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, 2019

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 28, 2019 (the last trading day of the registrant's second fiscal quarter of 2019) was: $406.8 million. There were 161,589,924 shares of the registrant's Common Stock outstanding as of March 12, 2020.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2020 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, 2019, 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 immuno-oncology ("I-O") company advancing an extensive pipeline of immune checkpoint antibodies, adoptive cell therapies and neoantigen cancer vaccines, to fight cancer. Our business is designed to drive success in I-O through speed, innovation and effective combination therapies. We believe that combination therapies and a deep understanding of each patient's cancer will drive substantial expansion of the patient 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 good manufacturing practice ("GMP") manufacturing. We believe that these fully integrated capabilities enable us to produce novel candidates on timelines that are shorter than the industry standard. Leveraging from our science and capabilities, we have forged important partnerships to advance our 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 most advanced antibody candidates are balstilimab (an anti-PD-1 antibody) and zalifrelimab (an anti-CTLA-4 antibody), which are currently in Phase 2 trials of balstilimab monotherapy and balstilimab/zalifrelimab combination for patients with second-line cervical cancer. Both of these trials are designed to support Biologics License Application ("BLA") filings under the U.S. Food and Drug Administration ("FDA") accelerated approval pathway. We announced interim data from these trials in February and March 2020 and expect to file two BLAs in the second half of 2020. We are also advancing our proprietary next-generation anti-CTLA-4 antibody, AGEN1181, which is designed to expand the population of patients currently benefiting from anti-CTLA-4 therapy. AGEN1181 is currently in a Phase 1 dose-escalation study as a monotherapy and also in combination with balstilimab.

In addition to our lead programs, Agenus 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 mechanism. For tumors not yet visible to the immune system, we are leveraging our immune educating neoantigen vaccine platform, designed to target mutationally based and biochemically based (phosphorylated) neoantigens (AutoSynVax and PhosphoSynVax) to prime the immune system to attack tumors. These vaccines may be applicable for patients where checkpoint modulating ("CPM") antibodies alone are not sufficient to bring about tumor control. To further improve patient response rates, Agenus scientists are developing therapies intended to address mechanisms of immune evasion and therapeutic resistance. These include "multi-specific" antibodies that are designed to condition the tumor microenvironment and augment the activity of immune cells. We and our partners initiated clinical trials with these assets in 2019. With this diverse pipeline, we are positioned to potentially deliver combination therapies with the goal to enhance response rates and benefit patients who are unresponsive to current immunotherapies.

In 2017, we formed a subsidiary, AgenTus Therapeutics, to bring innovative living drugs to cancer patients. AgenTus is focused on advancing allogeneic cell therapies that include unmodified iNKT cells, and a pipeline of T cell receptors ("TCR") and chimeric antigen receptors ("CAR") formulated in allogeneic cell formats. We anticipate filing our first cell therapy investigational new drug application ("IND") through AgenTus and advancing our differentiated allogeneic cell format towards an IND in 2020 and are positioned to develop our allogeneic cell therapies alone and in combination with Agenus' portfolio of CPIs.

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 vaccines.

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

Our Vision

We believe that combination therapies and a deep understanding of each patient's cancer will be key drivers of success in substantially expanding the patient population benefiting from current I-O therapies. In addition, delivering innovation with speed is critical for our future success, as drug development timelines in oncology shorten while product obsolescence rates climb. We believe our fully integrated, end-to-end capabilities from novel target discovery, antibody generation, cell line development, to GMP manufacturing, together with a comprehensive portfolio consisting of antibody-based therapeutics, adjuvants and cancer vaccines, will uniquely position us to produce novel therapies on accelerated timelines. We believe that a balanced pipeline of product candidates should focus on both validated targets as well as novel targets designed to address tumor escape mechanisms. CTLA-4 and PD-1 antagonists are recognized as the first clinically validated immunotherapy combination. These, in combination with innovative immunomodulatory antibodies or immune education vaccines, could be a focal point of the next generation of I-O combinations. Therefore, we plan to develop, register and launch our proprietary antibodies targeting PD-1 and CTLA-4 aggressively through the clinic and expand with novel combination therapies designed to improve clinical response and the durability of response of existing therapies.

