdom ("UK") and clinical operations in eastern Europe, and we expect to pursue pathways to develop and commercialize our product candidates in both U.S. and ex-U.S. jurisdictions. Various risks associated with foreign operations may impact our success. Possible risks of foreign operations include fluctuations in the value of foreign and domestic currencies, requirements to comply with various jurisdictional requirements such as data privacy regulations, disruptions in the import, export, and transportation of patient tumors and our products or product candidates, the product and service needs of foreign customers, difficulties in building and managing foreign relationships, the performance of our licensees or collaborators, geopolitical instability, unexpected regulatory, economic, or political changes in foreign and domestic markets, including without limitation any resulting from the UK's withdrawal from the EU or our current political regime, and limitations on the flexibility of our operations and costs imposed by local labor laws.

Although we do not anticipate a material impact to our global business operations, our subsidiary Atlant Clinical has employees in Russia who could be adversely affected by the impact of the Russian invasion of Ukraine. The war may impact staffing and adversely impact existing business, new business development, the completion of projects and adherence to timelines by affected employees.

***The exit of the UK from the European Union may materially affect the regulatory regime that governs our handling of EU personal data and expose us to legal and business risks under European data privacy and protection law.***

As a result of the UK exiting the EU, commonly known as Brexit, since January 1, 2021, any transfers of personal data to the UK are subject to the requirements of Chapter V of the GDPR and of the Law Enforcement Directive and absent an adequacy finding under GDPR, transfers of personal data from the EU to the UK, including to our facility in Cambridge, UK, would be illegal without adequate safeguards provided for under EC-approved mechanisms, such as current standard contractual clauses or, if approved in the future, an EU-UK privacy shield similar to the current framework in place between the EU and the United States. The extensive authority of UK intelligence and law enforcement agencies, including to conduct surveillance on personal data flows, could reduce the likelihood that the EC would give the UK an adequacy finding and reduce the likelihood that the EC would approve an EU-UK privacy shield. Accordingly, we may be exposed to legal risk for any of our EU-UK personal data transfers, including those that involve sensitive data such as patient and genetic data. Given the uncertainties surrounding the UK's departure from the EU, it is difficult to precisely identify or quantify the risks described above.

Additionally, it is possible that, over time, the UK Data Protection Act could become less aligned with the GDPR, which could require us to implement different compliance measures for the UK and the European Union and result in potentially enhanced compliance obligations for EU personal data.

As a result, Brexit adds legal risk, uncertainty, complexity and cost to our handling of EU personal information and our privacy and data security compliance programs. If we do not successfully manage such risk, our prospects may be materially harmed.

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

As of December 31, 2024, we had U.S. federal and state net operating loss, or Net Operating Losses ("NOLs"), carryforwards of $910.1 million and $437.1 million, respectively, which may be available to offset future taxable income. The federal NOLs include $505.6 million which expire at various dates through 2037 and $404.5 million which carryforward indefinitely. The state NOLs expire at various dates through 2044, with the exception of $1.7 million of these net operating loss carryforwards which do not expire. As of December 31, 2024, we also had U.S. federal and state research and development tax credit carryforwards of $5.8 million and $1.4 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2025. In addition, in general, under Sections 382 and 383 of the Code and corresponding provisions of state law, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, including in connection with our recent private placements, IPO and other transactions. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code and our ability to utilize NOLs or credits may be impaired. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above under "Risk factors—Risks Related to Our Financial Position and Need for Additional Capital," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income

necessary to utilize our NOLs or credits that are subject to limitation by Sections 382 and 383 of the Code. The reduction of the corporate tax rate under the TCJA caused a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, net operating loss carryforwards generated after December 31, 2017 will not be subject to expiration.

**Risks Related to Our Intellectual Property**

***If we are unable to obtain and enforce patent protection for our product candidates and related technology, our business could be materially harmed.***

We rely upon a combination of patents, trade secrets and confidentiality agreements to protect the intellectual property related to our product candidates and technology. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to duplicate or surpass our technological achievements, eroding our competitive position in the market. Our patent applications may not result in issued patents, and, even if issued, the patents may be challenged and invalidated. Moreover, our patents and patent applications may not be sufficiently broad to prevent others from practicing our technologies or developing competing products. We also face the risk that others may independently develop similar or alternative technologies or may design around our proprietary property.

Issued patents may be challenged, narrowed, invalidated or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own, or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from biosimilar or generic versions of our product candidates. Furthermore, the product development timeline for biotechnology products is lengthy and it is possible that our issued patents covering our product candidates in the United States and other jurisdictions may expire prior to commercial launch. For example, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product candidates under patent protection could be reduced.

Our strategy depends on our ability to identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we and our current or future licensors or licensees may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or our current licensors or licensees, or any future licensors or licensees, may not identify patentable aspects of inventions made in the course of development and commercialization activities in time to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc. If we or our current licensors or licensees, or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current licensors or licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented

product and practicing our own patented technology. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent landscapes in the fields of antibody, adjuvant and adoptive cell therapy development, manufacture and commercialization are crowded. For example, we are aware of third-party patents directed to methods for identifying and producing therapeutic products such as antibodies, adjuvants and adoptive cell therapies. We are also aware of third-party patents directed to products targeting numerous antigens for which we also seek to identify, develop, and commercialize products. For example, some patents claim products based on competitive binding with existing products, some claim products based on specifying sequence or other structural information, and some claim various methods of discovery, production, or use of such products.

These or other third-party patents could impact our freedom to operate in relation to our technology platforms, as well as in relation to development and commercialization of products identified by us as therapeutic candidates. As we discover and develop our candidates, we will continue to conduct analyses of these third-party patents to determine whether we believe we might infringe them, and if so, whether they would be likely to be deemed valid and enforceable if challenged. If we determine that a license for a given patent or family of patents is necessary or desirable, there can be no guarantee that a license would be available on favorable terms, or at all. Inability to obtain a license on favorable terms, should such a license be determined to be necessary or desirable, could, without limitation, result in increased costs to design around the third-party patents, delay product launch, or result in cancellation of the affected program or cessation of use of the affected technology.

Third parties may also seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

In addition, as we advance our research and development efforts with our institutional and corporate collaborators, we are seeking patent protection for newly identified therapeutic antibodies and product candidates. We can provide no assurance that any of our patents, including the patents that we acquired or in-licensed in connection with our acquisition of 4-AB, will have commercial value, or that any of our existing or future patent applications, including the patent applications that we acquired or in-licensed in connection with our acquisition of 4-AB, will result in the issuance of valid and enforceable patents.

The patent position of biopharmaceutical, pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in biopharmaceutical, pharmaceutical or biotechnology patents. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Outside the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, we cannot predict whether additional patents protecting our technology will issue in the United States or in foreign jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide competitive advantage. Moreover, we cannot predict whether third parties will be able to successfully obtain claims or the breadth of such claims. The allowance of broader claims may increase the incidence and cost of patent interference proceedings, opposition proceedings, post-grant review, inter partes review, and/or reexamination proceedings, the risk of infringement litigation, and the vulnerability of the claims to challenge. On the other hand, the allowance of narrower claims does not eliminate the potential for adversarial proceedings and may fail to provide a competitive advantage. Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage.

***If any of our owned or in-licensed patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.***

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. Our patent positions, and those of other biopharmaceutical, pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific, and factual questions. The standards which the United States Patent and Trademark Office ("USPTO") uses to grant patents, and the standards which courts use to interpret patents, are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, the level of protection, if any, that will be provided by our patents if we attempt to enforce them and they are challenged, is uncertain. In addition, the type and extent of patent claims that will be issued to us in the future is

uncertain. Any patents that are issued may not contain claims that permit us to stop competitors from using similar technology. With respect to both in- licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

***If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.***

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued which protect our product candidates or patents which effectively prevent others from commercializing competitive technologies and product candidates.

No consistent policy regarding the scope of claims allowable in patents in the biotechnology field has emerged in the United States. The patent situation outside of the United States is even more uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our products and the methods used to manufacture those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our patented product candidates and practicing our proprietary technology. Our issued patent and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or limit the length of the term of patent protection that we may have for our product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or license issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and patents that we own or license may be challenged in the courts or patent offices in the United States and abroad. We or our licensors may be subject to a third party preissuance submission of prior art to the USPTO or to foreign patent authorities or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings or other similar proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in-licensed patent rights, allow third parties to commercialize our product candidates, and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our licensor's priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may in the future co-own patent rights relating to future product candidates with third parties. Some of our in-licensed patent rights are, and may in the future be, co-owned with third parties. In addition, our licensors may co-own the patent rights we in-license with other third parties with whom we do not have a direct relationship. Our exclusive rights to certain of these patent rights are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such patent rights, who are not parties to our license agreements. If our licensors do not have exclusive control of the grant of licenses under any such third-party co-owners' interest in such patent rights or we are otherwise unable to secure such exclusive rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

***If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.***

We are currently party to various intellectual property license agreements. These license agreements impose, and we expect that future license agreements may impose, various diligence, milestone payment, royalty, insurance, prosecution, enforcement and other obligations on us. These licenses typically include an obligation to pay an upfront payment, yearly maintenance payments and royalties on sales. If we fail to comply with our obligations under the licenses, the licensors or licensees may have the right to terminate their respective license agreements, in which event we might not be able to market or obtain royalties or other revenue from any product that is covered by the agreements. Termination of the license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, which could adversely affect our competitive business position and harm our business. In addition, court decisions may introduce uncertainty with respect to terms of a license agreement such as the impact of a challenge to the validity of a licensed patent on the payment obligations or termination rights of the license.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. 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 territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our product candidates, and our 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 and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. 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 patents at risk of being invalidated or interpreted narrowly and our 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. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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 own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel or service providers to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. In addition, we are responsible for the payment of patent fees for patent rights that we have licensed from other parties.

If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time-consuming and inherently uncertain. In addition, the United States has enacted and implemented wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

***If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.***

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign

rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery.

Depending upon the nature of the product and the specifics of the related FDA marketing approval, data exclusivity under the BPCIA or related laws in the U.S. or certain foreign countries and territories may be available for our products. The BPCIA provides that FDA shall not approve certain biosimilars from the date of first licensure of a reference product for 12 years, subject to certain restrictions. However, we may not obtain or be eligible for data exclusivity because of, for example, the nature of the product with respect to other products on the market, our relationships with our partners (including our licensors and licensees), failing to claim the exclusivity at the appropriate time or otherwise failing to satisfy applicable requirements. If we are unable to obtain data exclusivity, our competitors may obtain earlier approval of competing products, and our business, financial condition, results of operations and prospects could be materially harmed.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.***

We may have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biopharmaceutical, biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.***

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. In particular, the patent landscapes around the discovery, development, manufacture and commercial use of our product candidates are crowded.

Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to any technology that we require may also materially harm our business, financial condition, and results of operations. Furthermore, we would be exposed to a threat of litigation.

In the biopharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us or our licensors or licensees, we or our licensors or licensees may be required to participate in interference, derivation or other proceedings to determine the

priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;

- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is a risk that a court would decide that we or our collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our collaborators may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

The biopharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates.***

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our

product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

***We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.***

Third parties may infringe or misappropriate our intellectual property, including our existing patents, patents that may issue to us in the future, or the patents of our licensors or licensees to which we have a license. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Further, we may not be able to prevent, alone or with our licensors or licensees, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

If we or one of our licensors or licensees were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidates is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent.

In addition, within and outside of the United States, there has been a substantial amount of litigation and administrative proceedings, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions, regarding patent and other intellectual property rights in the biopharmaceutical industry. Notably, the AIA, introduced new procedures, including inter partes review and post grant review. These procedures may be used by competitors to challenge the scope and/or validity of our patents, including those patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges.

Even after they have been issued, our patents and any patents which we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

The following are non-exclusive examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;
- third parties may initiate opposition proceedings, post-grant review, inter partes review, or reexamination proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and/or licensors or licensees to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us;
- the USPTO may initiate an interference or derivation proceeding between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our collaborators and/or licensors or licensees to participate in an interference or derivation proceeding to determine the priority of invention, which could jeopardize our patent rights; or
- third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. There is a risk that a court or administrative body could decide that our patents are invalid or not infringed by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents could limit our ability to assert our patents against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. An adverse outcome may also put our pending patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administrative panel to affect the validity or enforceability of a claim, for example, if a priority claim is found to be improper. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our relevant product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, during the course of litigation or administrative proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed. Any of these occurrences could adversely affect our competitive business position, business prospects, and financial condition.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable.

***If we do not obtain patent term extension and/or data exclusivity for any product candidates we may develop, our business may be materially harmed.***

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

***We may be subject to claims challenging the inventorship of our patents and other intellectual property.***

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our licensors' ownership of our owned or in-licensed patent rights, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. We also have partners who may market or refer to our trademarks or trade names and may use the trademarks or trade names in ways that impair our branding strategy. For example, Betta Pharmaceuticals has rights to our antibody, zalifrelimab, in greater China and may adopt a marketing strategy in their territories, including use or registration of trademarks and tradenames for our antibody, that could impair our brand identity or strategy and possibly cause market confusion. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. 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. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

***Intellectual property rights do not necessarily address all potential threats.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Risks Related to Business Operations, Employee Matters and Managing Growth**

***We have consolidated certain sites while expanding others to focus on our core priorities and future needs. We may encounter difficulties in managing these growth and/or consolidation efforts, either of which could disrupt our operations.***

In the past our headcount has increased through various acquisitions and the expansion of our research, development and manufacturing infrastructure and associated activities both nationally and internationally. However, we continuously reassess our business needs to ensure our internal headcount and internal capabilities is balanced with business priorities, needs and financing. , In May 2022, we announced that we had reduced expenses by approximately 20% to improve efficiency and focus on our most promising development candidates, such as botensilimab. Further, in August 2023, we announced that we had further realigned our personnel and resources to focus on progression of our lead program, botensilimab, in metastatic MSS CRC, including a 25% overall reduction in employees. In December 2024, we announced additional staff reductions. To manage these organizational changes, we must continue to implement and improve our managerial, operational, and financial systems and continue to recruit, train and retain qualified personnel. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our timelines may be delayed, our ability to generate revenue could be reduced, and we may not be able to implement our business strategy.

If as a result of these or similar future efforts we identify management or operational gaps in connection with our changes, it could cause delays in discovery timelines and increased costs for certain of our internal and partnered programs, which also could have an adverse effect on our business, financial condition and results of operations.

***Product liability and other claims against us may reduce demand for our products and/or result in substantial damages.***

We face an inherent risk of product liability exposure related to testing our product candidates in human clinical trials and manufacturing antibodies in our Berkeley, CA facility and may face even greater risks if we ever sell products commercially. An individual may bring a product liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. Product liability claims may result in:

- regulatory investigations;
- injury to our reputation;
- withdrawal of clinical trial volunteers;
- costs of and distraction related to litigation;
- substantial monetary awards to plaintiffs; and
- decreased demand for any future products.

We have limited product liability coverage for use of our product candidates. Our product liability policy provides $10.0 million aggregate coverage and $10.0 million per occurrence coverage. This limited insurance coverage may be insufficient to fully cover us for future claims.

We are also subject to domestic and international laws generally applicable to businesses, including but not limited to, federal, state and local wage and hour, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects.

***We are highly reliant on certain members of our management team. In addition, we have limited internal resources and if we fail to recruit and/or retain the services of key employees and external consultants as needed, we may not be able to achieve our strategic and operational objectives.***

Garo H. Armen, Ph.D., the Chairman of our Board of Directors and our Chief Executive Officer who co-founded the Company in 1994 is integral to building our company and developing our technology. Jennifer Buell, Ph.D., Chair of Agenus' Executive Council and Robin Taylor, Ph.D., our Chief Commercial Officer, also provide key strategic advice. If either Dr. Armen, Dr. Buell or Dr. Taylor is unable or unwilling to continue his or her relationship with Agenus, our business may be adversely impacted. We have an employment agreement with Dr. Armen. Dr. Armen plays an important role in our day-to-day activities, and we do not carry key employee insurance policies for Dr. Armen or any other employee. The loss of the services of these employees, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. Dr. Buell also serves as Chief Executive Officer for MiNK Therapeutics, and Dr. Armen is Chairman of the Board of Directors of MiNK Therapeutics.

The bulk of our operations are conducted at our facilities in Cambridge, UK, Lexington, MA and Berkeley, CA. The Cambridge, UK, greater Boston area, and Northern California regions are headquarters to many other biopharmaceutical companies and many academic and research institutions. 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 future growth success depends to a significant extent on the skills, experience and efforts of our executive officers and key members of our clinical and scientific staff. We face intense competition for qualified individuals from other pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions, particularly in the historically tight labor market prevailing currently. To attract and retain employees at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Employment of our key employees is at-will, which means that any of our employees could leave our employment at any time, with or without notice. We may be unable to retain our current personnel or attract or assimilate other highly qualified management and clinical personnel in the future on acceptable terms. The loss of any or all of these individuals could harm our business and could impair our ability to support our collaboration partners or our growth generally.

***Our internal computer systems, or those of our third-party CROs, CMOs, licensees, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption in our business and operations or could subject us to sanctions and penalties that could have a material adverse effect on our reputation or financial condition.***

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs, CMOs, licensees, collaborators and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Potential vulnerabilities can also be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In July 2020, the United States Government charged a pair of Chinese hackers working on behalf of China’s intelligence service in relation to the hacking of U.S. based biotechnology companies researching COVID-19 vaccines. We anticipate that U.S. companies may also be targeted by Russia and/or its supporters as the result of the U.S.’s support of Ukraine. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents. While we are not aware of any such material system failure, accident or security breach to date, 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, on-going or future clinical trials could result in delays in our regulatory approval efforts and significant costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture certain of our drug candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development and commercialization of our product candidates could be delayed. We do not maintain cyber liability insurance and would therefore have no coverage for any losses resulting from any data security incident.

We use and store customer, vendor, employee and business partner and, in certain instances patient, personally identifiable information in the ordinary course of our business. We are subject to various domestic and international privacy and security regulations, including but not limited to the HIPAA, which mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of

individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. Failure to comply with these standards, or a computer security breach or cyber-attack that affects our systems or results in the unauthorized release of proprietary or personally identifiable information, could subject us to criminal penalties and civil sanctions, and our reputation could be materially damaged, and our operations could be impaired. We may also be exposed to a risk of loss or litigation and potential liability, which could have a material adverse effect on our business, results of operations and financial condition.

***Natural or man-made calamities, or public health crises, could disrupt our business and materially adversely affect our operations and those of our strategic partners.***

Our operations, and those of our CROs, CMOs, and other contractors and consultants together with regulatory agencies such as the FDA or EMA, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could prevent us, or our collaborators and business partners or regulators, from using all or a significant portion of our, or their, facilities or disrupt our supply chain, and, it may be difficult or, in certain cases, impossible for us to continue certain activities, such as for example our manufacturing capabilities, for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses and delays as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. We rely in part on third-party manufacturers to produce and process some of our product candidates. Our ability to obtain some of our clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

We own an antibody pilot plant manufacturing facility and in November 2020, entered into a long-term lease in Emeryville, CA for cGMP commercial manufacturing space. Construction of this end-to-end 83,000 square foot. GMP clinical & commercial biologics manufacturing facility (from cell line development through Drug Product fill & finish, packaging and labeling) is being commissioned. These locations are in an area of seismic activity near active earthquake faults and active wildfire activity. We do not maintain earthquake insurance coverage for our owned and leased properties in Berkeley, CA or Emeryville, CA.

In March 2020, we put in place a number of protective measures in response to the COVID-19 pandemic that have since been lifted. We revisited the various health and safety measures on a regular basis as the pandemic evolved, and we could take additional action if instructed by national, state and local governmental agencies or as we deem necessary to protect our employees. These measures resulted, and any future actions may result, in potential disruption to our business. Our employees are also impacted by the local government regulations that impact schools and other public services for lengthy periods of time. Not all of our employees are able to perform their duties or function remotely.

The operations of our strategic partners could also be impacted by calamities or public health crises, which could materially and adversely affect our cash resources and operations. For instance, at the beginning of 2020, we projected receipt of approximately $60.0 million of cash milestone payments from existing partners in 2020. Although we did receive $25.1 million of this in 2020, as a result of the impact of COVID-19 on our partner's programs and trials, the remaining $35.0 million was delayed and not received in 2020, which impacted our cash runway and ability to fund our operations. Additional delays resulting from other crises are likely to materially adversely affect our business.

Although we do not expect Russia's invasion of Ukraine to materially impact our global operations, the war may impact our business, and that of our wholly-owned, independently-operated subsidiary Atlant Clinical based in Moscow, Russia. We have employees in Russia that may be adversely affected by the war. The war may make it difficult for these employees to work, travel and may result in disruption to certain programs and timelines as well as future business opportunities. The Russian invasion of Ukraine may also adversely impact the ability of our existing strategic partners to conduct business in the Ukraine and Russia.

***Failure to realize the anticipated benefits of our strategic acquisitions and licensing transactions could adversely affect our business, operations and financial condition.***

An important part of our business strategy has been to identify and advance a pipeline of product candidates by acquiring and in-licensing product candidates, technologies and businesses that we believe are a strategic fit with our existing business. Since we acquired 4-AB in 2014, we have completed numerous additional strategic acquisitions and licensing transactions. The ultimate success of these strategic transactions entails numerous operational and financial risks, including:

- higher than expected development and integration costs;
- difficulty in combining the technologies, operations and personnel of acquired businesses with our technologies, operations and personnel;
- exposure to unknown liabilities;
- difficulty or inability to form a unified corporate culture across multiple office sites both nationally and internationally;
- inability to retain key employees of acquired businesses;
- disruption of our business and diversion of our management's time and attention; and
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed product candidates, technologies or businesses.

We have limited resources to integrate acquired and in-licensed product candidates, technologies and businesses into our current infrastructure, and we may fail to realize the anticipated benefits of our strategic transactions. Any such failure could have an adverse effect on our business, operations and financial condition.

***Our subsidiary, MiNK, successfully closed an IPO in October 2021. We have made substantial investments in MiNK. There is no guarantee that it will be able to continue to attract funding from other sources, and, even if the business receives such funding, there is no guarantee that it will be successful.***

MiNK closed an IPO in October 2021. As of December 31, 2024, we owned 2,177,286 shares, representing approximately 55% of MiNK's common stock. There is no guarantee that MiNK will be able to attract external funding in the future. If external funding is available, there is no guarantee that it will be on attractive or acceptable terms, or that it will be adequate to advance the business to an inflection point for additional funding. Similarly, there is no guarantee that partnership opportunities will be available on attractive terms, if at all. Even if adequate funding and partnership opportunities are available, there is no guarantee that MiNK will be successful in advancing one or more product candidates through clinical development. In February 2024, we acquired from MiNK a convertible promissory note in the principal amount of $5 million.

**Risks Related to our Common Stock**

***The trading volume and public trading price of our common stock has been volatile.***

During the period from our initial public offering on February 4, 2000 to December 31, 2024, and the twelve-months ended December 31, 2024, the closing price of our common stock has fluctuated between $2.57 and $6,315.60 per share and $2.57 and $18.56 per share, respectively. The average daily trading volume for the twelve-months ended December 31, 2024 was approximately 637,497 shares. The market in general, and biotechnology companies in particular, may experience significant price and volume fluctuations that are often unrelated to the operating performance of individual companies. In addition to general market volatility, many factors may have a significant adverse effect on the market price of our stock, including:

- continuing operating losses, which we expect over the next several years if we are able to transition to a commercial organization;
- announcements of decisions made by public officials or delays in any such announcements;
- results of our pre-clinical studies and clinical trials or delays in anticipated timing;
- delays in our regulatory filings or those of our partners;
- announcements of new collaboration agreements with strategic partners or developments by our existing collaboration partners;
- announcements of acquisitions;
- announcements of technological innovations, new commercial products, failures of products, or progress toward commercialization by our competitors or peers;
- failure to realize the anticipated benefits of acquisitions;
- developments concerning proprietary rights, including patent and litigation matters;

- publicity regarding actual or potential results with respect to product candidates under development;
- quarterly fluctuations in our financial results, including our average monthly cash used in operating activities;
- variations in the level of expenses related to any of our product candidates or clinical development programs;
- additions or departures of key management or scientific personnel;
- conditions or trends in the biopharmaceutical, biotechnology and pharmaceutical industries generally;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In the past, securities class action litigation has often been brought against a company following a significant decline in the market price of its securities. This risk is especially relevant for us because many biopharmaceutical, biotechnology and pharmaceutical companies experience significant stock price volatility.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock, or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

On December 4, 2023, we were notified by the Nasdaq Staff that we are not in compliance with the Bid Price Requirement because the bid price for our common stock had closed below the minimum $1.00 per share requirement for 30 consecutive business days. On April 3, 2024, we held a Special Meeting of Stockholders, at which our stockholders voted in favor of an amendment to our Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of our issued and outstanding common stock at a ratio of 1-for-20. Although we regained compliance with the Bid Price Requirement following the reverse stock split, there is no assurance that the reverse stock split alone will guarantee our continued listing on The Nasdaq Capital Market in the future.

***We do not intend to pay cash dividends on our common stock and, consequently your ability to obtain a return on your investment will depend on appreciation in the price of our common stock.***

We have never declared or paid any cash dividend on our common stock and do not intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or maintain their current value.

***Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 and to comply with changing regulation of corporate governance and public disclosure could have a material adverse effect on our operating results and the price of our common stock.***

The Sarbanes-Oxley Act of 2002 and rules adopted by the SEC and Nasdaq have resulted in significant costs to us. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations regarding the required assessment of our internal control over financial reporting, and our independent registered public accounting firm's audit of internal control over financial reporting, have required commitments of significant management time. We expect these commitments to continue.

Our internal control over financial reporting (as defined in Rules 13a-15 of the Exchange Act) is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external purposes in accordance with U.S. GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect all deficiencies or weaknesses in our financial reporting. While our management has concluded that there were no material weaknesses in our internal control over financial reporting as of December 31, 2024, our procedures are subject to the risk that our controls may become inadequate because of changes in conditions or as a result of a deterioration in compliance with such

procedures. No assurance is given that our procedures and processes for detecting weaknesses in our internal control over financial reporting will be effective.

Changing laws, regulations and standards relating to corporate governance and public disclosure, are creating uncertainty for companies. Laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided, which could result in continuing uncertainty regarding compliance matters and higher costs caused by ongoing revisions to disclosure and governance practices. If we fail to comply with these laws, regulations and standards, our reputation may be harmed, and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our operating results and the market price of our common stock.

***The sale of a significant number of shares could cause the market price of our stock to decline.***

The sale by us or the resale by stockholders of a significant number of shares of our common stock could cause the market price of our common stock to decline. As of March 13, 2025, we had 25,308,841, shares of common stock outstanding. Certain of these shares are subject to sales volume and other limitations. We have filed registration statements to permit the sale of approximately 6,510,000 shares of common stock under our equity incentive plans, and to permit the sale of 175,000 shares of common stock under our 2015 Inducement Equity Plan. We have also filed registration statements to permit the sale of approximately 108,350 shares of common stock under our Employee Stock Purchase Plan, to permit the sale of 63,750 shares of common stock under our Directors' Deferred Compensation Plan, to permit the sale of approximately 1,555,015 shares of common stock pursuant to various private placement agreements and to permit the sale of up to 31,334,015 shares of our common stock pursuant to our At Market Issuance Sales Agreement. As of December 31, 2024, an aggregate of approximately 18.1 million of these shares remained available for sale. As part of our collaboration with Betta Pharmaceuticals, we completed a private placement of 248,138 shares of common stock in July 2020. As part of our collaboration with Gilead, we completed a private placement of 555,555 shares of common stock in January 2019, and on October 25, 2019, we filed a Registration Statement on Form S-3 to register the resale of these shares by Gilead, as required under our agreement. In addition, we may be obligated in the future to pay certain contingent milestones payments, payable at our election in cash or shares of our common stock of up to $30.0 million in the aggregate. If we elect to pay any of these contingent milestones in shares, we are obligated to file registration statements covering any such shares. The market price of our common stock may decrease based on the expectation of such sales.

As of December 31, 2024, warrants to purchase approximately 964,500 shares of our common stock with a weighted average exercise price per share of $21.29 were outstanding.

As of December 31, 2024, options to purchase 5,242,916 shares of our common stock with a weighted average exercise price per share of $28.76 were outstanding. These options are subject to vesting that occurs over a period of up to four years following the date of grant. As of December 31, 2024, we had 2,534,682 vested options and 42,222 non-vested shares outstanding.

As of December 31, 2024, our outstanding shares of Series A-1 Convertible Preferred Stock were convertible into 16,666 shares of our common stock.

We may issue additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options or warrants are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock or the exercise of stock options or warrants would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of securities held by existing investors.

***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 certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us without the consent of our Board of Directors. Our certificate of incorporation provides for a staggered board and removal of directors only for cause. Accordingly, stockholders may elect only a minority of our Board at any annual meeting, which may have the effect of delaying or preventing changes in management. In addition, under our certificate of incorporation, our Board of Directors may issue additional shares of preferred stock and determine the terms of those shares of stock without any further action by our stockholders. Our issuance of additional preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock and thereby effect a change in the composition of our Board of Directors. Our certificate of incorporation also provides that our

stockholders may not take action by written consent. Our bylaws require advance notice of stockholder proposals and director nominations and permit only our president or a majority of the Board of Directors to call a special stockholder meeting. These provisions may have the effect of preventing or hindering attempts by our stockholders to replace our current management. In addition, Delaware law prohibits a corporation from engaging in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our Board of Directors may use this provision to prevent changes in our management. Also, under applicable Delaware law, our Board of Directors may adopt additional anti-takeover measures in the future.

These anti-takeover provisions and other provisions in our certificate of incorporation and 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 our stockholders and other stockholders to elect directors of their choosing or cause us to take other corporate actions they 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.

***We have broad discretion in the use of our existing cash, cash equivalents and investments and may not use them effectively.***

Our management has broad discretion in the application of our cash, cash equivalents and investments. Because of the number and variability of factors that will determine our use of our cash, cash equivalents and investments, their ultimate use may vary substantially from their currently intended use. Our management might not apply our cash, cash equivalents and investments in ways that ultimately increase the value of our stockholders investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest our cash in short-term, investment- grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not use our resources in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

***If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

**Item 1B.** ***Unresolved Staff Comments***

None.

## Item 1C. Cybersecurity

***Cybersecurity Risk Management and Strategy***

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information.

We design and assess our program based on the Information Systems Audit and Control Association's Control Objectives for Information Technologies framework and National Institute of Standards and Technology cybersecurity framework, as well as threat trends identified by multiple external and internal cybersecurity intelligence reports.

Our cybersecurity risk management program is aligned to our business strategy and has been incorporated into our enterprise risk management process.

We contract with external firms to assess our cybersecurity controls. We have processes in place to identify and evaluate risks associated with third party vendors and suppliers. In addition, we have systems in place to maintain business continuity and disaster recovery. To date, we have not experienced any material cybersecurity incidents.

We describe whether and how risks from cybersecurity threats are reasonably likely to affect our business, results of operations and financial condition, under the heading "Our internal computer systems, or those of our third-party CROs, CMOs, licensees, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption in our business and operations or could subject us to sanctions and penalties that could have a material adverse effect on our reputation or financial condition." included as part of our Item 1A. Risk Factors of this Annual Report on Form 10-K, which is incorporated by reference into this Item 1C.

***Cybersecurity Governance***

Our Audit Committee of the Board of Directors has oversight responsibility for risks and incidents related to cybersecurity threats. Our Chief Information Officer is a member of our Enterprise Risk Management Committee and provides the Audit Committee and the Board of Directors periodic reports on our cybersecurity risks and any material cybersecurity incidents.

Our team of cybersecurity professionals is led by our Chief Information Officer, who has over 20 years of experience in cybersecurity in regulated industries. Our cybersecurity team monitors the prevention and detection of cybersecurity events and is responsible for incident response and remediation.

## Item 2. *Properties*

We lease our main research and development, manufacturing and corporate offices in Lexington, Massachusetts occupying approximately 82,000 square feet. This lease agreement terminates in August 2033.

We own a manufacturing facility of approximately 24,000 square feet in Berkeley, California that is used in the production and manufacture of antibody product candidates.

In November 2020, we entered into a long-term lease in Emeryville, California for cGMP commercial manufacturing space. Construction of this end-to-end 83,000 square foot clinical and commercial biologics manufacturing facility (from cell line development through Drug Product fill & finish, packaging and labeling) has been completed and the facility is being commissioned for GMP manufacturing. This lease terminates in December 2036 with the option to renew for two additional ten-year terms.

We also lease research and office facilities in Cambridge, United Kingdom. This lease terminates in November 2025.

We believe substantially all of our property and equipment is in good condition and that we have sufficient capacity to meet our current operational needs. We do not anticipate experiencing significant difficulty in retaining occupancy of any of our research and development, manufacturing or office facilities and will do so through lease renewals prior to expiration or through replacing them with equivalent facilities.

## Item 3. *Legal Proceedings*

In September 2024, a putative securities class action lawsuit captioned *In re Agenus Inc. Securities Litigation*, No. 1:24-cv-12299, was filed in the U.S. District Court for the District of Massachusetts (the "Court") against the Company and certain of its executives and directors. The Court appointed a lead plaintiff pursuant to the Private Securities Litigation Reform Act, and the lead plaintiff filed an amended complaint on February 7, 2025.

The lawsuit alleges that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder, by making false and misleading statements and omissions of material fact related to the efficacy and commercial prospects of botensilimab and balstilimab. The lead plaintiff seeks to represent all persons who purchased or otherwise

acquired Agenus securities between January 23, 2023, and July 17, 2024 and seeks damages and interest, and an award of costs, including attorneys' fees. We have not recorded any accrual for a contingent liability associated with these legal proceedings. The defendants' deadline to respond to the complaint is April 8, 2025.

The Company has been served with three derivative actions in the Court filed by purported stockholders, captioned *Royse v. Armen, et al.*, No. 1:24-cv-12823 (the "Royse Action"); *Chen v. Armen, et al.*, No. 1:24-cv-13088 (the "Chen Action"), *Ferraioli v. Armen, et al.*, No. 1:24-cv-13083 (the "Ferraioli Action"). The actions name certain of the Company's executives and directors and allege that defendants made false or misleading statements and omissions of material fact related to the efficacy and commercial prospects of botensilimab and balstilimab. Plaintiffs seek an award of damages and an order directing the Company to reform and improve its corporate governance and internal procedures. The Court consolidated the Royse Action and Chen Action on January 16, 2025 and defendants submitted an unopposed motion to stay all deadlines pending future developments in the securities class action on February 25, 2025. Defendants' deadline to respond to the complaint in the Ferraioli Action is March 10, 2025.

In September 2024, the Company received a subpoena from the Boston Regional Office of the U.S. Securities and Exchange Commission (the "SEC") seeking records relating to certain of our product candidates, correspondence with the FDA, public disclosure, and other matters. We have produced records pursuant to the subpoena. At this time, the Company cannot predict the outcome of the SEC's investigation.

We are not currently a party to any other 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***

Our common stock is currently listed on The Nasdaq Capital Market under the symbol "AGEN." As of February 28, 2025, there were 360 holders of record of our common stock. This number does not reflect the beneficial holders of our common stock who hold shares in street name through brokerage accounts or other nominees.

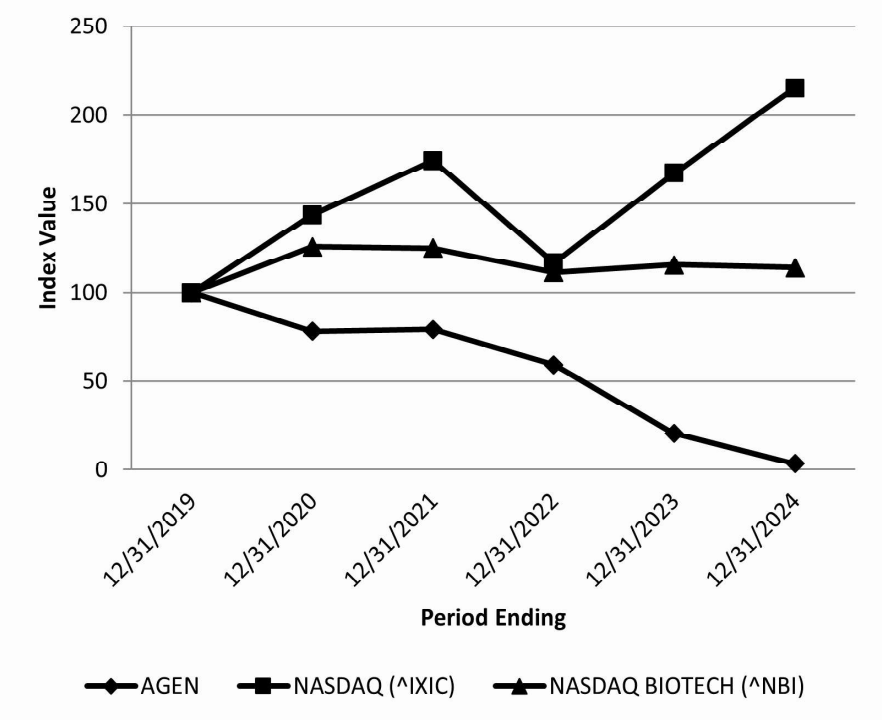
We have never paid cash dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain future earnings, if any, for the future operation and expansion of our business. Any future payment of dividends on our common stock will be at the discretion of our Board of Directors and will depend upon, among other things, our earnings, financial condition, capital requirements, level of indebtedness, and other factors that our Board of Directors deem relevant.

**Stock Performance**

The following graph shows the cumulative total stockholder return on our common stock over the period spanning December 31, 2019 to December 31, 2024, as compared with that of the Nasdaq Stock Market (U.S. Companies) Index and the Nasdaq Biotechnology Index, based on an initial investment of $100 in each on December 31, 2019. Total stockholder return is measured by dividing share price change plus dividends, if any, for each period by the share price at the beginning of the respective period and assumes reinvestment of dividends.

This stock performance graph shall not be deemed "filed" with the SEC or subject to Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any of our filings under the Securities Act of 1933, as amended (the "Securities Act").

**COMPARISON OF CUMULATIVE TOTAL RETURN OF AGENUS INC., NASDAQ STOCK MARKET (U.S. COMPANIES) INDEX AND NASDAQ BIOTECHNOLOGY INDEX**



| | 12/31/2019 | 12/31/2020 | 12/31/2021 | 12/31/2022 | 12/31/2023 | 12/31/2024 |
|---|---|---|---|---|---|---|
| Agenus Inc. | $ 100.00 | $ 78.13 | $ 79.12 | $ 58.97 | $ 20.39 | $ 3.37 |
| Nasdaq Stock Market (U.S. Companies) Index | $ 100.00 | $ 143.64 | $ 174.36 | $ 116.65 | $ 167.30 | $ 215.22 |
| Nasdaq Biotechnology Index | $ 100.00 | $ 125.69 | $ 124.89 | $ 111.27 | $ 115.42 | $ 113.84 |

**Item 6.** ***[Reserved]***

**Item 7.** ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

## Overview

Agenus Inc. (including its subsidiaries, collectively referred to as "Agenus," the "Company," "we," "us," and "our") is a clinical-stage biotechnology company specializing in discovering and developing therapies to activate the body's immune system against cancer and infections. Our pipeline includes immune-modulatory antibodies, adoptive cell therapies (via MiNK Therapeutics, Inc. ("MiNK")), and vaccine adjuvants (via SaponiQx, Inc. ("SaponiQx")). Our primary focus is immuno-oncology ("I-O"), and our diverse pipeline is supported by our in-house capabilities, including current good manufacturing practice ("cGMP") manufacturing and a clinical operations platform. To succeed in I-O, innovation and speed are paramount. We are a vertically integrated biotechnology company equipped with a suite of technology platforms to advance from novel target identification through manufacturing for clinical trials of antibodies and cell therapies. By understanding each patient's cancer, we aim to substantially expand the population benefiting from current I-O therapies. In addition to a diverse pipeline, we have assembled fully integrated end-to-end capabilities including novel target discovery, antibody generation, cell line development and cGMP manufacturing. Leveraging our science and capabilities, we have established strategic partnerships to advance innovation. We believe the next generation of cancer treatment will build on clinically validated antibodies targeting CTLA-4 and PD-1 combined with novel immunomodulatory agents designed to address underlying tumor escape mechanisms.

Our I-O portfolio is driven by several platforms and programs, which we plan to utilize individually and in combination:

- Multiple antibody discovery platforms, including proprietary display technologies, to identify future antibody candidates.
- Antibody candidate programs, including our lead assets, botensilimab ("BOT") (a multifunctional immune cell activator and human Fc-enhanced cytotoxic T-lymphocyte antigen 4 (CTLA-4) blocking antibody, also known as AGEN1181) and balstilimab ("BAL") (a programmed death receptor-1 (PD-1) blocking antibody).
- Our saponin-based vaccine adjuvant platform, primarily centered around our STIMULON™ cultured plant cell ("cpc") QS-21 adjuvant ("STIMULON cpcQS-21").
- A pipeline of novel allogeneic invariant natural killer T cell ("iNKT") therapies for treating cancer and other immune-mediated diseases, controlled by MiNK.

We regularly evaluate development, commercialization, and partnering strategies for each product candidate based on various factors, including pre-clinical and clinical trial results, competitive positioning, funding requirements, and available resources. Our lead program, BOT is progressing through multiple clinical programs as a monotherapy and in combination with BAL. In April 2023, BOT in combination with BAL received Fast Track designation from the U.S. Food and Drug Administration ("FDA") for the treatment of patients with non-microsatellite instability-high ("MSI-H") and/or deficient mismatch repair ("dMMR") metastatic colorectal cancer without active liver involvement. This designation specifically targets patients who are heavily pretreated and have shown resistance or intolerance to standard chemotherapies, including fluoropyrimidine, oxaliplatin, and irinotecan, as well as those who have received a VEGF inhibitor, an EGFR inhibitor, and/or a BRAF inhibitor, if indicated. Based on the BOT/BAL clinical data generated to date, we have developed designs for registration-enabling trials in MSS CRC across neoadjuvant, first-line, and late-line mCRC. These trial(s) will launch upon completion of strategic transactions. The options being considered are partnerships, licensing, or joint ventures.

We have entered into collaborations with several companies, including Bristol-Myers Squibb Company ("BMS"), Betta Pharmaceuticals Co., Ltd. ("Betta"), UroGen Pharma Ltd. ("UroGen"), Gilead Sciences, Inc. ("Gilead"), Incyte Corporation ("Incyte"), and Merck Sharp & Dohme ("Merck"). These collaborations, along with our internal programs, have resulted in over a dozen antibody pre-clinical or clinical development programs.

Pursuant to our collaboration agreement with Incyte, we had exclusively licensed to Incyte monospecific antibodies targeting GITR, OX40, TIM-3 and LAG-3, as well as an additional undisclosed target. Under the terms of our agreement, Incyte was responsible for all future development expenses, and we were eligible to receive up to an additional $315.0 million in potential milestone payments plus royalties on any future sales. Incyte has terminated the OX40 program, effective October 2023, and both the GITR program and undisclosed program, effective May 2024. Upon termination, the rights to the OX40, GITR, and undisclosed programs reverted back to us. In July 2024, Incyte announced that it would discontinue further development of the LAG-3 program and TIM-3 program and in February 2025, Incyte notified us of their intent to terminate the entire Collaboration Agreement, effective February 2026. Upon termination the rights to the remaining programs will revert back to us.

Pursuant to our collaboration and license agreement with Merck, we exclusively licensed MK-4830 to Merck, which Merck advanced in a Phase 2 clinical trial. In 2024, Merck notified us that the further clinical development of MK-4830 will be limited to a

neoadjuvant ovarian study of MK-4830 in combination with pembrolizumab and chemotherapy with or without bevacizumab that is ongoing.

In September 2018, we, through our wholly-owned subsidiary, Agenus Royalty Fund, LLC, entered into a royalty purchase agreement (the "XOMA Royalty Purchase Agreement") with XOMA (US) LLC ("XOMA US"). Pursuant to the terms of the XOMA Royalty Purchase Agreement, XOMA US purchased 33% of all future royalties and 10% of all future milestone payments that we were then entitled to receive from Incyte and Merck, net of certain of our obligations to a third party.

In December 2018, we entered into collaboration agreements with Gilead for the development and commercialization of up to five novel I-O therapies (the "Gilead Collaboration Agreements"). Gilead received worldwide exclusive rights to our bispecific antibody, AGEN1423, and the exclusive option to license AGEN1223, a bispecific antibody, and AGEN2373, a monospecific antibody. Gilead elected to return AGEN1423 to us in November 2020 and terminated the license agreement. We ceased development of AGEN1223 in the third quarter of 2021, and the option and license agreement for AGEN1223 was formally terminated in October 2021. In August 2024, Gilead elected not to exercise the option to license AGEN2373 and the option and license agreement was formally terminated.

In November 2019, we entered into a license agreement with UroGen, granting them an exclusive, worldwide license (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions) to develop, manufacture, and commercialize zalifrelimab for the treatment of cancers of the urinary tract via intravesical delivery. We received an upfront payment of $10.0 million and are eligible to receive up to $200.0 million in milestone payments, as well as royalties on future sales.

In June 2020, we entered into a license and collaboration agreement (the "Betta License Agreement") with Betta, pursuant to which we granted Betta an exclusive license to develop, manufacture and commercialize balstilimab and zalifrelimab in Republic of China, Hong Kong, Macau and Taiwan ("Greater China"). Under the terms of the Betta License Agreement, we received $15.0 million upfront and are eligible to receive up to $100.0 million in milestone payments plus royalties on any future sales in Greater China.

In May 2021, we entered into a License, Development, and Commercialization Agreement with BMS for our pre-clinical anti-TIGIT bispecific antibody program, AGEN1777. BMS received an exclusive worldwide license to develop, manufacture, and commercialize AGEN1777 and its derivatives. We received a non-refundable upfront cash payment of $200.0 million. In October 2021, we achieved a $20.0 million milestone upon the dosing of the first patient in the AGEN1777 Phase 1 clinical trial and in December 2023, we announced that the first patient was dosed in an AGEN1777 Phase 2 clinical trial, triggering the achievement of a $25.0 million milestone. We received this milestone in January 2024. On July 30, 2024, we received notice from BMS was voluntarily terminating the BMS License Agreement, effective as of January 26, 2025. Upon termination, BMS returned AGEN1777 to us.

In May 2024, we, and certain wholly-owned subsidiaries, entered into a Purchase and Sale Agreement (the "Ligand Purchase Agreement") with Ligand Pharmaceuticals Incorporated ("Ligand") for the sale to Ligand of (i) 31.875% of the development, regulatory and commercial milestone payments we were then eligible to receive under our agreements with BMS, UroGen, Gilead, Merck and Incyte, (the "Covered License Agreements") (ii) 18.75% of the royalties we receive under the Covered License Agreements; and (iii) a 2.625% synthetic royalty on worldwide net sales of botensilimab and balstilimab (collectively the "Purchased Assets"). The total amounts payable to Ligand are subject to a 50% reduction in the event total payments to Ligand exceed a specified return hurdle. The synthetic royalty is subject to a reduction if annual worldwide net sales exceed a specified level, and a cap on annual worldwide net sales if annual worldwide net sales exceed a higher specified level. The synthetic royalty can increase by 1% based on the occurrence of certain future events. After taking into account our obligations under the Ligand Purchase Agreement, XOMA Royalty Purchase Agreement and the recent status of our collaboration agreements, we remain eligible to receive up to approximately $136.3 million and $49.4 million in potential development, regulatory, and commercial milestones from UroGen and Merck, respectively.

In September 2021, we launched SaponiQx to lead innovation in novel adjuvant discovery and vaccine design, focusing on our saponin-based adjuvants. We are particularly dedicated to the development of the next-generation cultured plant cell QS-21. To support this initiative, we partnered with Ginkgo Bioworks, Inc. to develop SaponiQx's saponin products from sustainably sourced raw materials. Our goal is to meet the demands of the vaccine industry, especially for pandemic vaccines.

Our bark extract QS-21 adjuvant is partnered with GSK and plays a vital role in multiple GSK vaccine programs. These programs are at various stages, including GSK's approved shingles and RSV vaccines, SHINGRIX and AREXVY, which received FDA approval in the United States in October 2017 and May 2023, respectively. In January 2018, we entered into a Royalty Purchase Agreement with Healthcare Royalty Partners III, L.P. and certain of its affiliates (together, "HCR"), pursuant to which HCR

purchased 100% of our worldwide rights to receive royalties from GSK on GSK's sales of vaccines containing our QS-21 adjuvant. We do not incur clinical development costs for products partnered with GSK. We were also entitled to receive up to $40.35 million in milestone payments from HCR based on sales of GSK's vaccines as follows: (i) $15.1 million upon reaching $2.0 billion last-twelve-months net sales any time prior to 2024 (the "First HCR Milestone") and (ii) $25.25 million upon reaching $2.75 billion last-twelve-months net sales any time prior to 2026 (the "Second HCR Milestone"). We received the First HCR Milestone after GSK's net sales of Shingrix for the twelve months ended December 31, 2019 exceeded $2.0 billion. The Second HCR Milestone was received in 2022 after GSK's net sales of Shingrix for the twelve months ended June 30, 2022 exceeded $2.75 billion.

In October 2021, we completed the initial public offering ("IPO") of MiNK, which trades on the Nasdaq Capital Market under the ticker symbol "INKT." MiNK is a clinical stage biopharmaceutical company focused on developing allogeneic invariant natural killer T ("iNKT") cell therapies to treat cancer and other life-threatening immune diseases. MiNK's most advanced product candidate, agenT-797, is an off-the-shelf, allogeneic, native iNKT cell therapy. MiNK is currently expanding its clinical programs, with an externally funded Phase 2 trial in second-line gastric cancer actively enrolling at Memorial Sloan Kettering Cancer Center. Additionally, MiNK is evaluating agenT-797 as a variant-agnostic therapy for patients with viral acute respiratory distress syndrome ("ARDS") in planning for a randomized Phase 2 study through a predominantly externally financed program. In May 2024, MiNK secured a $5.8 million private placement financing at a 25% premium, led by GKCC, LLC. This funding will be used for the clinical development of MiNK-215, its leading allogeneic CAR-iNKT cell therapy targeting fibroblast activation protein ("FAP") in solid tumors, which is scheduled to enter clinical trials in early 2025. In addition to its lead clinical program, MiNK has announced a collaboration with ImmunoScape, Inc. ("ImmunoScape") to discover and develop next-generation T-cell receptor therapies targeting novel solid tumor antigens. This partnership leverages MiNK's proprietary library of T-cell antigens and ImmunoScape's platform for rapid discovery of novel T-cell receptors.

Our business activities include product research, preclinical and clinical development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development activities, and support of our collaborations. Our product candidates require successful clinical trials and approvals from regulatory agencies, as well as acceptance in the marketplace. Part of our strategy is to develop and commercialize some of our product candidates through arrangements with academic and corporate collaborators and licensees.

Our common stock is currently listed on The Nasdaq Capital Market under the symbol "AGEN."

Our research and development expenses for the years ended December 31, 2024, 2023, and 2022, were $155.5 million, $234.6 million, and $186.7 million, respectively. We have incurred significant losses since our inception. As of December 31, 2024, we had an accumulated deficit of $2.18 billion. We are likely to continue to incur losses until we become a commercial company generating profits.

**Historical Results of Operations**

The comparison of 2023 to 2022 results has been omitted from this Form 10-K but can be found in our Form 10-K for the year ended December 31, 2023 – "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" filed on March 14, 2024.

***Year Ended December 31, 2024 Compared to the Year Ended December 31, 2023***

*Research and development revenue*

We recognized research and development ("R&D") revenue of approximately $0.5 million and $38.8 million during the years ended December 31, 2024 and 2023, respectively. R&D revenues for the year ended December 31, 2023, primarily consisted of a $25.0 million milestone earned under our BMS License Agreement and $12.2 million related to the recognition of deferred revenue earned under our Gilead Collaboration Agreements.

*Non-cash royalty revenue related to the sale of future royalties*

In January 2018, we sold 100% of our worldwide rights to receive royalties from GSK on sales of GSK's vaccines containing our QS-21 STIMULON adjuvant to HCR. As described in Note 17 to our Consolidated Financial Statements, this transaction has been recorded as a liability that amortizes over the estimated life of our Royalty Purchase Agreement with HCR. As a result of this liability accounting, even though the royalties are remitted directly to HCR, we record these royalties from GSK as revenue. Non-cash royalty revenue related to our agreement with GSK decreased $13.6 million, to approximately $101.0 million for the year ended December

31, 2024, from $114.6 million for the year ended December 31, 2023, due to decreased net sales of GSK's vaccines containing our QS-21 STIMULON adjuvant.

*Research and development expense*

R&D expense include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, contract research organization costs, costs of consultants, and related administrative costs. R&D expense decreased 34% to $155.5 million for the year ended December 31, 2024 from $234.6 million for the year ended December 31, 2023. Decreased R&D expenses in the year ended December 31, 2024 primarily relate to a $52.7 million decrease in third-party services and other expenses, largely due to the timing of expenses related to the advancement of our antibody programs, a $11.4 million decrease in personnel related expenses, mainly due to a decrease in headcount, and a $18.1 million decrease in expenses attributable to the activities of our subsidiaries. These decreases were partially offset by a $3.2 million increase in other research and development expenses.

*General and administrative expense*

General and administrative ("G&A") expense consists primarily of personnel costs, facility expenses, and professional fees. G&A expense decreased 9% to $71.9 million for the year ended December 31, 2024 from $78.7 million for the year ended December 31, 2023. Decreased G&A expenses in the year ended December 31, 2024 primarily relate to a $4.6 million decrease in personnel related expenses, mainly due to decreased share based compensation expense and a decrease in headcount, a $0.3 million decrease in professional fees and a $3.3 million decrease in expenses attributable to the activities of our subsidiaries. These decreases were partially offset by a $1.3 million increase in other general and administrative expenses.

*Fair value adjustments*

For the year ended December 31, 2024, the fair value adjustment represents the change in fair value of the Purchaser Upsize Option issued under the Ligand Purchase Agreement. The fair value of the Purchaser Upsize Option is based on a scenario analysis and uses assumptions we believe would be made by a market participant. For the year ended December 31, 2023, the fair value adjustment represents the change in the fair value of our contingent purchase price consideration. The fair value of our contingent purchase price considerations is mainly based on estimates from a Monte Carlo simulation of our share price.

*Non-operating income*

Non-operating income increased $5.8 million for the year ended December 31, 2024, from income of $37,000 for the year ended December 31, 2023, to income of $5.8 million for the year ended December 31, 2024, primarily due to the recognition of a $5.3 million gain on the early termination of two operating leases and the recognition of R&D tax credits in the UK, compared to de minimis activity in 2023.

*Interest expense, net*

Interest expense, net increased to $117.6 million for the year ended December 31, 2024 from $97.9 million for the year ended December 31, 2023, mainly due to increased non-cash interest recorded in connection with our Royalty Purchase Agreement with HCR and the addition of non-cash interest expense recorded in connection with our Ligand Purchase Agreement.

**Inflation**

We believe that inflation has not had a material adverse effect on our business, results of operations, or financial condition to date.

**Research and Development Programs**

For the year ended December 31, 2024, our R&D programs consisted largely of our antibody programs as indicated in the following table (in thousands).

| Research and Development Program | Product | For the Year Ended December 31, 2024 | 2023 | 2022 | Prior to 2022 | Total |
|---|---|---|---|---|---|---|
| Antibody programs | Various | $ 113,135 | $ 178,445 | $ 133,108 | $ 739,165 | $1,163,853 |
| Vaccine adjuvant | STIMULON cpcQS-21 | 1,844 | 10,296 | 10,789 | 21,397 | 44,326 |
| Cell therapies | Various | 7,558 | 16,283 | 24,300 | 61,129 | 109,270 |
| Other research and development programs | Various | 32,991 | 29,545 | 18,494 | 477,091 | 558,121 |
| Total research and development expenses | | $ 155,528 | $ 234,569 | $ 186,691 | $1,298,782 | 1,875,570 |

Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions and our review of the status of each program. Our product candidates are in various stages of development and significant additional expenditures will be required if we start new clinical trials, encounter delays in our programs, apply for regulatory approvals, continue development of our technologies, expand our operations, and/or bring our product candidates to market. The total cost of any particular clinical trial is dependent on a number of factors such as trial design, length of the trial, number of clinical sites, number of patients, and trial sponsorship. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because of the current stage of our product candidates, among other factors, we are unable to reliably estimate the cost of completing our research and development programs or the timing for bringing such programs to various markets or substantial partnering or out-licensing arrangements, and, therefore, when, if ever, material cash inflows are likely to commence.

***Product Development Portfolio***

*Antibody Discovery Platforms and Immunotherapy Programs*

Immunotherapies regulate the body's immune response to cancer, and have achieved positive outcomes in a number of cancers that were considered untreatable only a few years ago. Our pipeline includes several classes of immunotherapies:

1. checkpoint inhibitors, which remove the tumor's defenses that evade and suppress the immune system;
2. immune activators, which train and activate a patient's own immune cells for a potent and durable anti-cancer response; and
3. tumor microenvironment ("TME") conditioning agents, which reduce local immune-suppression and attract immune cells to the cancer site.

We possess a suite of antibody discovery platforms that are designed to drive the discovery of future antibody candidates. We are planning to employ a variety of techniques to identify and optimize monospecific and multispecific antibody candidates, internally.

We currently have multiple antibody programs in pre-clinical or clinical development, which include our next generation anti-CTLA-4 antibody, botensilimab, an IgG1 anti-CTLA-4 antagonist, our anti-PD-1, balstilimab, and anti-CTLA-4, zalifrelimab, programs (both partnered with Betta in Greater China), our anti-CD137, AGEN2373, an anti-TIGIT bispecific antibody, AGEN1777, an ILT2 monospecific antibody, AGEN1571, an anti-LAG3, INCAGN2385, and anti-TIM3, INCAGN2390. For additional information regarding our antibody discovery platforms and immunotherapy programs, please read Part I-Item 1. "Business" of this Annual Report on Form 10-K.

*QS-21 STIMULON Adjuvant*

QS-21 STIMULON is an adjuvant, which is a substance added to a vaccine or other immunotherapy that is intended to enhance an immune response to the target antigens. QS-21 is a natural product, a triterpene glycoside, or saponin, purified from the bark of the Chilean soapbark tree, Quillaja, and has the ability to stimulate an antibody-mediated immune response and has also been shown to activate cellular immunity. It has become a key component in the development of investigational preventive vaccine adjuvants across a wide variety of diseases. These studies have been carried out by academic institutions and pharmaceutical companies in the United

States and internationally. A number of these studies have shown QS-21 to be significantly more effective in stimulating immune responses than aluminum hydroxide or aluminum phosphate, the adjuvants most commonly used in approved vaccines in the United States today. In January 2019, we announced that the Bill & Melinda Gates Foundation awarded us a grant to develop an alternative, plant cell culture-based manufacturing process to ensure the continuous future supply of QS-21 STIMULON adjuvant which our subsidiary, SaponiQx, is pursuing in partnership with Phyton Biotech and Ginkgo Bioworks. For additional information regarding QS-21 STIMULON, please read Part I-Item 1. "Business" of this Annual Report on Form 10-K.

*Cell Therapies*

Our majority owned subsidiary, MiNK, is a focused on developing allogeneic iNKT cell therapies to treat cancer and other immune-mediated diseases. iNKTs have a dual-mechanism of action with an internal targeting and homing device that modulates both arms of immunity, innate and adaptive. iNKTs combine the killing features of natural killer cells with the durable memory response of T cells. iNKT cells have been demonstrated to be highly effective in treating solid tumor cancers in their native form and MiNK has demonstrated that these cells can be further engineered or edited for super-targeting. For additional information regarding iNKT cell therapies, please read Part I-Item 1. "Business" of this Annual Report on Form 10-K.

**Liquidity and Capital Resources**

We have incurred annual operating losses since inception, and we had an accumulated deficit of $2.18 billion as of December 31, 2024. We expect to incur significant losses over the next several years as we continue development of our technologies and product candidates, manage our regulatory processes, initiate and continue clinical trials, and prepare for potential commercialization of products. From our inception through December 31, 2024, we have raised aggregate net proceeds of approximately $2.01 billion through the sale of common and preferred stock, the exercise of stock options and warrants, proceeds from our Employee Stock Purchase Plan, royalty monetization transactions, and the issuance of convertible and other notes.

We maintain an effective registration statement (the "Registration Statement") covering up to $300.0 million of common stock, preferred stock, warrants, debt securities and units. The Registration Statement includes prospectuses covering the offer, issuance and sale of up to 20.6 million shares of our common stock from time to time in "at-the-market offerings" pursuant to an At Market Issuance Sales Agreement (the "Sales Agreement") with B. Riley Securities, Inc. as our sales agent. We sold approximately 3.6 million and 1.6 million shares of our common stock pursuant to the Sales Agreement during the year ended December 31, 2024 and the period of January 1, 2025 through March 13, 2025, respectively, and received aggregate net proceeds totaling $37.5 million. As of March 13, 2025, approximately 16.5 million shares remained available for sale under the Sales Agreement.

Our cash, cash equivalents and short-term investments at December 31, 2024 were $40.4 million, a decrease of $35.7 million from December 31, 2023. Since year end, we have raised $4.4 million through at-the-market sales. Cash and cash equivalents of our subsidiary, MiNK, at September 30, 2024, were $6.3 million. MiNK cash can only be accessed by Agenus through a declaration of a dividend by the MiNK Board of Directors or through settlement of intercompany balances.

As of December 31, 2024, we had debt outstanding of $35.2 million in principal, $2.5 million of which was paid in February 2025, $10.5 million is due July 2026, and $22.0 million is due November 2026.

Based on our current plans and projections, we believe our cash resources of $40.4 million as of December 31, 2024, along with additional cash inflows we may receive in 2025, will be sufficient to satisfy our critical liquidity requirements through the second quarter of 2025. To support operations on an ongoing basis we require additional funding. Since our founding we have financed our operations principally through income and revenues generated from corporate partnerships, advance royalty sales, and proceeds from debt and equity issuances. We transact at-the-market sales from time to time in order to manage our cash balances. We execute at-the-market offerings based on market conditions and our stock price. We do not have in place a program whereby at-the-market offerings are executed automatically based on our trading volume.

Currently we are in discussions with entities including operating companies and financial entities to provide the funding necessary to support our operations through our planned registration and launch strategy for botensilimab/balstilimab. However, because the completion of cash funding transactions is not entirely within our control, and in accordance with accounting standards, substantial doubt continues to exist about our ability to continue as a going concern for a period of one year after the date of filing of this Annual Report on Form 10-K. The financial statements have been prepared on a basis that assumes Agenus will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business. Management continues to diligently address the Company's liquidity needs and has continued to adjust spending in order

to preserve liquidity. We expect our sources of funding to include additional out-licensing agreements, asset sales, project financing, and/or sales of equity securities.

Our future cash requirements include, but are not limited to, supporting clinical trial and regulatory efforts and continuing our other research and development programs. Since inception, we have entered into various cancelable agreements with contract manufacturers, institutions, and clinical research organizations (collectively "third party providers") to perform pre-clinical activities and to conduct and monitor our clinical studies. Under these agreements, subject to the enrollment of patients and performance by the applicable third-party provider, we have estimated our total payments to be $660.7 million over the term of the related activities. Through December 31, 2024, we have expensed $616.5 million as research and development expenses and $578.3 million has been paid under these agreements. The timing of expense recognition and future payments related to these agreements is subject to the enrollment of patients and performance by the applicable third-party provider. We plan to enter into additional agreements with third party providers and we anticipate significant additional expenditures will be required to initiate and advance our various programs.

Net cash used in operating activities for the years ended December 31, 2024 and 2023 was $158.3 million and $224.2 million, respectively. Our future ability to generate cash from operations will depend on achieving regulatory approval and market acceptance of our product candidates, achieving benchmarks as defined in existing collaboration agreements, and our ability to enter into new collaborations. Part of our strategy is to develop and commercialize some of our product candidates by entering into collaborations. As a result of our collaboration agreements, we will not completely control the efforts to attempt to bring those product candidates to market. Please see the “Note Regarding Forward-Looking Statements” of this Annual Report on Form 10-K and the risks highlighted under Part I-Item 1A. “Risk Factors” of this Annual Report on Form 10-K.

The table below summarizes our material cash requirements from known contractual and other obligations as of December 31, 2024 (in thousands).

| | | Payments by Period | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years |
| Long-term debt (1) | $ 37,459 | $ 3,660 | $ 33,799 | $ — | $ — |
| Operating leases (2) | 101,419 | 8,609 | 16,819 | 17,667 | 58,324 |
| Finance leases | 5,002 | 4,879 | 123 | — | — |
| Total | $ 143,880 | $ 17,148 | $ 50,741 | $ 17,667 | $ 58,324 |

(1) Includes fixed interest payments. See Note 16 of the notes to our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K for further description of our debt.
(2) The leases for our properties expire at various times between 2025 and 2036.

**Critical Accounting Policies and Estimates**

The SEC defines “critical accounting policies” as those that require the application of management’s most difficult, subjective, or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods.

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base those estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

The following listing is not intended to be a comprehensive list of all of our accounting policies. Our significant accounting policies are described in Note 2 of the notes to our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K. In many cases, the accounting treatment of a particular transaction is dictated by U.S. generally accepted accounting principles, with no need for our judgment in its application. There are also areas in which our judgment in selecting an available alternative would not produce a materially different result. We have identified the following as a critical accounting policy.

***Non-cash Interest Expense on Liability Related to Sale of Future Royalties***

We are party to multiple royalty financing transactions. We have recorded the proceeds from these transactions as a liability on our consolidated balance sheets that will be amortized using the interest method over the estimated life of the associated agreement.

As a result, we impute interest on the transactions and record non-cash interest expense at the estimated interest rate. Our estimate of the interest rate under each agreement is based on the amount of royalty payments to be received by the purchaser over the life of the arrangement. We periodically assess the expected royalty payments using multiple sources, including historical results, forecasts from market data sources and internally developed forecasts. To the extent such payments are greater or less than our initial estimates or the timing of such payments is materially different than our original estimates, we will prospectively adjust the amortization of the liability. There are a number of factors that could materially affect the amount and timing of royalty payments, all of which are not fully within our control. Such factors include, but are not limited to, failures or delays in clinical development, failure to receive marketing approval from governmental health authorities or delay in that approval, changing standards of care, the introduction of competing products, manufacturing or other delays, biosimilar competition, patent protection, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates, and other events or circumstances that could result in reduced royalty payments made to the purchasers, all of which would result in a reduction of non-cash royalty revenues and the non-cash interest expense over the life of the associated agreement. Conversely, if sales of the underlying products are more than expected, the non-cash royalty revenues and the non-cash interest expense recorded by us would be greater over the life of the associated agreement.

**Recent Accounting Pronouncements**

Refer to Note 2 to our consolidated financial statements included within Item 8 of this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our business.

**Item 7A.** ***Quantitative and Qualitative Disclosures About Market Risk***

Our primary market risk exposure is foreign currency exchange rate risk. International revenues and expenses are generally transacted by our foreign subsidiaries and are denominated in local currency. Approximately 2.1% and 1.0% of our cash used in operations for the years ended December 31, 2024 and 2023, respectively, was from our foreign subsidiaries. We are exposed to foreign currency exchange rate fluctuation risk related to our transactions denominated in foreign currencies. We do not currently employ specific strategies, such as the use of derivative instruments or hedging, to manage these exposures. Our currency exposures vary but are primarily concentrated in the British Pound and Swiss Franc, in large part due to our subsidiaries, Agenus UK Limited and AgenTus Therapeutics Limited, both with operations in England, and Antigenics SA, a company with operations in Switzerland.

We had cash and cash equivalents at December 31, 2024 of $40.4 million, which are exposed to the impact of interest and foreign currency exchange rate changes, and our interest income fluctuates as interest rates change. Additionally, in the normal course of business, we are exposed to fluctuations in interest rates as we seek debt financing and invest excess cash. Due to the short-term nature of our investments in money market funds, our carrying value approximates the fair value of these investments at December 31, 2024, however, we are subject to investment risk.

We invest our cash and cash equivalents in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs, and maximize yields. We review our investment policy periodically and amend it as deemed necessary. Currently, the investment policy prohibits investing in any structured investment vehicles and asset-backed commercial paper. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer, or type of investment. We do not invest in derivative financial instruments. Accordingly, we do not believe that there is currently any material market risk exposure with respect to derivatives or other financial instruments that would require disclosure under this item.

**Item 8.** ***Financial Statements and Supplementary Data***

## INDEX TO FINANCIAL STATEMENTS

## Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Agenus Inc.:

*Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheets of Agenus Inc. and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2024, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 17, 2025 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

*Going Concern*

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the 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 audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

*Critical Audit Matter*

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: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter 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.

*Accounting for the Purchase and Sale Agreement with Ligand Pharmaceuticals Incorporated*

As discussed in Note 17 to the consolidated financial statements, the Company received $75.0 million in gross proceeds from the Purchase and Sale Agreement with Ligand Pharmaceuticals Incorporated (the Ligand Purchase Agreement). The $75.0 million in gross proceeds was allocated to the components of the transaction, including the liability related to the sale of future royalties and milestones, the Purchaser Upsize Option, and the Ligand Warrant.

We identified the assessment of the accounting for the Ligand Purchase Agreement as a critical audit matter. Subjective auditor judgment was required in evaluating the Company's classification of the components of the transaction because of the nature of the agreement.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the Company’s accounting for the Ligand Purchase Agreement, including the classification of the components of the transaction. We read the Ligand Purchase Agreement and evaluated whether management's accounting position considered the relevant facts and terms included in the agreement. We involved professionals with specialized skills and knowledge who assisted in assessing whether the Company’s accounting for the transaction was in accordance with the relevant accounting guidance.

/s/ KPMG LLP

We have served as the Company’s auditor since 1997.

Boston, Massachusetts
March 17, 2025

**AGENUS INC. AND SUBSIDIARIES**
**CONSOLIDATED BALANCE SHEETS**
**(Amounts in thousands, except share and per share amounts)**

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| **ASSETS** | | |
| Cash and cash equivalents | $ 40,437 | $ 76,110 |
| Accounts receivable | 407 | 25,836 |
| Prepaid expenses | 2,315 | 8,098 |
| Other current assets | 2,415 | 2,372 |
| Total current assets | 45,574 | 112,416 |
| Property, plant and equipment, net of accumulated amortization and depreciation of $72,553 and $61,943 at December 31, 2024 and 2023, respectively | 120,087 | 133,421 |
| Operating lease right-of-use assets | 27,308 | 29,606 |
| Goodwill | 24,092 | 24,723 |
| Acquired intangible assets, net of accumulated amortization of $16,986 and $17,688 at December 31, 2024 and 2023, respectively | 3,376 | 4,411 |
| Other long-term assets | 5,834 | 9,336 |
| Total assets | $ 226,271 | $ 313,913 |
| **LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT** | | |
| Current portion, long-term debt | $ 2,698 | $ 146 |
| Current portion, liability related to sale of future royalties and milestones | 111,978 | 132,502 |
| Current portion, deferred revenue | 31 | 18 |
| Current portion, operating lease liabilities | 2,446 | 2,587 |
| Accounts payable | 61,470 | 61,446 |
| Accrued liabilities | 34,961 | 45,283 |
| Other current liabilities | 7,817 | 13,915 |
| Total current liabilities | 221,401 | 255,897 |
| Long-term debt, net of current portion | 30,473 | 12,768 |
| Liability related to sale of future royalties and milestones, net of current portion | 224,389 | 124,556 |
| Deferred revenue, net of current portion | 1,143 | 1,143 |
| Operating lease liabilities, net of current portion | 54,551 | 62,511 |
| Other long-term liabilities | 738 | 5,420 |
| Commitments and contingencies (Note 19) | | |
| STOCKHOLDERS' DEFICIT | | |
| Preferred stock, par value $0.01 per share; 5,000,000 shares authorized: | | |
| Series A-1 convertible preferred stock; 31,620 shares designated, issued, and outstanding at December 31, 2024 and 2023; liquidation value of $34,101 and $33,886 at December 31, 2024, and 2023, respectively | 0 | 0 |
| Common stock, par value $0.01 per share; 800,000,000 shares authorized at December 31, 2024 and 2023; 23,634,670 shares and 19,718,662 shares issued at December 31, 2024 and 2023, respectively | 236 | 197 |
| Additional paid-in capital | 1,857,662 | 1,796,095 |
| Accumulated other comprehensive loss | (1,398) | (955) |
| Accumulated deficit | (2,182,880) | (1,955,668) |
| Total stockholders' deficit attributable to Agenus Inc. | (326,380) | (160,331) |
| Non-controlling interest | 19,956 | 11,949 |
| Total stockholders' deficit | (306,424) | (148,382) |
| Total liabilities, convertible preferred stock and stockholders' deficit | $ 226,271 | $ 313,913 |

See accompanying notes to consolidated financial statements.

**AGENUS INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**For the Years Ended December 31, 2024, 2023, and 2022**
**(Amounts in thousands, except per share amounts)**

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| Revenue: | | | |
| Research and development | $ 482 | $ 38,764 | $ 16,975 |
| Service revenue | 2,003 | 2,978 | 10,514 |
| Royalty sales milestone | — | — | 25,250 |
| Non-cash revenue related to the sale of future royalties | 100,978 | 114,572 | 45,285 |
| Total revenues | 103,463 | 156,314 | 98,024 |
| Operating expenses: | | | |
| Cost of service revenue | (486) | (3,111) | (10,568) |
| Research and development | (155,528) | (234,569) | (186,691) |
| General and administrative | (71,878) | (78,739) | (81,007) |
| Fair value adjustments | 3,954 | 556 | 815 |
| Operating loss | (120,475) | (159,549) | (179,427) |
| Other income (expense): | | | |
| Loss on modification of debt | — | — | (1,937) |
| Non-operating income | 5,830 | 37 | 12,571 |
| Interest expense, net | (117,626) | (97,925) | (61,863) |
| Net loss | (232,271) | (257,437) | (230,656) |
| Dividends on Series A-1 convertible preferred stock | (215) | (213) | (212) |
| Less: net loss attributable to non-controlling interest | (5,059) | (11,676) | (10,582) |
| Net loss attributable to Agenus Inc. common stockholders | $ (227,427) | $ (245,974) | $ (220,286) |
| Per common share data: | | | |
| Basic and diluted net loss attributable to Agenus Inc. common stockholders | $ (10.59) | $ (13.75) | $ (15.64) |
| Weighted average number of Agenus Inc. common shares outstanding: | | | |
| Basic and diluted | 21,473 | 17,894 | 14,087 |
| Other comprehensive loss: | | | |
| Foreign currency translation loss | $ (443) | $ (1,870) | $ (577) |
| Other comprehensive loss | (443) | (1,870) | (577) |
| Comprehensive loss | $ (227,870) | $ (247,844) | $ (220,863) |

See accompanying notes to consolidated financial statements.