Our Strategy

Our strategy is to bring innovative combination therapies for cancer patients to substantially expand the patient population benefiting from current I-O therapies. Our diverse pipeline of antibodies, vaccines and adjuvants enable us to pursue optimal combinations for optimal efficacy. We are pursuing a tiered risk profile and targeting compressed timelines for regulatory filings. We expect our lead trials of balstilimab monotherapy and balstilimab/zalifrelimab combination therapy to support BLA filings in the second half of 2020 for accelerated approval to treat second-line cervical cancer. We believe that we are positioned to take advantage of accelerated pathways for approval with a relatively small number of patients and surrogate or short-term endpoints in our trials. In addition, we plan to pursue additional select indications to further expedite market entry.

Our strategy for our more novel, earlier stage programs include (i) pursuit of effective I-O antibodies, allogeneic cell-therapy combinations with CTLA-4 and/or PD-1 targeted antibodies as the backbone and (ii) advancement of our differentiated clinical stage antibody programs such as our next generation anti-CTLA-4 (AGEN1181), our bispecific programs (AGEN1223 and others), differentiated CD137 (AGEN2373) and TIGIT antibodies.

Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing arrangements with collaborators and licensees and by entering into new collaborations.

Our Assets

Our I-O assets include antibody-based therapeutics, monospecific and bispecific antibodies, neoantigen cancer vaccines (individualized and off-the shelf) platforms and adjuvants. Our proprietary CTLA-4 and PD-1 antagonists are in clinical development; we believe we have the most advanced clinical stage proprietary anti-CTLA-4 and anti-PD-1 antibodies in clinical combinations.

To complement our most advanced balstilimab and zalifrelimab programs, we and our partners are advancing additional clinical-stage antibodies as follows:

- AGEN1181 – a next-generation anti-CTLA-4 monospecific antibody currently in a Phase 1 dose escalation study being advanced by Agenus;
- AGEN2373 – an anti-CD137 monospecific antibody currently in a Phase 1 clinical trial being advanced by Agenus, and which Gilead Sciences, Inc. (“Gilead”) has an option to license exclusively;
- AGEN1223 – a novel bispecific antibody designed to deplete regulatory T cells currently in a Phase 1 clinical trial being advanced by Agenus, and which Gilead has an option to license exclusively;
- GS-1423 – a tumor microenvironment conditioning anti-CD73/TGFβ TRAP bifunctional antibody exclusively licensed to Gilead and being advanced by Gilead in a Phase 1 clinical trial;
- INCAGN1876 – an anti-GITR monospecific antibody exclusively licensed to Incyte Corporation (“Incyte”) and being advanced by Incyte in a Phase 1 clinical trial;
- INCAGN1949 – an anti-OX40 monospecific antibody exclusively licensed to Incyte and being advanced by Incyte in a Phase 1 clinical trial;
- INCAGN2390 – an anti-TIM-3 monospecific antibody exclusively licensed to Incyte and being advanced by Incyte in a Phase 1 clinical trial;
- INCAGN2385 – an anti-LAG-3 monospecific antibody exclusively licensed to Incyte and being advanced by Incyte in a Phase 1 clinical trial; and
- MK-4830 – a monospecific antibody targeting ILT4 exclusively licensed to Merck Sharpe & Dohme (“Merck”) and being advanced by Merck in a Phase 1 clinical trial.

Further, our neoantigen vaccine platforms include: (i) Individualized AutoSynVax™ (ASV™), which targets the unique antigens expressed by a patient’s own tumor, and (ii) off-the-shelf (or pre-manufactured) PhosphoSynVax™ (PSV™), which targets antigens expressed across patients and tumors, thereby seeking to treat broader categories of patients. Our vaccines are powered by our proprietary adjuvant, QS-21 Stimulon™ and have demonstrated safety in Phase 1 clinical trials. We believe our vaccines will be an important part of a durable memory responses and are well-positioned to optimize their use in combination with antibodies and cell therapeutic platforms.