**AGENUS INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)**
**For the Years Ended December 31, 2024, 2023, and 2022**
**(Amounts in thousands)**

| | Series A-1 Convertible Preferred Stock | | Common Stock | | | Treasury Stock | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number of Shares | Par Value | Number of Shares | Par Value | Additional Paid-In Capital | Number of Shares | Amount | Accumulated Other Comprehensive Income (Loss) | Non-controlling Interest | Accumulated Deficit | Total |
| Balance at December 31, 2021 | 32 | $ 0 | 12,844 | $ 128 | $ 1,522,653 | — | $ — | $ 1,492 | $ 13,469 | $ (1,489,833) | 47,909 |
| Net loss | — | — | — | — | — | — | — | — | (10,582) | (220,074) | (230,656) |
| Other comprehensive loss | — | — | — | — | — | — | — | (577) | — | — | (577) |
| Share-based compensation | — | — | — | — | 15,200 | — | — | — | 3,195 | — | 18,395 |
| Vesting of nonvested shares | — | — | 12 | — | — | — | — | — | — | — | — |
| Shares sold at the market | — | — | 2,257 | 24 | 99,187 | — | — | — | — | — | 99,211 |
| Issuance of warrants | — | — | — | — | 2,332 | — | — | — | — | — | 2,332 |
| Issuance of shares for services | — | — | 2 | — | 138 | — | — | — | — | — | 138 |
| Issuance of director deferred shares | — | — | — | — | 19 | — | — | — | — | — | 19 |
| Exercise of stock options and employee share purchases | — | — | 22 | — | 898 | — | — | — | — | — | 898 |
| Issuance of shares for milestone achievement | — | — | 9 | — | 500 | — | — | — | — | — | 500 |
| Issuance of subsidiary shares for employee bonus | — | — | — | — | — | — | — | — | 294 | — | 294 |
| Issuance of shares for employee bonuses | — | — | 205 | 2 | 6,647 | (1,447) | (3,632) | — | — | — | 3,017 |
| Retirement of treasury shares | — | — | (72) | (1) | (13) | 1,447 | 3,632 | — | — | — | 3,618 |
| Balance at December 31, 2022 | 32 | $ 0 | 15,279 | $ 153 | $ 1,647,561 | — | $ — | $ 915 | $ 6,376 | $ (1,709,907) | $ (54,902) |

See accompanying notes to consolidated financial statements.

**AGENUS INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)**
**(Continued)**
**For the Years Ended December 31, 2024, 2023, and 2022**
**(Amounts in thousands)**

| | Series A-1 Convertible Preferred Stock | | Common Stock | | | Treasury Stock | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number of Shares | Par Value | Number of Shares | Par Value | Additional Paid-In Capital | Number of Shares | Amount | Accumulated Other Comprehensive Income (Loss) | Non-controlling Interest | Accumulated Deficit | Total |
| Net loss | — | $ — | — | $ — | $ — | — | $ — | $ — | $ (11,676) | $ (245,761) | $ (257,437) |
| Other comprehensive loss | — | — | — | — | — | — | — | (1,870) | — | — | (1,870) |
| Share-based compensation | — | — | — | — | 18,526 | — | — | — | 3,825 | — | 22,351 |
| Shares sold at the market | — | — | 4,221 | 42 | 133,115 | — | — | — | — | — | 133,157 |
| Payment of CEO payroll in shares | — | — | 8 | — | 146 | — | — | — | — | — | 146 |
| Issuance of director deferred shares | — | — | 13 | 1 | 982 | — | — | — | — | — | 983 |
| Issuance of shares for services | — | — | 20 | — | 690 | — | — | — | — | — | 690 |
| Vesting of nonvested shares | — | — | 5 | — | — | — | — | — | — | — | — |
| Exercise of stock options and employee share purchases | — | — | 25 | — | 736 | — | — | — | 71 | — | 807 |
| MiNK stock dividend | — | — | — | — | (14,888) | — | — | — | 14,888 | — | — |
| MiNK stock purchases | — | — | — | — | 1,940 | — | — | — | (2,546) | — | (606) |
| Issuance of subsidiary shares for employee bonus | — | — | — | — | — | — | — | — | 1,011 | — | 1,011 |
| Issuance of shares for employee bonus | — | — | 232 | 2 | 7,303 | (17) | (4,072) | — | — | — | 3,233 |
| Retirement of treasury shares | — | — | (83) | (1) | (16) | 17 | 4,072 | — | — | — | 4,055 |
| Balance at December 31, 2023 | 32 | $ 0 | 19,720 | $ 197 | $ 1,796,095 | — | $ — | $ (955) | $ 11,949 | $ (1,955,668) | $ (148,382) |

See accompanying notes to consolidated financial statements.

**AGENUS INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)**
**(Continued)**
**For the Years Ended December 31, 2024, 2023, and 2022**
**(Amounts in thousands)**

| | Series A-1 Convertible Preferred Stock | | Common Stock | | | Treasury Stock | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number of Shares | Par Value | Number of Shares | Par Value | Additional Paid-In Capital | Number of Shares | Amount | Accumulated Other Comprehensive Income (Loss) | Non-controlling Interest | Accumulated Deficit | Total |
| Net loss | — | $ — | — | $ — | $ — | — | $ — | $ — | $ (5,059) | $ (227,212) | $ (232,271) |
| Other comprehensive loss | — | — | — | — | — | — | — | (443) | — | — | (443) |
| Share-based compensation | — | — | — | — | 24,515 | — | — | — | 2,812 | — | 27,327 |
| Shares sold at the market | — | — | 3,632 | 36 | 32,987 | — | — | — | — | — | 33,023 |
| Payment of CEO payroll in shares | — | — | 66 | 1 | 415 | — | — | — | — | — | 416 |
| Issuance of shares in connection with debt agreement | — | — | 153 | 2 | 474 | — | — | — | — | — | 476 |
| Issuance of warrants, net of expenses | | | — | — | 6,983 | — | — | — | — | — | 6,983 |
| Vesting of nonvested shares | — | — | 17 | — | — | — | — | — | — | — | — |
| Exercise of stock options and employee share purchases | — | — | 47 | — | 627 | — | — | — | 20 | — | 647 |
| MiNK private placement stock sale | — | — | — | — | (4,434) | — | — | — | 10,234 | — | 5,800 |
| Balance at December 31, 2024 | 32 | $ 0 | 23,635 | $ 236 | $ 1,857,662 | — | $ — | $ (1,398) | $ 19,956 | $ (2,182,880) | $ (306,424) |

See accompanying notes to consolidated financial statements.

**AGENUS INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**For the Years Ended December 31, 2024, 2023, and 2022**
**(Amounts in thousands, except per share amounts)**

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| Cash flows from operating activities: | | | |
| Net loss | $ (232,271) | $ (257,437) | $ (230,656) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 13,343 | 13,588 | 6,946 |
| Share-based compensation | 17,390 | 22,869 | 18,337 |
| Non-cash royalty revenue | (100,978) | (114,572) | (45,285) |
| Non-cash interest expense | 118,095 | 100,551 | 62,955 |
| Loss (gain) on sale or disposal of assets, net | 1,153 | (1,408) | (16,196) |
| Loss on impairment of assets | 1,973 | — | 6,111 |
| Gain on forgiveness of liability | (1,788) | — | (2,791) |
| Loss on modification of debt | — | — | 1,937 |
| Gain on lease terminations | (5,334) | — | — |
| Fair value adjustments | (3,954) | (556) | (815) |
| Other, net | 1,452 | 2,007 | — |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | 25,344 | (23,461) | 122 |
| Prepaid expenses | 5,782 | 6,032 | 11,865 |
| Accounts payable | 2,013 | 21,366 | 6,494 |
| Deferred revenue | 20 | (12,249) | (10,368) |
| Accrued liabilities and other current liabilities | 136 | 20,613 | 2,034 |
| Other operating assets and liabilities | (691) | (1,545) | 13,937 |
| Net cash used in operating activities | (158,315) | (224,202) | (175,373) |
| Cash flows from investing activities: | | | |
| Proceeds from sale of property, plant and equipment | 24 | 3,363 | 21,998 |
| Purchases of property, plant and equipment | (576) | (9,954) | (53,062) |
| Purchases of available-for-sale securities | — | (14,647) | (24,629) |
| Proceeds from sale of available-for-sale securities | — | 30,000 | 25,000 |
| Purchase of long-term investment | — | (5,396) | — |
| Proceeds from sale of long-term investment | 579 | 34 | — |
| Cash paid for business acquisition, net | — | — | (2,917) |
| Net cash provided by (used in) investing activities | 27 | 3,400 | (33,610) |
| Cash flows from financing activities: | | | |
| Net proceeds from sale of equity | 33,023 | 133,157 | 99,211 |
| Net proceeds from sale of subsidiary shares in private placement | 5,800 | — | — |
| Proceeds from employee stock purchases and option exercises | 647 | 807 | 898 |
| Purchase of treasury shares to satisfy tax withholdings | — | (4,566) | (3,789) |
| Purchase of subsidiary shares | — | (606) | — |
| Proceeds from Ligand Purchase Agreement, net of expenses | 73,851 | — | — |
| Proceeds from the issuance of long-term debt, net | 20,000 | — | — |
| Payment of finance lease obligations | (10,481) | (8,926) | (490) |
| Net cash provided by financing activities | 122,840 | 119,866 | 95,830 |
| Effect of exchange rate changes on cash | (260) | (628) | (104) |
| Net decrease in cash, cash equivalents and restricted cash | (35,708) | (101,564) | (113,257) |
| Cash, cash equivalents and restricted cash, beginning of period | 79,779 | 181,343 | 294,600 |
| Cash, cash equivalents and restricted cash, end of period | $ 44,071 | $ 79,779 | $ 181,343 |
| Supplemental cash flow information: | | | |
| Cash paid for interest | $ 2,278 | $ 3,168 | $ 1,143 |
| Supplemental disclosures - non-cash activities: | | | |
| Purchases of plant and equipment in accounts payable and accrued liabilities | $ — | $ — | $ 4,580 |
| Issuance of stock options for payment of certain employee bonuses | 9,321 | — | — |
| Issuance of common stock, $0.01 par value, in connection with the issuance of long-term debt | 220 | — | — |
| Issuance of common stock, $0.01 par value, for payment of certain employee bonuses | — | 7,288 | 6,635 |
| Issuance of common stock, $0.01 par value, in connection with payment for services | — | 690 | 138 |
| Issuance of common stock, $0.01 par value, for milestone achievement | — | — | 500 |
| Issuance of subsidiary stock options for payment of certain employee bonuses | 1,032 | — | — |
| Issuance of subsidiary shares for employee bonus | — | 1,011 | 294 |

| | | | |
|---|---|---|---|
| Insurance financing agreements | 771 | 707 | 1,377 |
| Lease right-of-use assets obtained in exchange for new operating lease liabilities | 105 | 318 | 9,206 |
| Lease right-of-use assets obtained in exchange for new finance lease liabilities | 122 | 4,812 | 25,027 |

See accompanying notes to consolidated financial statements.

**(1) Description of Business**

Agenus Inc. (including its subsidiaries, collectively referred to as "Agenus," the "Company," "we," "us," and "our") is a clinical-stage biotechnology company specializing in discovering and developing therapies to activate the body's immune system against cancer and infections. Our pipeline includes immune-modulatory antibodies, adoptive cell therapies (via MiNK Therapeutics, Inc. ("MiNK")), and vaccine adjuvants (via SaponiQx, Inc. ("SaponiQx")). Our primary focus is immuno-oncology ("I-O"), and our diverse pipeline is supported by our in-house capabilities, including current good manufacturing practice ("cGMP") manufacturing and a clinical operations platform. To succeed in I-O, innovation and speed are paramount. We are a vertically integrated biotechnology company equipped with a suite of technology platforms to advance from novel target identification through manufacturing for clinical trials of antibodies and cell therapies. By understanding each patient's cancer, we aim to substantially expand the population benefiting from current I-O therapies. In addition to a diverse pipeline, we have assembled fully integrated end-to-end capabilities including novel target discovery, antibody generation, cell line development and cGMP manufacturing. Leveraging our science and capabilities, we have established strategic partnerships to advance innovation. We believe the next generation of cancer treatment will build on clinically validated antibodies targeting CTLA-4 and PD-1 combined with novel immunomodulatory agents designed to address underlying tumor escape mechanisms.

Our I-O portfolio is driven by several platforms and programs, which we plan to utilize individually and in combination:

- Multiple antibody discovery platforms, including proprietary display technologies, to identify future antibody candidates.
- Antibody candidate programs, including our lead assets, botensilimab (a multifunctional immune cell activator and human Fc-enhanced cytotoxic T-lymphocyte antigen 4 (CTLA-4) blocking antibody, also known as AGEN1181) and balstilimab (a programmed death receptor-1 (PD-1) blocking antibody).
- Our saponin-based vaccine adjuvant platform, primarily centered around our STIMULON™ cultured plant cell ("cpc") QS-21 adjuvant ("STIMULON cpcQS-21").
- A pipeline of novel allogeneic invariant natural killer T cell therapies for treating cancer and other immune-mediated diseases, controlled by MiNK.

Our business activities include product research, preclinical and clinical development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development activities, and support of our collaborations. Our product candidates require successful clinical trials and approvals from regulatory agencies, as well as acceptance in the marketplace. Part of our strategy is to develop and commercialize some of our product candidates through arrangements with academic and corporate collaborators and licensees.

Our cash and cash equivalents at December 31, 2024 were $40.4 million, a decrease of $35.7 million from December 31, 2023. Cash and cash equivalents of our subsidiary, MiNK, at September 30, 2024, were $6.3 million. MiNK cash can only be accessed by Agenus through a declaration of a dividend by the MiNK Board of Directors or through settlement of intercompany balances. We have incurred significant losses since our inception in 1994. As of December 31, 2024, we had an accumulated deficit of $2.18 billion.

Based on our current plans and projections, we believe that our cash resources of $40.4 million at December 31, 2024, along with additional cash inflows we may receive in 2025, will be sufficient to satisfy our critical liquidity requirements through the second quarter of 2025. To support operations on an ongoing basis we require additional funding. Since our founding we have financed our operations principally through income and revenues generated from corporate partnerships, advance royalty sales, and proceeds from debt and equity issuances.

Currently we are in discussions with entities including operating companies and financial entities to provide the funding necessary to support our operations through our planned registration and launch strategy for botensilimab/balstilimab. However, because the completion of cash funding transactions is not entirely within our control, and in accordance with accounting standards, substantial doubt continues to exist about our ability to continue as a going concern for a period of one year after the date of filing of this Annual Report on Form 10-K. The financial statements have been prepared on a basis that assumes Agenus will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business. Management continues to diligently address the Company's liquidity needs and has continued to adjust spending in order to preserve liquidity. We expect our sources of funding to include additional out-licensing agreements, asset sales, project financing, and/or sales of equity securities.

Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions, and our review of the status of each program. Our product candidates are in various stages of development and significant additional expenditures will be required if we start new trials, encounter delays in our programs, apply for regulatory

approvals, continue development of our technologies, expand our operations, and/or bring our product candidates to market. The eventual total cost of each clinical trial is dependent on a number of factors such as trial design, length of the trial, number of clinical sites, and number of patients. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because many of our antibody programs are early stage, and because any further development is dependent on clinical trial results, among other factors, we are unable to reliably estimate the cost of completing our research and development programs or the timing for bringing such programs to various markets or substantial partnering or out-licensing arrangements, and, therefore, when, if ever, material cash inflows are likely to commence. We will continue to adjust our spending as needed in order to preserve liquidity.

**(2) Summary of Significant Accounting Policies**

***(a) Basis of Presentation and Principles of Consolidation***

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles and include the accounts of Agenus and our subsidiaries. All significant intercompany transactions and accounts have been eliminated in consolidation. Non-controlling interest in the consolidated financial statements represents the portion of two of our subsidiaries not 100% owned by Agenus. Refer to Note 10 for additional detail.

On April 4, 2024, we executed a reverse stock split of our issued and outstanding common stock, par value $0.01, at a ratio of 1-for-20 with a record date of April 12, 2024 (the “Reverse Stock Split”). All common share, per share and related information included in the accompanying financial statements and footnote disclosures have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split. Refer to Note 9 for additional detail.

In the years ended December 31, 2024 and 2023, we deconsolidated certain foreign subsidiaries and recognized gains of approximately $185,000 and $132,000, respectively, included in "Other income (expense)" on our consolidated statements of operations and comprehensive loss.

***(b) Segment Information***

We are managed and currently operate as four segments. However, we have concluded that our operating segments meet the criteria required by Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 280, *Segment Reporting* to be aggregated into one reportable segment. Our operating segments have similar economic characteristics and are similar with respect to the five qualitative characteristics specified in ASC 280. Accordingly, we do not have separately reportable segments as defined by ASC 280. Refer to Note 21 for additional detail.

***(c) Use of Estimates***

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. We base those estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

***(d) Cash and Cash Equivalents***

We consider all highly liquid investments purchased with maturities at acquisition of three months or less to be cash equivalents. Cash equivalents consist primarily of money market funds.

***(e) Concentrations of Credit Risk***

Financial instruments that potentially subject us to concentrations of credit risk are primarily cash equivalents, investments, and accounts receivable. We invest our cash, cash equivalents and short-term investments in accordance with our investment policy, which specifies high credit quality standards and limits the amount of credit exposure from any single issue, issuer, or type of investment. We carry balances in excess of federally insured levels; however, we have not experienced any losses to date from this practice.

***(f) Accounts Receivable***

Accounts receivable are amounts due from our collaboration partners and customers as a result of research and development and other services provided, as well as the shipment of clinical product. We considered the need for an allowance for doubtful accounts and have concluded that no allowance was needed as of December 31, 2024 and 2023, as the estimated risk of loss on our accounts receivable was determined to be minimal.

***(g) Property, Plant and Equipment***

Property, plant and equipment, including software developed for internal use, are carried at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Amortization of leasehold improvements is computed over the shorter of the lease term or estimated useful life of the asset. Additions and improvements are capitalized, while repairs and maintenance are charged to expense as incurred. Amortization and depreciation of plant and equipment was $12.8 million, $11.9 million, and $4.7 million, for the years ended December 31, 2024, 2023, and 2022, respectively.

Construction in progress represents direct and indirect construction costs for leasehold improvements and costs of acquisition and installation of equipment. Amounts classified as construction in progress are transferred to their respective property and equipment account when the activities necessary to prepare the assets for their intended use are completed and the assets are placed in service. Depreciation is not recorded for assets classified as construction in progress.

***(h) Fair Value of Financial Instruments***

The estimated fair values of all our financial instruments approximate their carrying amounts in the consolidated balance sheets. The fair value of our outstanding debt is based on a present value methodology. The outstanding principal amount of our debt, including the current portion, was $35.2 million and $13.1 million at December 31, 2024 and 2023, respectively.

***(i) Revenue Recognition***

We account for revenue in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606").

For the years ended December 31, 2024, 2023 and 2022, 98%, 73% and 72%, respectively, of our revenue was earned from one collaboration partner.

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for these goods and services. To achieve this core principle, we apply the following five steps:

*1) Identify the contract with the customer*

A contract with a customer exists when (i) the Company enters into an enforceable contract with a customer that defines each party's rights regarding the goods or services to be transferred and identifies the related payment terms, (ii) the contract has commercial substance, and (iii) the Company determines that collection of substantially all consideration for goods and services that are transferred is probable based on the customer's intent and ability to pay the promised consideration. The Company applies judgment in determining the customer's intent and ability to pay, which is based on a variety of factors including the customer's historical payment experience, or in the case of a new customer, published credit and financial information pertaining to the customer.

*2) Identify the performance obligations in the contract*

Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct, whereby the customer can benefit from the good or service either on its own or together with other available resources, and are distinct in the context of the contract, whereby the transfer of the good or service is separately identifiable from other promises in the contract. To the extent a contract includes multiple promised goods and services, the Company must apply judgment to determine whether promised goods and services are capable of being distinct and are distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation.

*3) Determine the transaction price*

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method depending on the nature of the variable consideration. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes. Determining the transaction price requires significant judgment, which is discussed in further detail for each of the Company's contracts with customers in Note 13.

*4) Allocate the transaction price to performance obligations in the contract*

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation on a relative stand-alone selling price basis unless the transaction price is variable and meets the criteria to be allocated

entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. The consideration to be received is allocated among the separate performance obligations based on relative stand-alone selling prices. Determining the amount of the transaction price to allocate to each separate performance obligation requires significant judgment, which is discussed in further detail for each of the Company's contracts with customers in Note 13.

*5) Recognize revenue when or as the Company satisfies a performance obligation*

The Company satisfies performance obligations either over time or at a point in time. Revenue is recognized over time if either 1) the customer simultaneously receives and consumes the benefits provided by the entity's performance, 2) the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced, or 3) the entity's performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date. If the entity does not satisfy a performance obligation over time, the related performance obligation is satisfied at a point in time by transferring the control of a promised good or service to a customer. Examples of control are using the asset to produce goods or services, enhance the value of other assets, settle liabilities, and holding or selling the asset. ASC 606 requires the Company to select a single revenue recognition method for the performance obligation that faithfully depicts the Company's performance in transferring control of the goods and services. The guidance allows entities to choose between two methods to measure progress toward complete satisfaction of a performance obligation:

1. Output methods - recognize revenue on the basis of direct measurements of the value to the customer of the goods or services transferred to date relative to the remaining goods or services promised under the contract (e.g. surveys of performance completed to date, appraisals of results achieved, milestones reached, time elapsed, and units of produced or units delivered); and
2. Input methods - recognize revenue on the basis of the entity's efforts or inputs to the satisfaction of a performance obligation (e.g., resources consumed, labor hours expended, costs incurred, or time elapsed) relative to the total expected inputs to the satisfaction of that performance obligation.

*Licenses of intellectual property:* If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

*Milestone payments:* At the inception of each arrangement that includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. ASC 606 suggests two alternatives to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used, it should be consistently applied throughout the life of the contract; however, it is not necessary for the Company to use the same approach for all contracts. The Company uses the most likely amount method for development and regulatory milestone payments. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability or achievement of each such milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

*Royalties:* For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

*Up-front Fees:* Depending on the nature of the agreement, up-front payments and fees may be recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

***(j) Foreign Currency Transactions***

Gains and losses from our foreign currency-based accounts and transactions, such as those resulting from the translation and settlement of receivables and payables denominated in foreign currencies, are included in the consolidated statements of operations within other income (expense). We recorded a foreign currency losses of $29,000, $0.1 million and $0.4 million for the years ended December 31, 2024, 2023 and 2022, respectively.

***(k) Research and Development***

Research and development expenses include the costs associated with our internal research and development activities, including salaries and benefits, share-based compensation, occupancy costs, clinical manufacturing costs, related administrative costs, and research and development conducted for us by outside advisors, such as sponsored university-based research partners and clinical study partners. We account for our internally managed clinical study costs by estimating the total cost to treat a patient in each clinical trial and recognizing this cost based on estimates of when the patient receives treatment, beginning when the patient enrolls in the trial. Research and development expenses also include the cost of clinical trial materials shipped to our research partners. Research and development costs are expensed as incurred.

***(l) Share-Based Compensation***

We account for share-based compensation in accordance with the provisions of ASC 718, *Compensation—Stock Compensation*. Share-based compensation expense is recognized based on the estimated grant date fair value. Compensation cost for awards with time-based vesting is recognized on a straight-line basis over the requisite service period of the award. Forfeitures are recognized as they occur. See Note 11 for a further discussion on share-based compensation.

***(m) Income Taxes***

Income taxes are accounted for under the asset and liability method with deferred tax assets and liabilities recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and net operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which such items are expected to be reversed or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the consolidated statement of operations in the period that includes the enactment date. Deferred tax assets which are not more likely than not to be realized are subject to valuation allowance.

***(n) Net Loss Per Share***

Basic income and loss per common share are calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our Directors' Deferred Compensation Plan). Diluted income per common share is calculated by dividing net income attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our Directors' Deferred Compensation Plan) plus the dilutive effect of outstanding instruments such as warrants, stock options, non-vested shares, convertible preferred stock, and convertible notes. Because we reported a net loss attributable to common stockholders for all periods presented, diluted loss per common share is the same as basic loss per common share, as the effect of utilizing the fully diluted share count would have reduced the net loss per common share. Therefore, the following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as of December 31, 2024, 2023, and 2022, as they would be anti-dilutive (in thousands):

| | Year Ended | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Warrants | 965 | 99 | 99 |
| Stock options | 5,243 | 2,141 | 1,799 |
| Nonvested shares | 42 | 27 | 18 |
| Series A-1 convertible preferred stock | 17 | 17 | 17 |

***(o) Goodwill***

Goodwill represents the excess of cost over the fair value of net assets of businesses acquired. Goodwill is not amortized, but instead tested for impairment at least annually. Annually we assess whether there is an indication that goodwill is impaired, or more frequently if events and circumstances indicate that the asset might be impaired during the year. We perform our annual impairment

test as of October 31 of each year. The first step of our impairment analysis compares the fair value of our reporting units to their net book value to determine if there is an impairment. We operate as four reporting units. As of December 31, 2024, our entire goodwill balance is allocated to a reporting unit with a negative carrying amount. In the year ended December 31, 2024, we recognized a goodwill impairment charge of approximately $0.6 million related to the full impairment of the goodwill assigned to one reporting unit. No goodwill impairment was recognized in the years ended December 31, 2023 and 2022.

***(p) Long-lived Assets***

If required based on certain events and circumstances, recoverability of assets to be held and used, other than goodwill and intangible assets not being amortized, is measured by a comparison of the carrying amount of an asset to the undiscounted future net cash flows expected to be generated by the asset or asset group. If the carrying amount of an asset exceeds its estimated future undiscounted cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. Authoritative guidance requires companies to separately report discontinued operations and extends that reporting to a component of an entity that either has been disposed of (by sale, abandonment, or in a distribution to owners) or is classified as held for sale. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

***(q) Leases***

We account for leases in accordance with ASC 842, *Leases* ("ASC 842").

At the inception of an agreement, we determine whether the contract contains a lease. If a lease is identified in such arrangement, we recognize a right-of-use asset and liability on our consolidated balance sheet and determine whether the lease should be classified as a finance or operating lease. We have elected not to recognize assets or liabilities for leases with lease terms of 12 months or less.

A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset by the end of the lease term, (ii) we hold an option to purchase the leased asset that we are reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, or (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term. All other leases are recorded as operating leases.

Our leases commence when the lessor makes the asset available for our use. Finance and operating lease right-of-use assets and liabilities are recognized at the lease commencement date. Lease liabilities are recognized as the present value of the lease payments over the lease term, net of any future lease incentives to be received, using the discount rate implicit in the lease. If the implicit rate is not readily determinable, as is the case with all our current leases, we utilize our incremental borrowing rate at the lease commencement date. Right-of-use assets are recognized based on the amount of the lease liability, adjusted for any advance lease payments paid, initial direct costs incurred, or lease incentives received prior to commencement. Right-of-use assets are subject to evaluation for impairment or disposal on a basis consistent with other long-lived assets.

Operating lease payments are expensed using the straight-line method as an operating expense over the lease term, unless the right-of-use asset reflects impairment. We will then recognize the amortization of the right-of-use asset on a straight-line basis over the remaining lease term with rent expense still included in operating expense in our consolidated statement of operations.

Finance lease assets are amortized to depreciation expense using the straight-line method over the shorter of the useful life of the related asset or the lease term, unless the lease includes a provision that either (i) results in the transfer of ownership of the underlying asset at the end of the lease term or (ii) includes a purchase option whose exercise is reasonably certain. In either of these instances, the right-of-use asset is amortized over the useful life of the underlying asset. Finance lease payments are bifurcated into (i) a portion that is recorded as imputed interest expense and (ii) a portion that reduces the finance lease liability.

We do not separate lease and non-lease components for any of our current asset classes when determining which lease payments to include in the calculation of its lease assets and liabilities. Variable lease payments are expensed in the period incurred. If a lease includes an option to extend or terminate the lease, we reflect the option in the lease term if it is reasonably certain the option will be exercised. Our right of use assets and lease liabilities generally exclude periods covered by renewal options and include periods covered by early termination options (based on our conclusion that it is not reasonably certain that we will exercise such options).

We accounted for the sublease of space in our main Lexington, Massachusetts facility from the perspective of a lessor. Our sublease was classified as an operating lease. We recorded sublease income as a reduction of operating expense.

Operating leases are recorded in “Operating lease right-of-use assets”, “Current portion, operating lease liabilities” and “Operating lease liabilities, net of current portion”, while finance leases are recorded in “Property, plant and equipment, net”, “Other current liabilities” and “Other long-term liabilities” on our consolidated balance sheets.

***(r) Recent Accounting Pronouncements***

***Recently Issued and Adopted***

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. ASU 2023-07 requires incremental annual and quarterly disclosures about segment measures of profit or loss as well as significant segment expenditures. It also requires public entities with a single reportable segment to provide all segment disclosures required by the amendments and all existing segment disclosures in Topic 280. We adopted the standard as of December 31, 2024. The adoption of this standard resulted in increased disclosures, including significant segment expenditures, in the notes to our consolidated financial statements.

***Recently Issued, Not Yet Adopted***

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. ASU 2023-09 requires incremental annual disclosures around income tax rate reconciliations, income taxes paid and other related disclosures. For public business entities, ASU 2023-09 is effective for fiscal years beginning after December 15, 2024. Early adoption is permitted for any annual periods for which financial statements have not been issued or made available for issuance. We are currently evaluating the impact that ASU 2023-09 will have on the disclosures in the notes to our consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses (DISE). This new guidance requires all public entities to incorporate disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. Public entities must adopt ASU 2024-03 prospectively for fiscal years beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption and retrospective application are permitted. We are currently evaluating the impact that ASU 2024-03 will have on our consolidated financial statements.

No other new accounting pronouncement issued or effective during the year ended December 31, 2024 had or is expected to have a material impact on our consolidated financial statements or disclosures.

**(3) Goodwill and Acquired Intangible Assets**

The following table sets forth the changes in the carrying amount of goodwill for year ended December 31, 2024 (in thousands):

| | |
|---|---|
| Balance, December 31, 2023 | $ 24,723 |
| Impairment | (602) |
| Effect of foreign currency | (29) |
| Balance, December 31, 2024 | $ 24,092 |

Acquired intangible assets consisted of the following at December 31, 2024 and 2023 (in thousands):

| | As of December 31, 2024 | | | |
|---|---|---|---|---|
| | Amortization period (years) | Gross carrying amount | Accumulated amortization | Net carrying amount |
| Intellectual Property | 7-15 years | $ 16,841 | $ (15,522) | $ 1,319 |
| Trademarks | 4-4.5 years | 882 | (882) | — |
| Other | 2-7 years | 582 | (582) | — |
| In-process research and development | Indefinite | 2,057 | — | 2,057 |
| Total | | $ 20,362 | $ (16,986) | $ 3,376 |

| | As of December 31, 2023 | | | |
|---|---|---|---|---|
| | Amortization period (years) | Gross carrying amount | Accumulated amortization | Net carrying amount |
| Intellectual Property | 7-15 years | $ 16,841 | $ (15,184) | $ 1,657 |
| Trademarks | 4-4.5 years | 1,213 | (1,185) | 28 |
| Other | 2-7 years | 1,988 | (1,319) | 669 |
| In-process research and development | Indefinite | 2,057 | — | 2,057 |
| Total | | $ 22,099 | $ (17,688) | $ 4,411 |

The weighted average amortization period of our finite-lived intangible assets is approximately 9 years. Amortization expense for the years ended December 31, 2024, 2023, and 2022 was $0.5 million, $1.5 million and $2.2 million, respectively. Amortization expense related to acquired intangibles is estimated at, $0.3 million for each of 2025, 2026, 2027 and 2028, and $40,000 for 2029.

IPR&D acquired in a business combination is capitalized at fair value until the underlying project is completed and is subject to impairment testing. Once the project is completed, the carrying value of IPR&D is amortized over the estimated useful life of the asset. Post-acquisition research and development expenses related to the acquired IPR&D are expensed as incurred.

**(4) Investments**

***Cash Equivalents***

Cash equivalents consisted of the following as of December 31, 2024 and 2023 (in thousands):

| | December 31, 2024 | | December 31, 2023 | |
|---|---|---|---|---|
| | Cost | Estimated Fair Value | Cost | Estimated Fair Value |
| Institutional Money Market Funds | $ 6,954 | $ 6,954 | $ 70,485 | $ 70,485 |
| Total | $ 6,954 | $ 6,954 | $ 70,485 | $ 70,485 |

As a result of the short-term nature of our investments, there were minimal unrealized holding gains or losses for the years ended December 31, 2024, 2023 and 2022.

Of the investments listed above, all were classified as cash equivalents on our consolidated balance sheets as of December 31, 2024 and 2023.

**(5) Restricted Cash**

As of December 31, 2024, 2023, and 2022 we maintained non-current restricted cash of $3.6 million, $3.7 million and $2.7 million, respectively. These amounts are included within “Other long-term assets” in our consolidated balance sheets and are comprised of deposits under letters of credit required under our facility leases.

The following table provides a reconciliation of cash, cash equivalents and restricted cash that agrees to the total of the aforementioned amounts shown in our consolidated statements of cash flows as of December 31, 2024, 2023 and 2022, respectively (in thousands):

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| Cash and cash equivalents | $ 40,437 | $ 76,110 | $ 178,674 |
| Restricted cash | 3,634 | 3,669 | 2,669 |
| Cash, cash equivalents and restricted cash | $ 44,071 | $ 79,779 | $ 181,343 |

**(6) Property, Plant and Equipment**

Property, plant and equipment, net as of December 31, 2024 and 2023 consist of the following (in thousands):

| | 2024 | 2023 | Estimated Depreciable Lives |
|---|---|---|---|
| Land | $ 12,286 | $ 12,286 | Indefinite |
| Building and building improvements | 5,837 | 5,837 | 35 years |
| Furniture and fixtures | 6,491 | 6,448 | 3 to 10 years |
| Laboratory, manufacturing and transportation equipment | 63,012 | 64,276 | 4 to 15 years |
| Leasehold improvements | 94,860 | 95,645 | 2 to 14 years |
| Software and computer equipment | 9,370 | 9,360 | 3 years |
| Construction in progress | 784 | 1,512 | |
| | 192,640 | 195,364 | |
| Less accumulated depreciation and amortization | (72,553) | (61,943) | |
| Total | $ 120,087 | $ 133,421 | |

During the year ended December 31, 2022, we sold land with a recorded value of $5.7 million and recorded a gain on the sale of $16.3 million, included in "other income" in our consolidated statements of operations and comprehensive loss.

**(7) Income Taxes**

We are subject to taxation in the U.S. and in various state, local, and foreign jurisdictions. We remain subject to examination by U.S. Federal, state, local, and foreign tax authorities for tax years 2021 through 2024. With a few exceptions, we are no longer subject

to U.S. Federal, state, local, and foreign examinations by tax authorities for the tax year 2020 and prior. However, net operating losses from the tax year 2020 and prior would be subject to examination if and when used in a future tax return to offset taxable income. Our policy is to recognize income tax related penalties and interest, if any, in our provision for income taxes and, to the extent applicable, in the corresponding income tax assets and liabilities, including any amounts for uncertain tax positions.

As of December 31, 2024, we had available net operating loss carryforwards of $910.1 million and $437.1 million for Federal and state income tax purposes, respectively, which are available to offset future Federal and state taxable income, if any, $404.5 million of these Federal and $1.7 million of these State net operating loss carryforwards do not expire, while the remaining net operating loss carryforwards expire between 2025 and 2044. Our ability to use these net operating losses may be limited by change of control provisions under Internal Revenue Code Section 382 and may expire unused. In addition, we have $5.8 million and $1.4 million of Federal and state research and development credits, respectively, available to offset future taxable income. These Federal and state research and development credits expire between 2025 and 2034 and 2025 and 2030, respectively. Additionally, we have $21,000 of state investment tax credits, available to offset future taxable income that expire in 2026. We also have foreign net operating loss carryforwards, which do not expire, available to offset future foreign taxable income of $2.6 million in the United Kingdom, $9.1 million in Belgium, $715,000 in Ireland, $289,000 in Hong Kong and $2.3 million in Russia. Additionally, we have $3.0 million of net operating loss carryforwards, in Switzerland, which begin to expire in 2030. The potential impacts of these provisions are among the items considered and reflected in management's assessment of our valuation allowance requirements.

Beginning January 1, 2022, the Tax Cuts and Jobs Act (the "Tax Act") eliminated the option to deduct research and development expenditures in the current year and requires taxpayers to capitalize such expenses pursuant to Internal Revenue Code ("IRC") Section 174. The capitalized expenses are amortized over a 5-year period for domestic expenses and a 15-year period for foreign expenses. We have included the impact of this provision, which results in additional deferred tax assets of approximately $87.0 million and $70.9 million as of December 31, 2024 and 2023, respectively.

The tax effect of temporary differences and net operating loss and tax credit carryforwards that give rise to significant portions of the deferred tax assets and deferred tax liabilities as of December 31, 2024 and 2023 are presented below (in thousands).

| | 2024 | 2023 |
|---|---|---|
| Deferred tax assets: | | |
| U.S. Federal and State net operating loss carryforwards | $ 216,158 | $ 191,671 |
| Foreign net operating loss carryforwards | 3,906 | 7,093 |
| Research and development tax credits | 7,153 | 8,348 |
| Share-based compensation | 4,675 | 5,083 |
| Intangible Assets | 19,279 | 24,563 |
| Interest expense carryforward | 15,369 | 12,183 |
| Deferred Revenue | 44,005 | 46,025 |
| Lease Liability | 13,246 | 17,709 |
| Capitalized research expenditures | 87,041 | 70,879 |
| Other | 5,920 | 8,773 |
| Total deferred tax assets | 416,752 | 392,327 |
| Less: valuation allowance | (401,491) | (376,483) |
| Net deferred tax assets | 15,261 | 15,844 |
| Foreign intangible assets | (441) | (462) |
| Right of use asset | (5,875) | (6,761) |
| Depreciable assets | (8,919) | (8,589) |
| Other | (138) | (144) |
| Deferred tax liabilities | (15,373) | (15,956) |
| Net deferred tax liability | $ (112) | $ (112) |

In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the net operating loss and tax credit carryforwards can be utilized or the temporary differences become deductible. We consider projected future taxable income and tax planning strategies in making this assessment. In order to fully realize the deferred tax asset, we will need to generate future taxable income sufficient to utilize net operating losses prior to their expiration. Based upon our history of not generating taxable income due to our business activities focused on product development, we believe that it is more likely than not that deferred tax assets will not be realized through future earnings. Accordingly, a valuation allowance has been established for deferred tax assets which will not be offset by the reversal of deferred tax liabilities. The valuation allowance on the deferred tax assets increased by $25.0 million and $28.6 million during the years ended December 31, 2024 and 2023, respectively.

Income tax expense was nil for the years ended December 31, 2024, 2023 and 2022. Income taxes recorded differed from the amounts computed by applying the U.S. Federal income tax rate of 21% to loss before income taxes as a result of the following (in thousands).

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| Computed "expected" Federal tax benefit | $ (48,780) | $ (54,096) | $ (48,438) |
| (Increase) reduction in income taxes benefit resulting from: | | | |
| Change in valuation allowance | 25,986 | 27,647 | 50,039 |
| (Decrease) increase due to uncertain tax positions | 40 | — | — |
| Nontaxable liquidation of subsidiaries | 1,402 | 1,925 | — |
| Loan forgiveness | — | — | 1,206 |
| State and local income benefit, net of Federal income tax benefit | 2,002 | 4,565 | (12,533) |
| Equity based compensation | 3,054 | 4,696 | 3,000 |
| Foreign rate differential | 396 | (213) | (267) |
| Change in fair value contingent consideration | — | — | (171) |
| Expiration of tax attributes | 14,250 | 14,288 | 10,428 |
| Other, net | 1,650 | 1,188 | (3,264) |
| Income tax benefit | $ — | $ — | $ — |

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows (in thousands):

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| Balance, January 1 | $ 3,433 | $ 3,291 | $ 3,148 |
| Increase (decrease) related to current year positions | (51) | (6) | 3 |
| Increase (decrease) related to previously recognized positions | (152) | 148 | 140 |
| Balance, December 31 | $ 3,230 | $ 3,433 | $ 3,291 |

These unrecognized tax benefits would all impact the effective tax rate if recognized. There are no positions which we anticipate could change within the next twelve months.

**(8) Accrued and Other Current Liabilities**

Accrued liabilities consist of the following as of December 31, 2024 and 2023 (in thousands):

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| Payroll | $ 10,872 | $ 14,512 |
| Professional fees | 4,695 | 7,101 |
| Contract manufacturing costs | 2,915 | 7,613 |
| Research services | 9,720 | 10,807 |
| Other | 6,759 | 5,250 |
| Total | $ 34,961 | $ 45,283 |

Other current liabilities consisted of the following as of December 31, 2024 and 2023 (in thousands):

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| Finance lease liabilities | $ 4,702 | $ 10,457 |
| Other | 3,115 | 3,458 |
| Total | $ 7,817 | $ 13,915 |

**(9) Equity**

Effective August 5, 2022, our certificate of incorporation was amended to increase the number of authorized shares of common stock from 400,000,000 to 800,000,000.

Under the terms and conditions of the Certificate of Designation creating the Series A-1 Preferred Stock, this stock is convertible by the holder at any time into our common stock, is non-voting, has an initial conversion price of $1,897.20 per common share, subject to adjustment, and is redeemable by us at its face amount ($31.6 million), plus any accrued and unpaid dividends. The Certificate of Designation does not contemplate a sinking fund. The Series A-1 Preferred Stock ranks senior to our common stock. In a liquidation, dissolution, or winding up of the Company, the Series A-1 Preferred Stock's liquidation preference must be fully satisfied before any distribution could be made to the holders of the common stock. Other than in such a liquidation, no terms of the Series A-1 Preferred Stock affect our ability to declare or pay dividends on our common stock as long as the Series A-1 Preferred Stock's dividends are accruing. The liquidation value of this Series A-1 Preferred stock is equal to $1,000 per share outstanding plus any accrued unpaid dividends. Dividends in arrears with respect to the Series A-1 Preferred Stock were approximately $2.5 million or $78.46 per share, and $2.3 million or $71.67 per share, at December 31, 2024 and 2023, respectively.

On July 22, 2020, we filed an Automatic Shelf Registration Statement on Form S-3ASR (file no. 333-240006) (the "First Registration Statement"). The First Registration Statement included both a base prospectus that covered the potential offering, issuance and sale from time to time of common stock, preferred stock, warrants, debt securities and units of Agenus and a prospectus covering the offering, issuance and sale of up to 5.0 million shares of our common stock from time to time in "at-the-market offerings" pursuant to an At Market Issuance Sales Agreement (the "Sales Agreement") entered into with B. Riley on July 22, 2020. On March 1, 2022, we filed a prospectus supplement in connection with the potential offer and sale of up to an additional 5.0 million shares of common stock pursuant to the Sales Agreement. This First Registration Statement expired in July 2023.

On June 23, 2023, we filed an Automatic Shelf Registration Statement on Form S-3ASR (file no. 333-272911) (the "Second Registration Statement"). The Second Registration Statement included both a base prospectus that covered the potential offering, issuance and sale from time to time of common stock, preferred stock, warrants, debt securities and units of Agenus and a prospectus supplement that covered the potential offer and sale of up to 9.2 million shares of common stock pursuant to the Sales Agreement.

On March 14, 2024, we filed a Post-effective Amendment to an Automatic Shelf Registration Statement on Form POSASR (file no. 333-272911) and a Post-Effective Amendment for Registration Statement on Form POS AM (file no. 333-272911) (together, the "Third Registration Statement"). The Third Registration Statement included both a base prospectus that covered the potential offering, issuance and sale from time to time of up to $300.0 million of common stock, preferred stock, warrants, debt securities and units of Agenus and a prospectus supplement for the potential offer and sale of up to 6,725,642 shares of common stock (the "Initial ATM Shares") in "at the market" offerings pursuant to the Sales Agreement. On August 8, 2024, we filed an additional prospectus supplement for the potential offer and sale of up to an additional 13,834,015 shares of common stock (together with the Initial ATM Shares, the "Placement Shares") in "at the market" offerings pursuant to the Sales Agreement. Sales pursuant to the Sales Agreement will be made only upon our instruction to the Sales Agent, and we cannot provide assurances that we will issue any additional Placement Shares pursuant to the Sales Agreement.

During the years ended December 31, 2024, 2023 and 2022 we received net proceeds of approximately $33.0 million, $133.2 million and $99.2 million from the sale of approximately 3.6 million shares, 4.2 million shares and 2.3 million shares, respectively, of our common stock at an average price per share of approximately $9.37, $32.60 and $45.40, respectively, in at-the-market offerings under the Sales Agreement.

On April 3, 2024, our stockholders approved a proposal to amend our Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), to effect the Reverse Stock Split of our issued and outstanding common stock at a ratio of 1-for-20. On April 4, 2024, we filed a Certificate of Eighth Amendment (the "Certificate of Amendment") to our Certificate of Incorporation with the Secretary of State of the State of Delaware to effect the Reverse Stock Split. Pursuant to the Certificate of Amendment, the Reverse Stock Split became effective at 12:01 a.m., Eastern Time, on April 12, 2024. As of the opening of trading on April 12, 2024, our common stock began trading on a post-split basis under CUSIP number 00847G 804.

All common share, per share and related information included in the accompanying financial statements and footnote disclosures have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split.

In connection with the Ligand Purchase Agreement described in Note 17, on May 6, 2024, we issued to Ligand a warrant to purchase 867,052 shares of our common stock, at an exercise price equal to $17.30 per share. The exercise price of the Ligand Warrant and the number of shares issuable upon exercise of the Ligand Warrant are subject to adjustments for stock splits, combinations, stock dividends or similar events. The Ligand Warrant is exercisable until May 6, 2029.

**(10) Non-controlling Interest**

Non-controlling interest recorded in our consolidated financial statements for the years ended December 31, 2024, 2023 and 2022, relates to the following approximate interests in certain consolidated subsidiaries, which we do not own.

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| MiNK Therapeutics, Inc. | 45% | 37% | 22% |
| SaponiQx, Inc. | 30% | 30% | 30% |

Changes in non-controlling interest for the years ended December 31, 2024, 2023 and 2022 were as follows (in thousands):

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| Beginning balance | $ 11,949 | $ 6,376 | $ 13,469 |
| Net loss attributable to non-controlling interest | (5,059) | (11,676) | (10,582) |
| Other items: | | | |
| Sale of subsidiary shares in private placement | 10,234 | — | — |
| Distribution of subsidiary shares to Agenus stockholders | — | 14,888 | — |
| Purchase of subsidiary shares | — | (2,546) | — |
| Issuance of subsidiary shares for employee stock purchase plan and exercise of options | 20 | 71 | — |
| Issuance of subsidiary shares for employee bonus | — | 1,011 | 294 |
| Subsidiary share-based compensation | 2,812 | 3,825 | 3,195 |
| Total other items | 13,066 | 17,249 | 3,489 |
| Ending balance | $ 19,956 | $ 11,949 | $ 6,376 |

***Sale of subsidiary shares in private placement***

On May 13, 2024, MiNK entered into a Stock Purchase Agreement with a certain investor (the "Purchaser"), pursuant to which MiNK issued and sold an aggregate of 464,000 shares of its Common Stock (the "MiNK Common Shares"), at a purchase price of $12.50 per share. The aggregate purchase price paid by the Purchaser for the MiNK Common Shares was approximately $5.8 million, net of offering expenses. The transaction closed on May 14, 2024.

***Distribution of subsidiary shares to Agenus stockholders***

On March 29, 2023, our Board of Directors declared a stock dividend (the "Dividend") consisting of an aggregate of 500,000 shares (the "Dividend Stock") of common stock, par value $0.00001 per share, of MiNK held by Agenus to record holders of Agenus' common stock, par value $0.01 per share as of the close of business on April 17, 2023 (the "Record Date").

On May 1, 2023, we paid the Dividend and distributed 0.0292 of a share of the Dividend Stock for each share of Agenus Common Stock outstanding as of the close of business on the Record Date. No fractional shares were issued in connection with the Dividend and the shareholders of Agenus who were entitled to receive fractional shares of the Dividend Stock received cash (without interest) in lieu of such fractional shares. Subsequent to the distribution of the Dividend Stock, we maintained a controlling voting interest in MiNK.

***Purchase of subsidiary shares***

During the year ended December 31, 2023, we purchased 44,649 shares of MiNK common stock in multiple open market transactions.

***Subsidiary Share-based Compensation***

Subsidiary share-based compensation attributed to non-controlling interest represents share-based compensation expense for awards issued by both MiNK Therapeutics and SaponiQx.

**(11) Share-based Compensation Plans**

On April 10, 2019, our Board of Directors adopted, and on June 19, 2019, our stockholders approved, our 2019 Equity Incentive Plan (the "2019 EIP"). On June 11, 2024, June 8, 2022 and June 15, 2021, our stockholders approved amendments to the 2019 EIP, increasing the number of shares available for issuance. The 2019 EIP provides for the grant of incentive stock options intended to qualify under Section 422 of the Code, nonstatutory stock options, restricted stock, unrestricted stock and other equity-based awards, such as stock appreciation rights, phantom stock awards, and restricted stock units, which we refer to collectively as Awards, for up to 6.5 million shares of our common stock (subject to adjustment in the event of stock splits and other similar events).

The Board of Directors appointed the Compensation Committee to administer the 2019 EIP. No awards will be granted under the 2019 EIP after June 19, 2029.

In the second quarter of 2019, our Board of Directors adopted, and on June 16, 2020, our stockholders approved the 2019 Employee Stock Purchase Plan (the "2019 ESPP") to provide eligible employees the opportunity to acquire our common stock in a program designed to comply with Section 423 of the Code. On June 12, 2023 and June 15, 2021, our stockholders approved

amendments to the 2019 ESPP, increasing the number of shares available for issuance. There are 0.1 million shares reserved for issuance under the 2019 ESPP.

Our Directors' Deferred Compensation Plan, as amended, permits each outside director to defer all, or a portion of, their cash compensation until their service as a director ends or until a specified date into a cash account or a stock account. On June 11, 2024 and June 8, 2022, our stockholders approved amendments to this plan, increasing the number of shares available for issuance. There are 63,750 shares of our common stock reserved for issuance under this plan. As of December 31, 2024, 16,363 shares had been issued. Amounts deferred to a cash account will earn interest at the rate paid on one-year Treasury bills with interest added to the account annually. Amounts deferred to a stock account will be converted on a quarterly basis into a number of units representing shares of our common stock equal to the amount of compensation which the participant has elected to defer to the stock account divided by the applicable price for our common stock. The applicable price for our common stock has been defined as the average of the closing price of our common stock for all trading days during the calendar quarter preceding the conversion date as reported by The Nasdaq Capital Market. Pursuant to this plan, a total of 63,750 units, each representing a share of our common stock at a weighted average common stock price of $46.74, had been credited to participants' stock accounts as of December 31, 2024. The compensation charges for this plan were immaterial for all periods presented.

On November 4, 2015, our Board of Directors adopted and approved our 2015 Inducement Equity Plan (the "2015 IEP") in compliance with and in reliance on Nasdaq Listing Rule 5635(c)(4), which exempts inducement grants from the general requirement of the Nasdaq Listing Rules that equity-based compensation plans and arrangements be approved by stockholders. In October 2023, our Board of Directors approved an increase to the number of shares available for issuance. There are 175,000 shares of our common stock reserved for issuance under the 2015 IEP.