Our proprietary QS-21 Stimulon is believed to be one of the most potent adjuvants known. QS-21 Stimulon is a key component in several GlaxoSmithKline plc (“GSK”) vaccines, including GSK’s Shingrix, which reported sales in excess of $2.0 billion in 2019, triggering a $15.1 million milestone payment to us from Healthcare Royalty Partners III, L.P. and certain of its affiliates (collectively, “HCR”) to be received in 2020. QS-21 is being used in numerous other clinical-stage vaccines, including our own cancer vaccines. In 2019, 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.

Our Antibody Discovery Platforms and CPM Programs

Checkpoint antibodies regulate immune response against tumor expressing antigens and are achieving positive outcomes in a number of cancers that were untreatable only a few years ago. Two classes of checkpoint targets include:

1. inhibitory checkpoints that help suppress an immune response in order to prevent excessive immune reaction resulting in undesired inflammation and/or auto-immunity; and

2. stimulatory checkpoints that can enhance or amplify an antigen-specific immune response.

We possess end-to-end capabilities in-house, from discovery to manufacturing, that have enabled us to advance our discoveries with efficiency and speed and at lower costs. These advantages allow us to manage a large portfolio of discoveries and have given rise to several clinical stage antibody candidates, a portfolio of more than a dozen pre-clinical programs advancing, and partnerships with companies such as Gilead, Incyte, Merck and GSK.

Our anti-CTLA-4 and anti-PD-1 programs (zalifrelimab and balstilimab, respectively) are in late phase clinical trials designed to support BLA filings in the second half of 2020 for accelerated approval to treat second-line cervical cancer. We presented data from our pre-planned interim analysis in February and March 2020, as well as at major oncology conferences, including the Society for Immunotherapy of Cancer ("SITC") in 2019, American Society of Clinical Oncology conference in June 2018 and the European Society for Medical Oncology congress in 2018. In addition, we presented pre-clinical data on our Fc engineered anti-TIGIT antibody at the SITC conference in 2019, our Gilead-partnered anti-CD137 (AGEN2373), and our Incyte-partnered programs anti-TIM-3 and anti-LAG-3 antibodies at the American Association for Cancer Research conference in April 2018.

To date, we have treated over 300 patients with zalifrelimab (anti-CTLA-4) and/or balstilimab (anti-PD-1) and have observed a safety profile consistent with the drug class.

In the first quarter of 2020, we reported the following clinical data:

- In our pre-planned interim analysis of our balstilimab monotherapy trial in patients with relapsed refractory or metastatic cervical cancer (N=42, patients with measurable disease), we reported overall response rates ("ORR") from an independent core laboratory of 11.9% in an all-comer population with 1 complete response (CR) and 4 partial responses (PR) (reported February 2020). This compares to a similar patient population treated with pembrolizumab (12.2% ORR in an all-comer population).
- In our pre-planned interim analysis of balstilimab plus zalifrelimab combination trial (N=34, patients with measurable disease), we reported a clinically meaningful benefit over PD-1 monotherapy with ORR from an independent core laboratory of 26.5% (4 CRs and 5 PRs) with 12.2 months median follow-up and irrespective of the PD-L1 status (reported March 2020). This more mature data shows the potential for a meaningful improvement over best available therapies for patients with relapsed refractory cervical cancer.

With respect to our novel discovery pipeline, our most advanced asset is our next generation anti-CTLA-4 antibody (AGEN1181), an IgG1 anti-CTLA-4 antagonist. Based on preclinical data and early data from a Phase 1 dose escalation study, we believe that this molecule has potential advantages over competing anti-CTLA-4 molecules, including:

(1) potential to induce enhanced T cell priming via the engineered Fc region, as T cell priming is a crucial step in generating potent immune responses against cancer,

(2) increased potential to deplete intratumoral regulatory T cells, which represent a significant barrier to successful anti-cancer immune responses,

(3) better combination potential with other antitumor or immunomodulatory antibodies, vaccines, and targeted therapies and

(4) potential therapeutic benefit to a wider patient population, including the estimated 40% of patients who are unlikely to fully benefit from the first generation CTLA-4 therapies due to a genetic predisposition.

AGEN1181 is currently in a Phase 1 dose escalation study as a monotherapy and in combination with AGEN2034. We have reported responses in our dose escalation and importantly, a complete response in our 1mg/kg dose cohort in a patient with metastatic endometrial cancer. This is an unusually exciting finding based on precedence. Outside of melanoma, there have been only four reported CRs in patients treated with first generation anti-CTLA-4 (Yervoy®) and all of the responses were observed in prostate cancer.

Partnered CPM Programs

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. During 2019, we received $22.5 million in milestone payments, and we remain eligible to receive up to an additional $1.7 billion in aggregate potential fees and milestones. At closing, Gilead received worldwide exclusive rights to our bispecific antibody, AGEN1423 (now GS-1423). Gilead also received the exclusive option to license exclusively AGEN1223, a bispecific antibody, and AGEN2373, a monospecific antibody. Both of these assets are currently advancing in Phase 1 clinical trials. We are responsible for developing the option programs up to the option decision points, at which time Gilead may acquire exclusive rights to the programs on option exercise. For either, but not both, of the option programs, we have the right to opt-in to share Gilead's development and commercialization costs in the United States in exchange for a profit (loss) share on a 50:50

basis and revised milestone payments. Gilead also received the right of first negotiation for two additional, undisclosed programs. At the closing, Gilead also purchased 11,111,111 shares of Agenus common stock for $30.0 million pursuant to a stock purchase agreement.

In January 2015, we entered into a collaboration with Incyte Corporation ("Incyte") to discover, develop and commercialize novel immuno-therapeutics using our antibody platforms. The collaboration was initially focused on four CPM programs targeting GITR, OX40, TIM-3 and LAG-3, and in November 2015, we expanded the alliance by adding three novel undisclosed CPM 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%. Concurrent with the execution of the original collaboration agreement, we and Incyte also entered into a stock purchase agreement pursuant to which Incyte purchased approximately 7.76 million shares of our common stock for an aggregate purchase price of $35.0 million. 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 anti-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 (anti-GITR agonist) and INCAGN1949 (anti-OX40 agonist). Concurrent with the execution of the amendment agreement, we and Incyte entered into a separate stock purchase agreement whereby Incyte purchased an additional 10 million shares of our common stock for an aggregate purchase price of $60.0 million. INCAGN1876 is currently in a Phase 2 trial exploring its safety, tolerability, and efficacy in combination with immune therapies, ipilimumab and nivolumab, in advanced or metastatic malignancies such as advanced or metastatic endometrial cancer, gastric cancer (including stomach, esophageal, and gastroesophageal junction), and squamous cell carcinoma of the head and neck. INCAGN1949 is currently in a Phase 1/2 trial exploring its safety, tolerability, and efficacy in combination with immune therapies, ipilimumab and nivolumab, in advanced or metastatic malignancies such as advanced or metastatic urothelial carcinoma or RCC. In 2018, Incyte initiated clinical trials for their INCAGN2385 (LAG-3) and INCAGN2390 (TIM-3) programs.

In April 2014, we entered into a collaboration and license agreement with Merck to discover and optimize fully-human antibodies against two undisclosed CPM targets. In 2016, Merck selected a lead product candidate against ILT4 to advance into preclinical studies, and subsequently initiated a Phase 1 clinical trial with this antibody in August 2018. Under the terms of the agreement, Merck is responsible for all future product development expenses for the selected antibody candidate, and Agenus is eligible to receive up to $95.0 million in potential milestones plus royalties on any future sales.

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 are entitled to receive from Incyte and Merck, net of certain of our obligations to a third party and excluding the milestone we received from Incyte in the fourth quarter of 2018. After taking into account our obligations under the XOMA Royalty Purchase Agreement, as of December 31, 2019, we remain eligible to receive up to $450.0 million and $85.5 million in potential development, regulatory and commercial milestones from Incyte and Merck, respectively.