We primarily use the Black-Scholes option pricing model to value options granted to employees and non-employees, as well as options granted to members of our Board of Directors. All stock option grants have 10-year terms and generally vest ratably over a 3 or 4-year period.

The fair value of each option granted during the periods was estimated on the date of grant using the following weighted average assumptions:

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| Expected volatility | 86% | 72% | 68% |
| Expected term in years | 6 | 6 | 6 |
| Risk-free interest rate | 3.8% | 3.3% | 1.8% |
| Dividend yield | 0% | 0% | 0% |

Expected volatility is based exclusively on historical volatility data of our common stock. The expected term of stock options granted is based on historical data and other factors and represents the period of time that stock options are expected to be outstanding prior to exercise. The risk-free interest rate is based on U.S. Treasury strips with maturities that match the expected term on the date of grant.

A summary of option activity for 2024 is presented below:

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2023 | 2,141,360 | $ 65.00 | | |
| Granted | 3,334,887 | 6.91 | | |
| Exercised | (16,668) | 12.26 | | |
| Forfeited | (93,758) | 26.87 | | |
| Expired | (122,905) | 63.56 | | |
| Outstanding at December 31, 2024 | 5,242,916 | 28.76 | 8.06 | $ — |
| Vested or expected to vest at December 31, 2024 | 5,242,916 | 28.76 | 8.06 | $ — |
| Exercisable at December 31, 2024 | 2,534,682 | $ 50.07 | 6.52 | $ — |

The weighted average grant-date fair values of options granted during the years ended December 31, 2024, 2023, and 2022, was $10.75, $28.20, and $35.00, respectively.

The aggregate intrinsic value in the table above represents the difference between our closing stock price on the last trading day of fiscal 2024 and the exercise price, multiplied by the number of in-the-money options that would have been received by the option holders had all option holders exercised their options on December 31, 2024 (the intrinsic value is considered to be zero if the exercise price is greater than the closing stock price). This amount changes based on the fair market value of our stock. The total intrinsic value of options exercised during the years ended December 31, 2024, 2023, and 2022, determined on the dates of exercise, was $64,000, $13,000, and $70,000, respectively.

During 2024, 2023, and 2022, all options were granted with exercise prices equal to the market value of the underlying shares of common stock on the grant date other than certain awards dated January 16, 2024 and January 17, 2024. In January 2024, our Board of Directors approved certain awards subject to forfeiture in the event stockholder approval was not obtained for an amendment to our 2019 EIP. This approval was obtained in June 2024. Accordingly, these awards have a grant date of June 2024, with an exercise price as of the date the Board of Director's approved the awards in January 2024.

As of December 31, 2024, there was $13.1 million of unrecognized share-based compensation expense related to these stock options and stock options granted under a subsidiary plan which, if all milestones are achieved, will be recognized over a weighted average period of 1.4 years.

Certain employees and consultants have been granted non-vested stock. The fair value of non-vested market-based awards is calculated based on a Monte Carlo simulation as of the date of issuance. The fair value of other non-vested stock is calculated based on the closing sale price of our common stock on the date of issuance.

A summary of non-vested stock activity for 2024 is presented below:

| | Nonvested Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Outstanding at December 31, 2023 | 27,163 | $ 37.20 |
| Granted | 48,561 | 11.96 |
| Vested | (17,002) | 29.11 |
| Forfeited | (16,500) | 21.82 |
| Outstanding at December 31, 2024 | 42,222 | $ 17.30 |

As of December 31, 2024, there was $1.1 million of unrecognized share-based compensation expense related to these non-vested shares and non-vested shares granted under a subsidiary plan which will be recognized over a weighted average period of 3.1 years. The total intrinsic value of shares vested during the years ended December 31, 2024, 2023, and 2022, was $0.2 million, $11.5 million, and $10.9 million, respectively.

Cash received from option exercises and purchases under our 2019 ESPP for the years ended December 31, 2024, 2023, and 2022, was $0.6 million, $0.8 million, and $0.9 million, respectively.

We issue new shares upon option exercises, purchases under our 2019 ESPP, vesting of non-vested stock and under the Directors' Deferred Compensation Plan. During the years ended December 31, 2024, 2023, and 2022, 16,668 shares, 2,337 shares, and 5,166 shares, respectively, were issued as a result of stock option exercises. During the years ended December 31, 2024, 2023, and 2022, 30,637 shares, 22,469 shares, and 16,310 shares, were issued under the 2019 ESPP, respectively. During the years ended December 31, 2024, 2023, and 2022, 17,002 shares, 4,804 shares, and 11,524 shares, respectively, were issued as a result of the vesting of non-vested stock. Additionally, during the years ended December 31, 2023, and 2022, 232,190 shares and 204,504 shares were issued as payment for certain employee bonuses, with 83,438 and 72,342 of those shares being withheld to cover taxes, resulting in a net share issuance of 148,752 and 132,162, respectively.

The impact on our results of operations from share-based compensation for the years ended December 31, 2024, 2023, and 2022, was as follows (in thousands).

| | Year Ended | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Research and development | $ 11,998 | $ 6,237 | $ 4,847 |
| General and administrative | 15,329 | 16,114 | 13,391 |
| Total share-based compensation expense | $ 27,327 | $ 22,351 | $ 18,238 |

**(12) License, Research, and Other Agreements**

On December 5, 2014, we entered into a license agreement with the Ludwig Institute for Cancer Research Ltd., or Ludwig, which replaced and superseded a prior agreement entered into between the parties in May 2011. Pursuant to the terms of the license

agreement, Ludwig granted us an exclusive, worldwide license under certain intellectual property rights of Ludwig and Memorial Sloan Kettering Cancer Center arising from the prior agreement to further develop and commercialize GITR, OX40 and TIM-3 antibodies. On January 25, 2016, we entered into a second license agreement with Ludwig, on substantially similar terms, to develop CTLA-4 and PD-1 antibodies. Pursuant to the December 2014 license agreement, we made an upfront payment of $1.0 million to Ludwig. The December 2014 license agreement also obligates us to make potential milestone payments of up to $20.0 million for events prior to regulatory approval of licensed GITR, OX40 and TIM-3 products, and potential milestone payments in excess of $80.0 million if such licensed products are approved in multiple jurisdictions, in more than one indication, and certain sales milestones are achieved. Under the January 2016 license agreement, we are obligated to make potential milestone payments of up to $12.0 million for events prior to regulatory approval of CTLA-4 and PD-1 licensed products, and potential milestone payments of up to $32.0 million if certain sales milestones are achieved. Under each of these license agreements, we will also be obligated to pay low to mid-single digit royalties on all net sales of licensed products during the royalty period, and to pay Ludwig a percentage of any sublicensing income, ranging from a low to mid-double digit percentage depending on various factors. The license agreements may each be terminated as follows: (i) by either party if the other party commits a material, uncured breach; (ii) by either party if the other party initiates bankruptcy, liquidation or similar proceedings; or (iii) by us for convenience upon 90 days' prior written notice. The license agreements also contain customary representations and warranties, mutual indemnification, confidentiality and arbitration provisions.

We have entered into various cancelable agreements with contract manufacturers, institutions, and clinical research organizations (collectively "third party providers") to perform pre-clinical activities and to conduct and monitor our clinical studies. Under these agreements, subject to the enrollment of patients and performance by the applicable third-party provider, we have estimated our total payments to be $660.7 million over the term of the studies. For the years ended December 31, 2024, 2023, and 2022, $64.2 million, $94.5 million, and $66.3 million, respectively, have been expensed in the accompanying consolidated statements of operations related to these third-party providers. Through December 31, 2024, we have expensed $616.5 million as research and development expenses and $578.3 million of this amount has been paid. The timing of expense recognition and future payments related to these agreements is subject to the enrollment of patients and performance by the applicable third-party provider.

**(13) Revenue from Contracts with Customers**

***Bristol Myers Squibb Company License Agreement***

On May 17, 2021, we entered into a License, Development and Commercialization Agreement ("BMS License Agreement") with Bristol Myers Squibb Company ("BMS") to collaborate on the development and commercialization of our proprietary anti-TIGIT bispecific antibody program AGEN1777. Pursuant to the BMS License Agreement, we received a non-refundable upfront cash payment of $200.0 million and were eligible to receive up to $1.36 billion in aggregate development, regulatory and commercial milestone payments plus the tiered royalties described below. In July 2021, the BMS License Agreement closed, and we received the $200.0 million upfront payment.

In December 2023, we announced that the first patient was dosed in an AGEN1777 Phase 2 clinical trial, triggering the achievement of a $25.0 million milestone. We received this milestone in January 2024. In October 2021, we announced that the first patient was dosed in the AGEN1777 Phase 1 clinical trial, triggering the achievement of a $20.0 million milestone. We received this milestone in December 2021.

Under the BMS License Agreement, we granted BMS an exclusive worldwide license under certain of our intellectual property rights to develop, manufacture and commercialize AGEN1777 and its derivatives in all fields; provided, we retained an option to access the licensed antibodies for use in clinical studies in combination with certain of our other pipeline assets subject to certain restrictions. In exchange, BMS was responsible for all of the development, regulatory approval, manufacturing and commercialization costs with respect to products containing AGEN1777. On July 30, 2024, we received notice from BMS that it was voluntarily terminating the BMS License Agreement, effective as of January 26, 2025. Upon termination, BMS returned AGEN1777 to us.

*License Revenue*

We identified a single performance obligation under the BMS License Agreement, the license of AGEN1777 ("AGEN1777 License"). All other promised goods/services were deemed immaterial in the context of the contract. We determined that the AGEN1777 License was both capable of being distinct and distinct within the context of the contract as the AGEN1777 License has significant stand-alone functionality as of contract inception and BMS can begin deriving benefit from the AGEN1777 License without consideration of the immaterial services. The $200.0 million upfront payment was allocated to the single performance obligation and recognized as revenue at contract inception.

For the year ended December 31, 2024, no revenue was recognized. For the year ended December 31, 2023, we recognized $25.0 million in research and development revenue related to the achievement of a milestone. For the year ended December 31, 2022, no revenue was recognized.

***Betta License Agreement***

In June 2020, we entered into a license and collaboration agreement (the "Betta License Agreement") with Betta Pharmaceuticals Co., Ltd. ("Betta"), pursuant to which we granted Betta an exclusive license to develop, manufacture and

commercialize balstilimab and zalifrelimab in Greater China. Under the terms of the Betta License Agreement, we received $15.0 million upfront in July 2020 and are eligible to receive up to $100.0 million in milestone payments plus royalties on any future sales in Greater China.

We also entered into a stock purchase agreement with Betta and a wholly-owned subsidiary of Betta ("Betta HK").

We identified the following performance obligations under the Betta License Agreement: (1) the license of balstilimab and zalifrelimab and (2) our obligation to complete manufacturing technology transfer activities to Betta (the "Technology Transfer") for balstilimab and zalifrelimab.

We determined that the license of balstilimab and zalifrelimab was both capable of being distinct and distinct within the context of the contract as the license has significant stand-alone functionality as of contract inception based on the advanced development stage of balstilimab and zalifrelimab. Betta can begin deriving benefit from the license prior to the Technology Transfer being completed. The Technology Transfer is completed over time and is separate from the transfer of the balstilimab and zalifrelimab license, which occurred at contract inception. As a result, we concluded that the balstilimab and zalifrelimab license and Technology Transfer are separate performance obligations.

We determined that there were no significant financing components, noncash consideration, or amounts that may be refunded to the customer, and as such the total upfront fixed consideration of $15.0 million would be included in the total transaction price and be allocated to the identified performance obligations using the relative standalone selling price method.

We determined the estimated standalone selling price of the balstilimab and zalifrelimab license by applying a risk adjusted, net present value, estimate of future cash flow approach. We determined the estimated standalone selling price of the Technology Transfer by using the estimated costs of satisfying the performance obligation, plus an appropriate margin for such services.

Revenue attributable to the balstilimab and zalifrelimab license was recognized at a point-in-time, upon delivery of the license to Betta at contract inception. The Technology Transfer is satisfied over time and revenue attributable to this performance obligation will be recognized as the related services are being performed using the input of costs incurred over total costs expected to be incurred. We believe this is the best measure of progress because other measures do not reflect how we transfer the performance obligation to Betta.

For the years ended December 31, 2024 and 2023, no revenue was recognized. For the year ended December 31, 2022, we recognized approximately $0.7 million of research and development revenue related to the Betta License Agreement.

***UroGen License Agreement***

In November 2019, we entered into a License Agreement with UroGen Pharma Ltd. (the "UroGen License Agreement") in which we granted a license of AGEN1884 for use with UroGen's sustained release technology for intravesical delivery in patients with urinary tract cancers. Pursuant to the terms of the UroGen License Agreement, we received an upfront cash payment from UroGen of $10.0 million. We are eligible to receive up to $200.0 million in potential development, regulatory and commercial milestones, as well as 14-20% royalties on net sales of the products containing AGEN1884.

We identified the following performance obligations under the UroGen License Agreement: (1) the license of AGEN1884 that we granted UroGen, and (2) the clinical supply of AGEN1884 that we agreed to supply to UroGen. We concluded that the combined standalone selling price of the license approximated the $10.0 million upfront fee and as such the full amount was recognized at a point-in-time, upon delivery of the license to UroGen at contract inception. Revenue related to the supply of AGEN1884 is recognized under the "as invoiced" practical expedient.

For the years ended December 31, 2024, 2023 and 2022, we recognized approximately $0.3 million, $0.1 million and $0.2 million, respectively, of research and development revenue related to the UroGen License Agreement.

***Gilead Collaboration Agreement***

Pursuant to the terms of two separate option and license agreements between the parties (each, an "Option and License Agreement" and together, the "Option and License Agreements"), we granted Gilead exclusive options to license exclusively ("License Option") our bispecific antibody, AGEN1223, and our monospecific antibody, AGEN2373 (together, the "Option Programs"), during the respective Option Periods (defined below). Pursuant to the terms of the Option and License Agreements, we agreed to grant Gilead an exclusive, worldwide license under our intellectual property rights to develop, manufacture and commercialize AGEN1223 or AGEN2373, as applicable, in all fields of use upon Gilead's exercise of the applicable License Option. In the third quarter of 2021 we ceased development of AGEN1223 and in October 2021 the AGEN1223 option and license agreement was formally terminated. In August 2024, Gilead elected not to exercise the option to license AGEN2373 and the option and license agreement was formally terminated. Gilead was entitled to exercise its License Option for either or both Option Programs at any time up until ninety (90) days following Gilead's receipt of a data package with respect to the first complete Phase 1b clinical trial for each Option Program (the "Option Period"). During the Option Period, we were responsible for the costs and expenses related to the development of the Option Programs.

*Research and Development Revenue*

For the year ended December 31, 2024, no revenue was recognized. For the year ended December 31, 2023, we recognized research and development revenue of $12.2 million based on the partial satisfaction of the over time performance obligations as of period end. For the year ended December 31, 2022, we recognized research and development revenue of $5.0 million related to the

achievement of a milestone and $9.5 million based on the partial satisfaction of the over time performance obligations as of period end.

***Incyte Collaboration Agreement***

On January 9, 2015, and effective February 19, 2015, we entered into a global license, development and commercialization agreement (the "Collaboration Agreement") with Incyte pursuant to which the parties plan to develop and commercialize novel immuno-therapeutics using our antibody discovery platforms. The Collaboration Agreement was initially focused on four checkpoint modulator programs directed at GITR, OX40, LAG-3 and TIM-3. In addition to the four identified antibody programs, the parties have an option to jointly nominate and pursue the development and commercialization of antibodies against additional targets during a five-year discovery period which, upon mutual agreement of the parties for no additional consideration, can be extended for an additional three years. In November 2015, we and Incyte jointly nominated and agreed to pursue the development and commercialization of three additional checkpoint targets. In February 2017, we amended the Collaboration Agreement by entering into a First Amendment to License, Development and Commercialization Agreement (the "First Amendment"). In October 2019, we further amended the Collaboration Agreement by entering into a Second Amendment to License, Development and Commercialization Agreement (the "Second Amendment"). See "Amendments" section below.

In October 2022, Incyte notified us of their intent to terminate the OX40 program, effective October 2023. Upon termination, the rights to the OX40 program reverted back to us. In May 2023, Incyte notified us of their intent to terminate both the GITR program and the undisclosed program, effective May 2024. Upon termination, the rights to the GITR program and the undisclosed program reverted back to us. In July 2024, Incyte announced that it would discontinue further development of the LAG-3 program and TIM-3 program and in February 2025, Incyte notified us of their intent to terminate the entire Collaboration Agreement, effective February 2026. Upon termination, the rights to all remaining programs will revert back to us.

Pursuant to the XOMA Royalty Purchase Agreement, we sold to XOMA 33% of the future royalties and 10% of the future milestones that we were entitled to receive from Incyte, excluding the $5.0 million milestone that we recognized in the three months ended September 30, 2018.

*Agreement Structure*

Under the terms of the Collaboration Agreement, we received non-creditable, nonrefundable upfront payments totaling $25.0 million. In addition, until the Amendment, the parties shared all costs and profits for the GITR, OX40 and two of the additional antibody programs on a 50:50 basis (profit-share products), and we were eligible to receive up to $20.0 million in future contingent development milestones under these programs. Until the terminations, Incyte was obligated to reimburse us for all development costs that we incur in connection with the TIM-3, LAG-3 and one of the additional antibody programs (royalty-bearing products) and we were eligible to receive (i) up to $155.0 million in future contingent development, regulatory, and commercialization milestone payments and (ii) tiered royalties on global net sales at rates generally ranging from 6% to 12%. For each royalty-bearing product, we also had the right to elect to co-fund 30% of development costs incurred following initiation of pivotal clinical trials in return for an increase in royalty rates. Additionally, we had the option to retain co-promotion participation rights in the United States on any profit-share product. Through the direction of a joint steering committee, until the Amendment, the parties anticipated that, for each program, we would serve as the lead for pre-clinical development activities through investigational new drug ("IND") application filing, and Incyte would serve as the lead for clinical development activities. The parties initiated the first clinical trials of antibodies arising from these programs in 2016.

*Amendments*

Pursuant to the terms of the First Amendment, the GITR and OX40 programs immediately converted from profit-share programs to royalty-bearing programs and we became eligible to receive a flat 15% royalty on global net sales should any candidates from either of these two programs be approved. Incyte is now responsible for global development and commercialization and all associated costs for these programs. In addition, the profit-share programs relating to TIGIT and one undisclosed target were removed from the collaboration, with the undisclosed target reverting to Incyte and TIGIT to Agenus. The terms for the remaining three royalty-bearing programs targeting TIM-3, LAG-3 and one undisclosed target remain unchanged, with Incyte being responsible for global development and commercialization and all associated costs. The Amendment gave Incyte exclusive rights and all decision-making authority for manufacturing, development, and commercialization with respect to all royalty-bearing programs.

In connection with the First Amendment, Incyte paid us $20.0 million in accelerated milestones related to the clinical development of the antibody candidates targeting GITR and OX40.

Pursuant to the terms of the Second Amendment, we transitioned preclinical development and IND preparation of the undisclosed target to Incyte.

*Research and Development Revenue*

For the year ended December 31, 2024, no revenue was recognized. For the years ended December 31, 2023 and 2022, we recognized approximately $1.4 million and $1.6 million, respectively, of research and development revenue for research and development services provided.

***GSK License and Amended GSK Supply Agreements***

In July 2006, we entered into a license agreement and a supply agreement with GSK for the use of QS-21 STIMULON (the "GSK License Agreement" and the "GSK Supply Agreement," respectively). In January 2009, we entered into an Amended and Restated Manufacturing Technology Transfer and Supply Agreement (the "Amended GSK Supply Agreement") under which GSK has the right to manufacture all of its requirements of commercial grade QS-21 STIMULON. GSK is obligated to supply us (or our affiliates, licensees, or customers) certain quantities of commercial grade QS-21 STIMULON for a stated period of time. Under these agreements, GSK paid an upfront license fee of $3.0 million and agreed to pay aggregate milestones of $5.0 million. In July 2007, the Amended GSK Supply Agreement was further amended, and we were paid an additional fixed fee of $7.3 million. In March 2012 we entered into a First Right to Negotiate and Amendment Agreement amending the GSK License Agreement and the Amended GSK Supply Agreement to clarify and include additional rights for the use of our QS-21 STIMULON (the "GSK First Right to Negotiate Agreement"). In addition, we granted GSK the first right to negotiate for the purchase of the Company or certain of our assets, which such rights expired in March 2017. As consideration for entering into the GSK First Right to Negotiate Agreement, GSK paid us an upfront, non-refundable payment of $9.0 million, $2.5 million of which is creditable toward future royalty payments. As of December 31, 2017, we had received all of the potential $24.3 million in upfront and milestone payments related to the GSK Agreements. We were also generally entitled to receive 2% royalties on net sales of prophylactic vaccines for a period of 10 years after the first commercial sale of a resulting GSK product. We sold these royalty rights to HCR in January 2018 pursuant to the HCR Royalty Purchase Agreement but continue to recognize revenue under the GSK Agreements because the sale to HCR was accounted for as a borrowing arrangement (See Note 17).

The GSK License and Amended GSK Supply Agreements may be terminated by either party upon a material breach if the breach is not cured within the time specified in the respective agreement. The termination or expiration of the GSK License Agreement does not relieve either party from any obligation which accrued prior to the termination or expiration. Among other provisions, the license rights granted to GSK survive expiration of the GSK License Agreement. The license rights and payment obligations of GSK under the Amended GSK Supply Agreement survive termination or expiration, except that GSK's license rights and future royalty obligations do not survive if we terminate due to GSK's material breach unless we elect otherwise.

For the years ended December 31, 2024 and 2023, we recognized $101.0 million and $114.6 million, respectively, of non-cash royalty revenue. For the year ended December 31, 2022, we recognized $25.3 million of royalty sales milestone revenue, which was cash-settled based on the terms of the arrangement with HCR, and $45.3 million of non-cash royalty revenue.

***Disaggregation of Revenue***

The following table presents revenue (in thousands) for years ended December 31, 2024, 2023 and 2022, disaggregated by geographic region and revenue type. Revenue by geographic region is allocated based on the domicile of our respective business operations.

| | Year ended December 31, 2024 | | |
|---|---|---|---|
| | United States | Rest of World | Total |
| **Revenue Type** | | | |
| Clinical product revenue | $ 482 | $ — | $ 482 |
| Other services | — | 2,003 | 2,003 |
| Non-cash royalties | 100,978 | — | 100,978 |
| | $ 101,460 | $ 2,003 | $ 103,463 |

| | Year ended December 31, 2023 | | |
|---|---|---|---|
| **Revenue Type** | | | |
| License fees and milestones | $ 25,000 | $ — | $ 25,000 |
| Clinical product revenue | 116 | — | 116 |
| Research and development services | 1,435 | — | 1,435 |
| Other services | — | 2,978 | 2,978 |
| Recognition of deferred research and development revenue | 12,213 | — | 12,213 |
| Non-cash royalties | 114,572 | — | 114,572 |
| | $ 153,336 | $ 2,978 | $ 156,314 |

| | Year ended December 31, 2022 | | |
|---|---|---|---|
| **Revenue Type** | | | |
| License fees and milestones | $ 5,000 | $ — | $ 5,000 |
| Royalty sales milestone | 25,250 | — | 25,250 |
| Clinical product revenue | 762 | — | 762 |
| Research and development services | 1,676 | — | 1,676 |
| Other services | — | 10,514 | 10,514 |
| Recognition of deferred research and development revenue | 9,537 | — | 9,537 |
| Non-cash royalties | 45,285 | — | 45,285 |
| | $ 87,510 | $ 10,514 | $ 98,024 |

***Contract Balances***

Contract assets primarily relate to our rights to consideration for work completed in relation to our research and development services performed but not billed at the reporting date. Contract assets are transferred to receivables when the rights become unconditional. Currently, we do not have any contract assets which have not transferred to a receivable. We had no asset impairment charges related to contract assets in the period. Contract liabilities primarily relate to contracts where we received payments but have not yet satisfied the related performance obligations. The advance consideration received from customers for research and development services or licenses bundled with other promises is a contract liability until the underlying performance obligations are transferred to the customer.

The following table provides information about contract liabilities from contracts with customers (in thousands):

| Year ended December 31, 2024 | Balance at beginning of period | Additions | Deductions | Balance at end of period |
|---|---|---|---|---|
| Contract liabilities: | | | | |
| Deferred revenue | $ 1,161 | $ 27 | $ (14) | $ 1,174 |

In the year ended December 31, 2024, we did not recognize any revenue from amounts included in the contract asset or the contract liability balances from performance obligations satisfied in previous periods. None of the costs to obtain or fulfill a contract were capitalized.

**(14) Related Party Transactions**

During the years ended December 31, 2024, 2023 and 2022, our Audit and Finance Committee approved the performance of research and development manufacturing services totaling $97,000, $150,000 and $106,000, respectively, for Protagenic Therapeutics, Inc (“Protagenic”). We are reimbursed for these services on an actual time and materials basis. Dr. Garo H. Armen, our CEO, is Executive Chairman of and has a greater than 10% equity interest in Protagenic.

In 2023, our Audit and Finance Committee approved a contract between Avillion Life Sciences LTD ("Avillion") and Agenus for the performance of up to $450,000 of clinical consulting services. Allison Jeynes, a former member of our Board of Directors, is chief executive officer of Avillion. For the year ended December 31, 2023, approximately $450,000 related to these services is included in “Research and development” expense in our consolidated statements of operations.

In June 2024, Dr. Jennifer Buell was appointed to our Board of Directors. Dr. Buell's spouse is a partner in the law firm of Wolf, Greenfield & Sachs, P.C. (“Wolf Greenfield”), which provides us legal services. For the year ended December 31, 2024, we expensed Wolf Greenfield fees totaling approximately $200,000. Dr. Buell’s spouse does not receive direct compensation from the fees we pay Wolf Greenfield and the fees we paid to Wolf Greenfield in the period were an insignificant amount of Wolf Greenfield’s revenues. Our Audit and Finance Committee approved these services under its related-party transactions policy.

**(15) Leases**

The majority of our operating lease agreements are for the office, research and development and manufacturing space we use to conduct our operations.

We lease space in Lexington, Massachusetts for our manufacturing, research and development, and corporate offices, office space in New York, New York for use as corporate offices, a facility in Emeryville, California for the development of a cGMP manufacturing facility and a facility in Cambridge, United Kingdom for research and development and corporate offices. We had subleased a small portion of the space in our main Lexington facility for part of the associated head lease. This sublease expired in 2022. These agreements expire at various times between 2025 and 2036, with options to extend certain of the leases.

We also have finance lease agreements for research and manufacturing equipment that expire at various times between 2025 and 2027. The terms of one of our finance lease agreements require us to maintain a specified minimum cash balance. As of December 31, 2024, our cash balance was below this threshold. Despite this, we remain current on all lease payments under the agreement. The financial institution has the contractual right to take remedial actions, including potentially reclaiming the leased assets until we regain compliance. As of December 31, 2024, the remaining amounts owed under this lease totaled approximately $4.7 million, with payments scheduled through September 2025.

The components of lease cost recorded in our consolidated statement of operations were as follows (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Operating lease cost | $ 8,695 | $ 10,000 | $ 9,351 |
| Finance lease cost | 5,104 | 5,024 | 309 |
| Variable lease cost | 3,467 | 3,375 | 3,108 |
| Sublease income | — | — | (613) |
| Net lease cost | $ 17,266 | $ 18,399 | $ 12,155 |

Finance lease cost for the years ended December 31, 2024 and 2023 includes $3.8 million and $2.8 million, respectively, related to amortization of the right-of-use assets and $1.2 million and $2.2 million, respectively, related to interest on the lease liabilities. Variable lease cost for the years ended December 31, 2024, 2023 and 2022, primarily related to common area maintenance, taxes, utilities and insurance associated with our operating leases. Short-term lease cost for the years ended December 31, 2024, 2023 and 2022 was immaterial.

Cash paid for amounts included in the measurement of operating lease liabilities for the years ended December 31, 2024, 2023 and 2022 was approximately $2.4 million, $2.8 million and $2.6 million, respectively. Cash paid for amounts included in the measurement of finance lease liabilities for the years ended December 31, 2024, 2023 and 2022 was approximately $10.5 million, $8.9 million and $0.5 million, respectively.

The following table presents supplemental balance sheet information related to our leases as of December 31, 2024 and 2023 (in thousands):

| | As of December 31, 2024 | As of December 31, 2023 |
|---|---|---|
| **Operating Leases** | | |
| Operating lease right-of-use assets | $ 27,308 | $ 29,606 |
| Total operating lease right-of-use assets | 27,308 | 29,606 |
| | | |
| Current portion, operating lease liabilities | 2,446 | 2,587 |
| Operating lease liabilities, net of current portion | 54,551 | 62,511 |
| Total operating lease liabilities | 56,997 | 65,098 |
| | | |
| **Finance Leases** | | |
| Property, plant and equipment, net | 31,686 | 35,629 |
| Total finance lease right-of-use assets | 31,686 | 35,629 |
| | | |
| Other current liabilities | 4,702 | 10,457 |
| Other long-term liabilities | 115 | 4,719 |
| Total finance lease liabilities | $ 4,817 | $ 15,176 |

During the years ended December 31, 2024 and 2022, we recognized operating lease right-of-use asset impairment losses of approximately $0.9 million and $6.1 million, respectively, resulting from the abandonment of three operating facility leases. These impairment losses are recorded in "other expense" in our consolidated statements of operations and comprehensive loss.

During the year ended December 31, 2024, we recognized a $5.3 million gain on the termination of two operating facility leases. This gain was recorded in "other expense" in our consolidated statements of operations and comprehensive loss.

Maturities of our lease liabilities as of December 31, 2024 were as follows (in thousands):

| Year | Operating Leases | Finance leases | Total future lease commitments |
|---|---|---|---|
| 2025 | $ 8,609 | $ 4,879 | $ 13,488 |
| 2026 | 8,297 | 107 | 8,404 |
| 2027 | 8,522 | 16 | 8,538 |
| 2028 | 8,773 | — | 8,773 |
| 2029 | 8,894 | — | 8,894 |
| Thereafter | 58,324 | — | 58,324 |
| Total | $ 101,419 | $ 5,002 | $ 106,421 |
| Less imputed interest | (44,422) | (185) | |
| Present value of lease liabilities | $ 56,997 | $ 4,817 | |

The weighted-average remaining lease terms and discount rates related to our leases were as follows:

| | December 31, 2024 | |
|---|---|---|
| | Operating | Finance |
| Weighted average remaining lease term (in years) | 11.0 | 0.8 |
| Weighted average discount rate | 11.0% | 11.6% |

**(16) Debt**

Debt obligations consisted of the following as of December 31, 2024 and 2023 (in thousands):

| Debt instrument | Balance at December 31, 2024 | Unamortized Debt Discount | Net balance at December 31, 2024 |
|---|---|---|---|
| Current Portion: | | | |
| 2015 Subordinated Notes | $ 2,471 | $ — | $ 2,471 |
| Debentures | 146 | — | 146 |
| Other | 81 | — | 81 |
| Long-term Portion: | | | |
| 2015 Subordinated Notes | 10,500 | — | 10,500 |
| Promissory Note | 22,000 | (2,027) | 19,973 |
| Total | $ 35,198 | $ (2,027) | $ 33,171 |

| Debt instrument | Balance at December 31, 2023 |
|---|---|
| Current Portion: | |
| Debentures | $ 146 |
| Long-term Portion: | |
| 2015 Subordinated Notes | 12,768 |
| Total | $ 12,914 |

As of December 31, 2024, and 2023, the principal amount of our outstanding debt balance was $35.2 million and $13.1 million, respectively.

***Promissory Note***

On November 26, 2024, we, through a subsidiary, entered into a promissory note (the "Note") with Ocean 1181 LLC (the "Lender") for a loan in an aggregate principal amount of $22.0 million (the "Loan"). The Loan has a two-year term and is principally secured by our manufacturing facility in Berkeley, CA and parcels of land located in Vacaville, CA (collectively, the "Mortgaged Properties").

We unconditionally guarantee to the Lender the payment and performance of the obligations under the Note. The Loan bears interest at a rate of 12% through November 30, 2025 and 13% from December 1, 2025 through November 30, 2026. Interest under the Note is payable monthly, one half in cash and one half of the Company's common stock. Additionally, $1.8 million of the Loan funds were held back to serve as an interest payment reserve for the Loan.

At the closing of the Loan, we paid the Lender 153,003 shares of the Company's common stock, representing the first month of interest, a 1% origination fee, as well as certain transaction expenses.

The Note contains customary representations, warranties and covenants, including customary events of default, including failure to repay the Loan when due. Any event of default, if not cured or waived in a timely manner, could result in the acceleration of the Loan under the Note.

If we pay off or release any of the Mortgaged Properties within 120 days of the closing of the Loan, then there will be a two percent payoff fee assessed on the released amount. In the event of a disposition of a Mortgaged Property, the loan is subject to prepayment in an amount equal to the amount of the Loan applicable to the disposed Mortgaged Property.

The Loan was accounted for as debt under the guidance of *ASU 470: Debt*. As part of the transaction, we reimbursed the Lender for transaction costs and paid a 1% origination fee. These costs totaled approximately $0.4 million. Additionally, as stated above, the Lender withheld approximately $1.8 million of the proceeds to serve as an interest payment reserve. We have deemed this amount to represent debt discount. These amounts are presented net of the liability in our consolidated balance sheets and will be amortized to interest expense over the term of the Loan.

***Subordinated Notes***

On February 20, 2015, we, certain existing investors and certain additional investors entered into an Amended and Restated Note Purchase Agreement (the "2015 Subordinated Notes") in the aggregate principal amount of $14.0 million and issued five year warrants (the "2015 Warrants") to purchase 70,000 shares of our common stock at an exercise price of $102.00 per share.

The 2015 Subordinated Notes bear interest at a rate of 8% per annum, payable in cash on the first day of each month in arrears. Among other default and acceleration terms customary for indebtedness of this type, the 2015 Subordinated Notes include default provisions which allow for the noteholders to accelerate the principal payment of the 2015 Subordinated Notes in the event we become involved in certain bankruptcy proceedings, become insolvent, fail to make a payment of principal or (after a grace period) interest on the 2015 Subordinated Notes, default on other indebtedness with an aggregate principal balance of $13.5 million or more if such default has the effect of accelerating the maturity of such indebtedness, or become subject to a legal judgment or similar order for the payment of money in an amount greater than $13.5 million if such amount will not be covered by third-party insurance.

In February 2020 we repaid $0.5 million of the 2015 Subordinated Notes and in April 2020 we repaid an additional $0.5 million of the 2015 Subordinated Notes and cancelled the related warrants.

On November 30, 2022, we entered into an Amendment to Notes, Termination of Warrants and Sale of New Warrants (the "2022 Amendment") pursuant to which we:

- extended the maturity date of the $13.0 million 2015 Subordinated Notes by two years from February 20, 2023 to February 20, 2025;
- terminated the warrants held by such noteholders to purchase 65,000 shares of the Company's common stock previously issued in 2015;
- terminated the warrants held by such noteholders to purchase 32,500 shares of the Company's common stock previously issued in 2020; and
- issued to such noteholders new warrants to purchase 65,000 shares of the Company's common stock that will expire February 20, 2026 and issued new warrants to purchase 32,500 shares of the Company's common stock that will expire February 20, 2028, all such warrants having an exercise price of $56.80 per share, which represented a 15% premium over the 30-day average trailing closing price of the Company's common stock for the period ending November 9, 2022, and (the "New Warrants").

The amended 2015 Subordinated Notes are not convertible into shares of our common stock and are set to mature on February 20, 2025, at which point we would be required to repay the full outstanding balance in cash. We may prepay the amended 2015 Subordinated Notes at any time, in part or in full, without premium or penalty.

In February 2025, we extended the maturity date of $10.5 million of the 2015 Subordinated Notes by sixteen months, from February 20, 2025 to July 20, 2026. Refer to Note 22 for additional detail.

The 2022 Amendment was accounted for as a debt extinguishment under the guidance of *ASU 470: Debt*. For the year ended December 31, 2022, we recorded a loss of approximately $1.9 million in other expense in our consolidated statements of operations and comprehensive loss, which primarily represents the fair value of the new warrants. The amended 2015 Subordinated Notes were recorded at fair value.

**(17) Liability Related to the Sale of Future Royalties and Milestones**

The following table shows the activity within the liability account in the year ended December 31, 2024 and for the period from the inception of the royalty transactions to December 31, 2024 (in thousands):

| | Year ended December 31, 2024 | Period from inception to December 31, 2024 |
|---|---|---|
| Liability related to sale of future royalties and milestones - beginning balance | $ 257,296 | $ — |
| Proceeds from sale of future royalties and milestones | 63,879 | 268,879 |
| Non-cash royalty and milestone revenue | (100,978) | (400,468) |
| Non-cash interest expense recognized | 117,342 | 469,128 |
| Liability related to sale of future royalties and milestones - ending balance | 337,539 | 337,539 |
| Less: unamortized transaction costs | (1,172) | (1,172) |
| Liability related to sale of future royalties and milestones, net | $ 336,367 | $ 336,367 |

***Healthcare Royalty Partners***

On January 6, 2018, we, through Antigenics, entered into the HCR Royalty Purchase Agreement with HCR, which closed on January 19, 2018. Pursuant to the terms of the HCR Royalty Purchase Agreement, we sold to HCR 100% of Antigenics' worldwide rights to receive royalties on sales of GSK's vaccines containing our QS-21 STIMULON adjuvant. At closing, we received gross proceeds of $190.0 million from HCR. As part of the transaction, we reimbursed HCR for transaction costs of $100,000 and incurred approximately $500,000 in transaction costs of our own, which are presented net of the liability in the consolidated balance sheet and will be amortized to interest expense over the estimated life of the HCR Royalty Purchase Agreement. Although we sold all of our rights to receive royalties on sales of GSK's vaccines containing QS-21, as a result of our obligation to HCR, we are required to account for the $190.0 million in proceeds from this transaction as a liability on our consolidated balance sheets that will be relieved in proportion to the royalty payments from GSK to HCR over the estimated life of the HCR Royalty Purchase Agreement. The liability is classified between the current and non-current portion of liability related to sale of future royalties and milestones in the consolidated balance sheets based on the estimated royalty payments to be received by HCR in the next 12 months from the financial statement reporting date.

In the years ended December 31, 2024, 2023 and 2022, we recognized $101.0 million, $114.6 million and $45.3 million, respectively, of non-cash royalty revenue and we recorded $106.7, $100.3 million and $62.7 million, respectively, of related non-cash interest expense related to the HCR Royalty Purchase Agreement.

As royalties are remitted to HCR from GSK, the balance of the recorded liability will be effectively repaid over the life of the HCR Royalty Purchase Agreement. To determine the amortization of the recorded liability, we are required to estimate the total amount of future royalty payments to be received by HCR. The sum of these royalty amounts less the $190.0 million proceeds we received will be recorded as interest expense over the life of the HCR Royalty Purchase Agreement. Periodically, we assess the estimated royalty payments to be paid to HCR from GSK, and to the extent the amount or timing of the payments is materially different from our original estimates, we will prospectively adjust the amortization of the liability, and the related recognition of interest expense. Since the inception of the HCR Royalty Purchase Agreement our estimate of the effective annual interest rate over the life of the agreement decreased to 23.8%, which results in a retrospective interest rate of 24.6%.

There are a number of factors that could materially affect the amount and timing of royalty payments from GSK, all of which are not within our control. Such factors include, but are not limited to, changing standards of care, the introduction of competing products, manufacturing or other delays, biosimilar competition, patent protection, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates, and other events or circumstances that could result in reduced royalty payments from GSK, all of which would result in a reduction of non-cash royalty revenues and the non-cash interest expense over the life of the HCR Royalty Purchase Agreement. Conversely, if sales of GSK's vaccines containing QS-21 are more than expected, the non-cash royalty revenues and the non-cash interest expense recorded by us would be greater over the life of the HCR Royalty Purchase Agreement.

Pursuant to the HCR Royalty Purchase Agreement, we were also entitled to receive up to $40.4 million in milestone payments from HCR (through the royalty payments from GSK) based on sales of GSK's vaccines as follows: (i) $15.1 million upon reaching $2.0 billion last-twelve-months net sales any time prior to 2024 and (ii) $25.3 million upon reaching $2.75 billion last-twelve-months net sales any time prior to 2026. In the fourth quarter of 2019, the $15.1 million milestone was achieved, as sales for the year ended December 31, 2019 exceeded $2.0 billion. In the second quarter of 2022, the final milestone was achieved, as sales for the 12 months ended June 30, 2022 exceeded $2.75 billion. As such, we recognized royalty sales milestone revenue of $25.3 million during the year ended December 31, 2022. This milestone was paid through royalties received from GSK.

***XOMA***

On September 20, 2018, we, through our wholly-owned subsidiary, Agenus Royalty Fund, LLC, entered into a Royalty Purchase Agreement (the "XOMA Royalty Purchase Agreement") with XOMA (US) LLC ("XOMA US"). Pursuant to the terms of the XOMA Royalty Purchase Agreement, XOMA US paid us $15.0 million at closing in exchange for the right to receive 33% of the future royalties and 10% of the future milestones that we were then entitled to receive from Incyte and Merck Sharp & Dohme ("Merck") under our agreements with each party (see Note 13), net of certain of our obligations to a third party and excluding the $5.0 million milestone from Incyte that we recognized in the quarter ended September 30, 2018. We retained 90% of the future milestones and 67% of the future royalties under our agreements with Incyte and Merck. Although we sold our rights to receive 33% of future royalties and 10% of future milestones, as a result of our significant continued involvement in the generation of the potential royalties and milestones, we are required to account for the full amount of these royalties and milestones as revenue when earned, and we recorded the $15.0 million in proceeds from this transaction as a liability on our consolidated balance sheet. Under the terms of the XOMA Royalty Purchase Agreement, should the percentage of milestones and royalties ultimately received by XOMA US fail to repay the amount received by us at closing we would have no further obligation to XOMA US. No royalty or milestone revenue was recognized under this agreement in the years ended December 31, 2024, 2023 or 2022.

***Ligand Pharmaceuticals***

In May 2024, we and certain wholly-owned subsidiaries, entered into a Purchase and Sale Agreement (the "Ligand Purchase Agreement") with Ligand Pharmaceuticals Incorporated ("Ligand"). Pursuant to the terms of the Ligand Purchase Agreement, Ligand

will receive (i) 31.875% of the development, regulatory and commercial milestone payments we were then eligible to receive under our agreements with BMS, UroGen, Gilead, Merck and Incyte, (the “Covered License Agreements”) (ii) 18.75% of the royalties the Company receives under the Covered License Agreements; and (iii) a 2.625% synthetic royalty on worldwide net sales of botensilimab and balstilimab (collectively the “Purchased Assets”). In the event that we relicense the programs in the Covered License Agreements, Ligand would retain its economic interest in any new agreement.

The total amounts payable to Ligand are subject to a 50% reduction in the event total payments to Ligand exceed a specified return hurdle. The synthetic royalty is subject to a reduction if annual worldwide net sales exceed a specified level, and a cap on annual worldwide net sales if annual worldwide net sales exceed a higher specified level. The synthetic royalty can increase by 1% based on the occurrence of certain future events.

In consideration for the sale of the Purchased Assets, we received gross proceeds of $75.0 million, less $0.9 million in reimbursable expenses, on the closing date. In addition, Ligand has a time-based option to invest an additional $25.0 million on a pro rata basis ("Purchaser Upsize Option"), which expires on June 30, 2025.

In connection with the sale of the Purchased Assets, we issued to Ligand a warrant (the "Ligand Warrant") to purchase 867,052 shares of our common stock, at an exercise price equal to $17.30 per share. See Note 9 - Equity for further detail.

The $75.0 million in gross proceeds was allocated to the identified components as follows (in thousands):

| | | |
|---|---|---|
| Liability related to sale of future royalties and milestones | $ | 63,879 |
| Ligand Warrant | | 7,098 |
| Purchaser Upsize Option | | 4,023 |
| Total Ligand Purchase Agreement gross proceeds | $ | 75,000 |

As a result of our significant continuing involvement in the generation of the cash flows of the Purchased Assets, we are required to account for $63.9 million of the proceeds from this transaction as a liability on our condensed consolidated balance sheet that will be recognized into revenue in proportion to the royalty and milestone payments paid to Ligand over the estimated life of the Ligand Purchase Agreement.

The Purchaser Upsize Option is considered a freestanding financial instrument as it is separately exercisable and can be legally transferred from the Ligand Purchase Agreement. As such, it is accounted for as a written option which is accounted for as a liability at fair value and remeasured at each balance sheet date with changes in fair value recorded in earnings. The fair value of the Purchaser Upsize Option at December 31, 2024 was $69,200.

The Ligand Warrant is considered a freestanding financial instrument as it is separately exercisable and can be legally transferred from the Ligand Purchase Agreement, which was determined to be equity-classified under ASC 815.

To allocate the proceeds, the Purchaser Upsize Option liability and equity-classified Ligand Warrants were recognized based on their fair values and the residual was allocated to a liability related to the sale of future royalties and milestones on our consolidated balance sheets.

During the year ended December 31, 2024, we recorded $10.6 million of non-cash interest expense related to the Ligand Purchase Agreement.

As royalties are remitted to us and milestone and sales are earned from the Purchased Assets, the balance of the recorded liability will be effectively repaid over the life of the Ligand Purchase Agreement. To determine the amortization of the recorded liability, we are required to estimate the total amount of future payments that Ligand is entitled to under the Ligand Purchase Agreement. The sum of these amounts less the $63.9 million proceeds allocated to the liability related to sale of future royalties and milestones will be recorded as interest expense over the life of the Ligand Purchase Agreement. Periodically, we assess the estimated royalty and milestone payments to be received and sales to be earned under the Ligand Purchase Agreement, and to the extent the amount or timing of the payments is materially different from our original estimates, we will prospectively adjust the amortization of the liability, and the related recognition of interest expense. As of December 31, 2024, our estimate of the effective annual interest rate over the life of the agreement was 24.3%.

**(18) Fair Value Measurements**

We measure our contingent purchase price consideration at fair value. The fair values of our contingent purchase price consideration of $0.3 million, included in "Other long-term liabilities" in our consolidated balance sheets, are based on significant inputs not observable in the market, which require them to be reported as Level 3 liabilities within the fair value hierarchy. The valuation of these liabilities uses assumptions we believe would be made by a market participant and are mainly based on estimates from a Monte Carlo simulation of our share price, as well as other factors impacting the probability of triggering the milestone payments. Share price was evolved using a geometric Brownian motion, calculated daily for the life of the contingent purchase price consideration.

We are required to measure the Purchaser Upsize Option issued under the Ligand Purchase Agreement at fair value. The $69,200 fair value of the Purchaser Upsize Option at December 31, 2024, included in "Other current liabilities" in our consolidated balance sheets, is based on significant inputs not observable in the market, which require it to be reported as a Level 3 liability within the fair value hierarchy. The valuation of this liability is determined based on a scenario analysis and uses assumptions we believe would be made by a market participant.

Assets and liabilities measured at fair value are summarized below (in thousands):

| Description | December 31, 2024 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Cash equivalents (Note 4) | $ 6,954 | $ 6,954 | $ — | $ — |
| Long-term investments | 1,006 | 1,006 | — | — |
| Total | $ 7,960 | $ 7,960 | $ — | $ — |
| Liabilities: | | | | |
| Purchaser Upsize Option (Note 17) | $ 69 | $ — | $ — | $ 69 |
| Contingent purchase price consideration | 318 | — | — | 318 |
| Total | $ 387 | $ — | $ — | $ 387 |

| Description | December 31, 2023 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Cash equivalents (Note 4) | $ 70,485 | $ 70,485 | $ — | $ — |
| Long-term investments | 3,222 | 3,222 | — | — |
| Total | $ 73,707 | $ 73,707 | $ — | $ — |
| Liabilities: | | | | |
| Contingent purchase price consideration | $ 318 | $ — | $ — | $ 318 |
| Total | $ 318 | $ — | $ — | $ 318 |

Long-term investments are included in "Other long-term assets" in our consolidated balance sheets.

There were no changes in the valuation techniques during the period and there were no transfers into or out of Levels 1 and 2.

The fair value of our outstanding debt balance at December 31, 2024 and 2023 was $36.3 million and $13.0 million, respectively, based on the Level 2 valuation hierarchy of the fair value measurements standard using a present value methodology which was derived by evaluating the nature and terms of each note and considering the prevailing economic and market conditions at the balance sheet date. The principal amount of our outstanding debt balance at December 31, 2024 and 2023 was $35.2 million and $13.1 million, respectively.

**(19) Contingencies**

In September 2024, a putative securities class action lawsuit was commenced in the U.S. District Court for the District of Massachusetts (the “Court”) naming as defendants Agenus and three of its current officers. The complaint alleges that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder, by making false

and misleading statements and omissions of material fact related to the efficacy and commercial prospects of botensilimab and balstilimab. The plaintiff seeks to represent all persons who purchased or otherwise acquired Agenus securities between January 23, 2023, and July 17, 2024. The plaintiff seeks damages and interest, and an award of costs, including attorneys' fees. We are unable to estimate a range of loss, if any, that could result were there to be an adverse decision in this action.

The Company has been served with three derivative actions in the Court filed by purported stockholders, captioned *Royse v. Armen, et al.*, No. 1:24-cv-12823 (the "Royse Action"); *Chen v. Armen, et al.*, No. 1:24-cv-13088 (the "Chen Action"), *Ferraioli v. Armen, et al.*, No. 1:24-cv-13083 (the "Ferraioli Action"). The actions name certain of the Company's executives and directors and allege that defendants made false or misleading statements and omissions of material fact related to the efficacy and commercial prospects of botensilimab and balstilimab. The Court consolidated the Royse Action and Chen Action on January 16, 2025 and defendants submitted an unopposed motion to stay all deadlines pending future developments in the securities class action on February 25, 2025. We are unable to estimate a range of loss, if any, that could result were there to be an adverse decision in this action.

In September 2024, we received a subpoena from the Boston Regional Office of the U.S. Securities and Exchange Commission seeking records relating to certain of our product candidates, correspondence with the FDA, public disclosure, and other matters. We have produced records pursuant to the subpoena. We are unable to estimate a range of loss, if any, that could result were there to be an adverse decision in this action.

**(20) Benefit Plans**

We sponsor a defined contribution 401(k) Savings Plan in the US and a defined contribution Group Personal Pension Plan in the UK (the "Plans") for all eligible employees, as defined in the Plans. Participants may contribute a portion of their compensation, subject to a maximum annual amount, as established by the applicable taxing authority. Each participant is fully vested in his or her contributions and related earnings and losses. During the years ended December 31, 2024, 2023, and 2022 we made discretionary contributions to the Plans of $1.3 million, $1.3 million, and $1.2 million, respectively. For the years ended December 31, 2024, 2023, and 2022, we expensed $1.3 million, $1.3 million, and $1.2 million, respectively, related to the discretionary contribution to the Plans.

**(21) Segment and Geographic Information**

***Segments***

We are managed and currently operate as four segments. However, we have concluded that our operating segments meet the criteria required by ASC 280 to be aggregated into one reportable segment. Our operating segments have similar economic characteristics and are similar with respect to the five qualitative characteristics specified in ASC 280. Accordingly, we have one reportable segment. Our one reportable segment is focused on the discovery, development and manufacturing of a comprehensive pipeline of immunological agents designed to expand patient populations benefiting from cancer immunotherapy.

Our Chief Executive Officer ("CEO") serves as our Chief Operating Decision Maker ("CODM") and is responsible for reviewing company performance and making decisions regarding resource allocation. Our CODM evaluates company performance based on net loss, as included in the Consolidated Statements of Operations and Comprehensive Loss, ensuring resource allocation

decisions support company goals. The measure of segment assets is total assets, as included in the Consolidated Balance Sheets. Refer to the consolidated financial statements for other financial information regarding our single reportable segment.

The following table presents selected financial information related to our single reportable segment for the years ended December 31, 2024, 2023 and 2022 (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Revenues | $ 103,463 | $ 156,314 | $ 98,024 |
| Operating expenses: | | | |
| External expenses | (133,683) | (202,205) | (169,812) |
| Payroll related expenses | (61,814) | (75,955) | (70,185) |
| Other operating expenses | (28,441) | (37,703) | (37,454) |
| Operating loss | (120,475) | (159,549) | (179,427) |
| Other income (expense): | | | |
| Interest expense | (120,421) | (103,859) | (64,120) |
| Interest income | 2,795 | 5,934 | 2,257 |
| Other income | 5,830 | 37 | 10,634 |
| Net loss | $ (232,271) | $ (257,437) | $ (230,656) |

In the table above, "Other operating expenses" includes items such as depreciation and amortization expense, stock-based compensation expense, fair value adjustments and expenses related to certain foreign subsidiaries.

***Geographic Information***

The following is geographical information regarding our revenues for the years ended December 31, 2024, 2023 and 2022 and our long-lived assets as of December 31, 2024 and 2023 (in thousands):

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| Revenue: | | | |
| United States | $ 101,460 | $ 153,336 | $ 87,510 |
| Rest of world | 2,003 | 2,978 | 10,514 |
| | $ 103,463 | $ 156,314 | $ 98,024 |

In the table above, revenue by geographic region is allocated based on the domicile of our respective business operations.

| | 2024 | 2023 |
|---|---|---|
| Long-lived Assets: | | |
| United States | $ 122,887 | $ 138,896 |
| Rest of world | 3,034 | 3,861 |
| Total | $ 125,921 | $ 142,757 |

In the table above, long-lived assets include "Property, plant and equipment, net" and "Other long-term assets" from the consolidated balance sheets, by the geographic location where the asset resides.

**(22) Subsequent Events**

***At the Market Offerings***

During the period of January 1, 2025 through March 14, 2025, we received net proceeds of approximately $4.4 million under the Sales Agreement.

***Subordinated Note Amendment***

On February 20, 2025, we entered into an Amendment to Notes, Amendment of Warrants and Sale of New Warrants (the "Amendment") with existing noteholders, pursuant to which we:

- extended the maturity date of $10.5 million of the 2015 Subordinated Notes by sixteen months from February 20, 2025 to July 20, 2026;
- increased the interest rate under the 2015 Subordinated Notes from 8% to 9% per annum;
- extended the expiration date of all A Warrants and B Warrants held by such noteholders to purchase a total of 97,500 shares of the Company's common stock previously issued in 2022 to February 20, 2030 and changed the exercise price to $3.25 per share, which represented a 60-day volume weighted average price as of February 14, 2025 (the "Amended A Warrants" and "Amended B Warrants");
- issued to certain noteholders new warrants to purchase 67,500 shares of the Company's common stock to expire February 30, 2030, and have an exercise price of $3.25 per share, (the "C Warrants" and, together with the Amended A Warrants and the Amended B Warrants, the "New Warrants"); and
- provided that if we conduct a financing of greater than $10.0 million at a price per share below $3.25 before February 20, 2026, the exercise price on the New Warrants will be reduced to the same price at which such financing was conducted.

## Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

Not applicable.

## Item 9A. *Controls and Procedures*

### Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act. Based on this evaluation, our Chief Executive Officer and our Principal Financial Officer concluded that our disclosure controls and procedures were functioning effectively as of the end of the period covered by this Annual Report on Form 10-K to provide reasonable assurance that the Company can meet its disclosure obligations.

### Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

KPMG LLP, our independent registered public accounting firm, has issued their report, included herein, on the effectiveness of our internal control over financial reporting.

### Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fourth quarter 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Agenus Inc.:

*Opinion on Internal Control Over Financial Reporting*

We have audited Agenus Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2024, and the related notes (collectively, the consolidated financial statements), and our report dated March 17, 2025 expressed an unqualified opinion on those consolidated financial statements.

*Basis for Opinion*

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. 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 audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

*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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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.

/s/ KPMG LLP

Boston, Massachusetts
March 17, 2025

**Item 9B.** ***Other Information***

*Trading Plans of Our Directors and Officers*

During the quarter ended December 31, 2024, none of our directors or executive officers adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each item is defined in Item 408 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 is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2025 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

**Item 11.** ***Executive Compensation***

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2025 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

**Item 12.** ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2025 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

**Item 13.** ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2025 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

**Item 14.** ***Principal Accounting Fees and Services***

Our independent registered public accounting firm is KPMG LLP, Boston, Massachusetts, Auditor Firm ID: 185.

All other information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2025 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

## PART IV

**Item 15.** ***Exhibits and Financial Statement Schedules***

(a) 1. *Consolidated Financial Statements*

The consolidated financial statements are listed under Item 8 of this Annual Report on Form 10-K.

2. *Financial Statement Schedules*

The financial statement schedules required under this Item and Item 8 are omitted because they are not applicable, or the required information is shown in the consolidated financial statements or the footnotes thereto.

3. *Exhibits*

The exhibits are listed below under Part IV Item 15(b).

(b) Exhibits

| Exhibit No. | Description |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation of Antigenics Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 10, 2002 and incorporated herein by reference. |
| 3.1.1 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Antigenics Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 11, 2007 and incorporated herein by reference. |
| 3.1.2 | Certificate of Ownership and Merger changing the name of the corporation to Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 6, 2011 and incorporated herein by reference. |
| 3.1.3 | Certificate of Second Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 30, 2011 and incorporated herein by reference. |
| 3.1.4 | Certificate of Third Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1.4 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2012 and incorporated herein by reference. |
| 3.1.5 | Certificate of Fourth Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on April 25, 2014 and incorporated herein by reference. |
| 3.1.6 | Certificate of Fifth Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 16, 2016 and incorporated herein by reference. |
| 3.1.7 | Certificate of Sixth Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 24, 2019 and incorporated herein by reference. |
| 3.1.8 | Certificate of Seventh Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on August 5, 2022 and incorporated herein by reference. |
| 3.1.9 | Certificate of Eighth Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on April 5, 2024 and incorporated herein by reference. |
| 3.2 | Sixth Amended and Restated By-laws of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on March 25, 2022 and incorporated herein by reference. |
| 3.3 | Certificate of Designations, Preferences and Rights of the Series A-1 Convertible Preferred Stock of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on February 5. 2013 and incorporated herein by reference. |

| Exhibit No. | Description |
|---|---|
| 3.4 | Form of Certificate of Designation of Preferences, Rights and Limitations of Series C-1 Convertible Preferred Stock. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on October 11, 2018 and incorporated herein by reference. |
| 4.1 | Form of Common Stock Certificate. Filed as Exhibit 4.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 6, 2011 and incorporated herein by reference. |
| 4.2 | Securities Exchange Agreement dated as of February 4, 2013 by and between Agenus Inc., and Mr. Brad Kelley. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on February 5, 2013 and incorporated herein by reference. |
| 4.3 | Amended and Restated Note Purchase Agreement dated as of February 20, 2015, as amended, by and between Agenus Inc. and the Purchasers listed on Schedule 1.1 thereto. Filed as Exhibit 4.2 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2015 and incorporated herein by reference. |
| 4.4 | Form of Senior Subordinated Note under the Amended and Restated Note Purchase Agreement dated as of February 20, 2015, as amended, by and between Agenus Inc. and the Purchasers listed on Schedule 1.1 thereto. Filed as Exhibit 4.3 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2015 and incorporated herein by reference. |
| 4.5 | Form of 2022 A Warrant under the Amended and Restated Note Purchase Agreement dated as of February 20, 2015, as amended, by and between Agenus Inc. and the Purchasers listed on Schedule 1.1 thereto. Filed as Exhibit 4.1 to our Current Report on Form 8-K (File No. 0-29089) on December 2, 2022 and incorporated herein by reference. |
| 4.6 | Form of 2022 B Warrant under the Amended and Restated Note Purchase Agreement dated as of February 20, 2015, as amended, by and between Agenus Inc. and the Purchasers listed on Schedule 1.1 thereto. Filed as Exhibit 4.2 to our Current Report on Form 8-K (File No. 0-29089) on December 2, 2022 and incorporated herein by reference. |
| 4.7 | Amendment to Notes and Warrants dated as of March 15, 2017 by and among Agenus Inc. and the Investors listed therein. Filed as Exhibit 4.27 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2016 and incorporated herein by reference. |
| 4.8 | Amendment to Notes and Warrants dated as of February 18, 2020 by and among Agenus Inc. and the Investors listed therein. Filed as Exhibit 4.7 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2019 and incorporated herein by reference. |
| 4.9 | Amendment to Notes, Termination of Warrants and Sale of New Warrants dated as of November 30, 2022 by and among Agenus Inc. and the Investors listed therein. Filed as Exhibit 4.9 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2022 and incorporated herein by reference. |
| 4.10 | Form of Indenture. Filed as Exhibit 4.1 to our Registration Statement on Form S-3 (File No. 333-221008) and incorporated herein by reference. |
| 4.11 | Royalty Purchase Agreement dated January 6, 2018, by and among Antigenics LLC, Healthcare Royalty Partners III, L.P. and certain of its affiliates. Filed as Exhibit 4.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2018 and incorporated herein by reference. |
| 4.11.1 | Amendment No. 1 to Royalty Purchase Agreement, dated June 22, 2021, by and among Antigenics LLC, Healthcare Royalty Partners III, L.P. and certain of its affiliates. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2021 and incorporated herein by reference. |
| 4.12 | Royalty Purchase Agreement dated September 20, 2018, by and among Agenus Inc., Agenus Royalty Fund, LLC and XOMA (US) LLC. Filed as Exhibit 4.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended September 30, 2018 and incorporated herein by reference. |
| 4.13 | Description of Securities. Filed as Exhibit 4.12 to our Annual Report on form 10-K (File No. 0-29089) for the year ended December 31, 2019 and incorporated herein by reference. |
| 4.14 | Amendment to Notes, Amendment of Warrants and Sale of New Warrants dated as of February 20, 2025 by and among Agenus Inc. and the Purchasers listed therein. Filed herewith. |
| 4.15 | Form of 2024 A Warrant. Filed as Exhibit 4.1 to our Current Report on Form 8-K (File No. 0-29089) on May 7, 2024 and incorporated herein by reference. |

| Exhibit No. | Description |
|---|---|
| 4.16 | Form of Amended and Restated 2022 A Warrant. Filed as Exhibit 4.1 to our Current Report on Form 8-K (File No. 0-29089) on February 26, 2025 and incorporated herein by reference. |
| 4.17 | Form of Amended and Restated 2022 B Warrant. Filed as Exhibit 4.2 to our Current Report on Form 8-K (File No. 0-29089) on February 26, 2025 and incorporated herein by reference. |
| 4.18 | Form of 2025 C Warrant. Filed as Exhibit 4.3 to our Current Report on Form 8-K (File No. 0-29089) on February 26, 2025 and incorporated herein by reference. |
| | **Employment Agreements and Compensation Plans** |
| 10.1* | Agenus Inc. Amended and Restated 2009 Equity Incentive Plan. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 16, 2016 and incorporated herein by reference. |
| 10.1.1* | Form of Restricted Stock Award Agreement for the Agenus Inc. Amended and Restated 2009 Equity Incentive Plan. Filed as Exhibit 10.2 to our Current Report on Form 8-K (File No. 0-29089) filed on June 15, 2009 and incorporated herein by reference. |
| 10.1.2* | Form of Restricted Stock Unit Agreement for the Agenus Inc. Amended and Restated 2009 Equity Incentive Plan. Filed as Exhibit 10.2 to our Current Report on Form 8-K (File No. 0-29089) filed on June 30, 2015 and incorporated herein by reference. |
| 10.1.3* | Form of Stock Option Agreement for the Agenus Inc. Amended and Restated 2009 Equity Incentive Plan. Filed as Exhibit 10.3 to our Current Report on Form 8-K (File No. 0-29089) filed on June 15, 2009 and incorporated herein by reference. |
| 10.2 | Agenus Inc. Amended and Restated Directors' Deferred Compensation Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed on April 26, 2018 and incorporated herein by reference. |
| 10.2.1 | Amendment to Agenus Amended and Restated Directors' Deferred Compensation Plan. Filed as Appendix A to our Definitive Proxy Statement on Schedule 14A filed on April 28, 2020 and incorporated herein by reference. |
| 10.2.2 | Amendment to Agenus Amended and Restated Directors' Deferred Compensation Plan. Filed as Appendix A to our Definitive Proxy Statement on Schedule 14A filed on April 29, 2022 and incorporated herein by reference. |
| 10.3* | Amended and Restated Executive Change-in-Control Plan applicable to Christine M. Klaskin. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on November 3, 2010 and incorporated herein by reference. |
| 10.3.1* | Modification of Rights in the Event of a Change of Control, dated as of June 14, 2012, by and between Agenus Inc. and Christine Klaskin. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2012 and incorporated herein by reference. |
| 10.4* | 2004 Executive Incentive Plan, as amended. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 27, 2011 and incorporated herein by reference. |
| 10.4.1* | Agenus Inc. 2016 Executive Incentive Plan. Filed as Exhibit 10.2 to our Current Report on Form 8-K (File No. 0-29089) filed on June 16, 2016 and incorporated herein by reference. |
| 10.5* | Employment Agreement dated December 1, 2005 between Agenus Inc. and Garo Armen. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on December 7, 2005 and incorporated herein by reference. |
| 10.5.1* | First Amendment to Employment Agreement dated July 2, 2009 between Agenus Inc. and Garo Armen. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended September 30, 2009 and incorporated herein by reference. |
| 10.5.2* | Second Amendment to Employment Agreement dated December 15, 2010 between Agenus Inc. and Garo Armen. Filed as Exhibit 10.12.2 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference. |
| 10.6* | Agenus Inc. 2015 Inducement Equity Plan. Filed as Exhibit 4.14 to our Registration Statement on Form S-8 (File No. 333-209074) filed on January 21, 2016 and incorporated herein by reference. |
| 10.6.1* | Form of Stock Option Agreement for the Agenus Inc. 2015 Inducement Equity Plan. Filed as Exhibit 4.15 to our Registration Statement on Form S-8 (File No. 333-209074) filed on January 21, 2016 and incorporated herein by reference. |

| Exhibit No. | Description |
|---|---|
| 10.6.2* | Form of Restricted Stock Award Agreement for the Agenus Inc. 2015 Inducement Equity Plan. Filed as Exhibit 4.16 to our Registration Statement on Form S-8 (File No. 333-209074) filed on January 21, 2016 and incorporated herein by reference. |
| 10.6.3* | Form of Restricted Stock Unit Agreement for the Agenus Inc. 2015 Inducement Equity Plan. Filed as Exhibit 4.17 to our Registration Statement on Form S-8 (File No. 333-209074) filed on January 21, 2016 and incorporated herein by reference. |
| 10.7* | Agenus Inc. 2019 Employee Stock Purchase Plan. Filed as Exhibit 4.11 to our Registration Statement on Form S-8 (File No. 333-233100) filed on August 7, 2019 and incorporated herein by reference. |
| 10.7.1* | Amendment to the Agenus Inc. 2019 Employee Stock Purchase Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed on April 30, 2021 and incorporated herein by reference. |
| 10.7.2* | Second Amendment to the Agenus Inc. 2019 Employee Stock Purchase Plan. Filed as Appendix A to our Definitive Proxy Statement on Schedule 14A filed on April 28, 2023 and incorporated herein by reference. |
| 10.8* | Agenus Inc. Amended and Restated 2019 Equity Incentive Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed on April 29, 2022 and incorporated herein by reference. |
| 10.8.1* | Form of Incentive Stock Option Agreement for the Agenus Inc. 2019 Equity Incentive Plan. Filed as Exhibit 10.10.1 to our Annual Report on form 10-K (File No. 0-29089) for the year ended December 31, 2019 and incorporated herein by reference. |
| 10.8.2* | Form of Non-Qualified Stock Option Agreement for the Agenus Inc. 2019 Equity Incentive Plan. Filed as Exhibit 10.10.2 to our Annual Report on form 10-K (File No. 0-29089) for the year ended December 31, 2019 and incorporated herein by reference. |
| 10.8.3* | Form of Restricted Stock Unit Award Agreement for the Agenus Inc. 2019 Equity Incentive Plan. Filed as Exhibit 10.10.3 to our Annual Report on form 10-K (File No. 0-29089) for the year ended December 31, 2019 and incorporated herein by reference. |
| 10.9* | Consulting Agreement dated January 1, 2020 between Agenus Inc. and Brian Corvese. Filed as Exhibit 4.2 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2020 and incorporated herein by reference. |
| 10.9A* | Amendment to Consulting Agreement between Agenus Inc. and Brian Corvese, dated December 31, 2023. Filed as Exhibit 10.9A to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2024 and incorporated herein by reference. |
| 10.10* | Executive Employment Agreement dated October 27, 2020 between Agenus Inc. and Steven O'Day. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) filed on May 10, 2022 and incorporated herein by reference. |
| | **License and Collaboration Agreements** |
| 10.11(1) | License Agreement by and between Agenus Inc. and GlaxoSmithKline Biologicals SA dated July 6, 2006. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2006 and incorporated herein by reference. |
| 10.12(1) | Amended and Restated Manufacturing Technology Transfer and Supply Agreement by and between Agenus Inc. and GlaxoSmithKline Biologicals SA dated January 19, 2009. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2009 and incorporated herein by reference. |
| 10.13(1) | First Right to Negotiate and Amendment Agreement between Agenus Inc., Antigenics LLC and GlaxoSmithKline Biologicals SA, dated March 2, 2012. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2012 and incorporated herein by reference. |
| 10.14(1) | License Agreement dated as of December 5, 2014 by and between 4-Antibody AG, a limited liability company organized under the laws of Switzerland (and wholly-owned subsidiary of Agenus Inc.) and Ludwig Institute for Cancer Research Ltd. Filed as Exhibit 10.21 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2014 and incorporated herein by reference. |

| Exhibit No. | Description |
|---|---|
| 10.15.1(1) | License, Development and Commercialization Agreement dated as of January 9, 2015 by and among Agenus Inc., 4-Antibody AG, a limited liability company organized under the laws of Switzerland (and wholly-owned subsidiary of Agenus Inc.), Incyte Corporation and Incyte Europe Sarl, a Swiss limited liability company (and wholly-owned subsidiary of Incyte Corporation). Filed as Exhibit 10.22 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2014 and incorporated herein by reference. |
| 10.15.2(1) | First Amendment to License, Development and Commercialization Agreement dated as of February 14, 2017 by and among Agenus Inc., Agenus Switzerland Inc. (f/k/a 4-Antibody AG) and Incyte Europe Sarl. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2017 and incorporated herein by reference. |
| 10.16(1) | License Agreement dated March 19, 2013, as amended, by and between the University of Virginia Patent Foundation d/b/a University of Virginia Licensing and Ventures Group and Agenus Inc. (as successor by merger to PhosImmune Inc.). Filed as Exhibit 10.24 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2015 and incorporated herein by reference. |
| 10.17(1) | License Agreement dated as of January 25, 2016 by and among Agenus Inc., 4-Antibody AG, a limited liability company organized under the laws of Switzerland (and wholly-owned subsidiary of Agenus Inc.), and Ludwig Institute for Cancer Research Ltd. Filed as Exhibit 10.25 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2015 and incorporated herein by reference. |
| 10.18(1) | Development and Manufacturing Services Agreement dated April 14, 2017 by and between Agenus Inc. and CMC ICOS Biologics, Inc. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2017 and incorporated herein by reference. |
| 10.19(1) | License Agreement dated December 20, 2018, by and between Agenus Inc. and Gilead Sciences, Inc. Filed as Exhibit 10.25 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2018 and incorporated herein by reference. |
| 10.20(1) | Option and License Agreement (AGEN1223) dated December 20, 2018, by and between Agenus Inc. and Gilead Sciences, Inc. Filed as Exhibit 10.26 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2018 and incorporated herein by reference. |
| 10.21(1) | Option and License Agreement (AGEN2373) dated December 20, 2018, by and between Agenus Inc. and Gilead Sciences, Inc. Filed as Exhibit 10.27 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2018 and incorporated herein by reference. |
| 10.22(1) | License and Collaboration Agreement, dated as of June 20, 2020, by and between Agenus Inc. and Betta Pharmaceuticals Co., Ltd. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2020 and incorporated herein by reference. |
| 10.23(1) | License, Development and Commercialization Agreement, dated May 17, 2021, by and among Agenus Inc. and Bristol Myers Squibb Company. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2021 and incorporated herein by reference. |
| | **Real Estate Leases** |
| 10.24 | Lease of Premises at 3 Forbes Road, Lexington, Massachusetts dated as of December 6, 2002 from BHX, LLC, as Trustee of 3 Forbes Realty Trust, to Agenus Inc. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 8, 2003 and incorporated herein by reference. |
| 10.24.1 | First Amendment of Lease dated as of August 15, 2003 from BHX, LLC, as trustee of 3 Forbes Road Realty, to Agenus Inc. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2004 and incorporated herein by reference. |
| 10.24.2 | Second Amendment of Lease dated as of March 7, 2007 from BHX, LLC as trustee of 3 Forbes Road Realty, to Agenus Inc. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2007 and incorporated herein by reference. |
| 10.24.3 | Third Amendment to Lease dated April 23, 2008 between TBCI, LLC, as successor to BHX, LLC, as Trustee of 3 Forbes Road Realty Trust, and Agenus Inc. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2008 and incorporated herein by reference. |

| Exhibit No. | Description |
|---|---|
| 10.24.4 | Fourth Amendment to Lease dated September 30, 2008 between TBCI, LLC, as successor to BHX, LLC, as Trustee of 3 Forbes Road Realty Trust, and Agenus Inc. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended September 30, 2008 and incorporated herein by reference. |
| 10.24.5 | Fifth Amendment to Lease dated April 11, 2011 between TBCI, LLC, as successor to BHX, LLC, as Trustee of 3 Forbes Road Realty Trust, and Agenus Inc. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2011 and incorporated herein by reference. |
| 10.25 | Office Lease by and between Bay Center Investor LLC and Agenus Inc. dated November 25, 2020. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on November 25, 2020 and incorporated herein by reference. |
| | **Sales Agreement** |
| 10.26 | At Market Issuance Sales Agreement dated July 22, 2020 by and between Agenus Inc. and B. Riley FBR, Inc. Filed as Exhibit 1.2 to our Registration Statement on Form S-3ASR (File No. 333-240006) on July 22, 2020 and incorporated herein by reference. |
| 19.1 | Insider Trading Policy. Filed herewith. |
| 21.1 | Subsidiaries of Agenus Inc. Filed herewith. |
| 23.1 | Consent of KPMG LLP, independent registered public accounting firm. Filed herewith. |
| 31.1 | Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith. |
| 31.2 | Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith. |
| 32.1 | Certification of Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Submitted herewith. |
| 97.1 | Policy for Recoupment of Executive Incentive Compensation in the Event of an Accounting Restatement. Filed as Exhibit 97.1 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2024 and incorporated herein by reference. |
| 101.INS | XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document) |
| 101.SCH | Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

* Indicates a management contract or compensatory plan.

(1) Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act or Rule 24b-2 of the Securities Exchange Act.

**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.

AGENUS INC.

By: /s/ GARO H. ARMEN, PH.D.

**Garo H. Armen, Ph.D.**

***Chief Executive Officer and***

***Chairman of the Board***

Dated: March 17, 2025

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /S/ GARO H. ARMEN, PH.D.<br>**Garo H. Armen, Ph.D.** | Chief Executive Officer and Chairman of the Board of Directors<br>(Principal Executive Officer) | March 17, 2025 |
| /S/ CHRISTINE M. KLASKIN<br>**Christine M. Klaskin** | Vice President Finance<br>(Principal Financial and Accounting Officer) | March 17, 2025 |
| /S/ JENNIFER S. BUELL, PH.D.<br>**Jennifer S. Buell, Ph.D.** | Director | March 17, 2025 |
| /S/ BRIAN CORVESE<br>**Brian Corvese** | Director | March 17, 2025 |
| /S/ TOM HARRISON<br>**Tom Harrison** | Director | March 17, 2025 |
| /S/ SUSAN HIRSCH<br>**Susan Hirsch** | Director | March 17, 2025 |
| /S/ TIMOTHY R. WRIGHT<br>**Timothy R. Wright** | Director | March 17, 2025 |