We also have a collaboration agreement with Recepta Biopharma SA for the development of our antibodies targeting CTLA-4 and PD-1, which gives Recepta certain rights to South American countries. We expect to continue exploring additional future collaborations.

Vaccine Platforms

Our current neoantigen vaccine platforms for the treatment of cancer, and potentially other indications, include our heat shock protein ("HSP") based Prophage vaccine candidates, and our fully synthetic, neoantigen vaccine candidates, ASV and PSV.

We, and others, have demonstrated that immunization with HSP complexes generate both CD4 and CD8 positive T-cell immune responses. These activated T-cells target the cancer cells of the tumor, from which the HSP complexes were derived, for destruction. Thus, HSP complexes isolated from cancer cells may be particularly helpful in mediating successful immunization. Since HSPs are expressed in all tumor cells, the approach of immunizing with the HSP complexes isolated from a particular tumor may be broadly applicable to a variety of cancer types. We believe that we pioneered the use of gp96, an HSP, purified from a patient's own tumor tissue, as a way to make I-O vaccine candidates.

Prophage Vaccine Candidates

Prophage (HSPPC-96), is an autologous cancer vaccine therapy derived from cancer tissues that are surgically removed from an individual patient designed to contain a broad sampling of potentially antigenic mutant proteins to educate the patient's immune system to seek out and destroy cancer. Prophage in combination with pembrolizumab (Keytruda®) is advancing in a Phase 2 clinical trial collaboration with the National Cancer Institute ("NCI") . The trial is being conducted by the Brain Tumor Trials Collaborative, led by Dr. Mark Gilbert, Chief of the Neuro-Oncology Branch at the NCI Center for Cancer Research with product provided by Agenus and Merck. The trial is ongoing.

Neoantigen Vaccine Platforms

Our neoantigen off-the-shelf vaccine platforms include: (i) individualized AutoSynVax™ (ASV®™), which targets the unique antigens expressed by a patient's own tumor, and (ii) off-the-shelf (or pre-manufactured) PhosphoSynVax™ (PSV™), which targets antigens expressed across patients and tumors, potentially enabling us to treat broader categories of patients.

Our neoantigen vaccines are designed with unique features, intending to confer important advantages: (1) proprietary methods to develop an effective and relevant "Blueprint" of immunogenic neoantigens for each patient; (2) HSPs to efficiently deliver neoantigens to the right immune cells to activate an anti-cancer immune response. Our proprietary linker technology is designed to enable efficient neoantigen loading for a robust cancer specific immune response with significantly less peptide; and (3) QS-21 Stimulon® adjuvant, a potent immune stimulator now in GSK's commercial shingles vaccine, Shingrix. Our vaccines are powered by our proprietary adjuvant, QS-21 Stimulon and have demonstrated safety in Phase 1 clinical trials with data reported at the Next Gen Immuno-oncology congress.

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 Stimulon is a natural product, a triterpene glycoside, or saponin, purified from the bark of the Chilean soapbark tree, Quillaja saponaria. QS-21 Stimulon 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 formulations 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 Stimulon 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.

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"). In addition, we granted GSK the first right to negotiate for the purchase of Agenus or certain of our assets, which expired in March 2017. 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. In 2017, we received a final milestone payment of $1.0 million from GSK and 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 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 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. GSK's net sales of Shingrix for the twelve months ended December 31, 2019 exceeded $2.0 billion. As a result, we received approximately $12.7 million of the First HCR Milestone in March 2020, and expect to receive the remaining $2.4 million of the First HCR Milestone in the second quarter of 2020.

Manufacturing

Manufacturing CPM Antibodies

In December 2015, we acquired an antibody manufacturing pilot plant in Berkeley, CA 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 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.

The quality control organization for all of our product candidates in Berkeley and Lexington performs a series of release assays designed to ensure that our antibody drug substance and vaccine product 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 current GMP ("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 and vaccine output. Our quality control and quality assurance staff is 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.

Manufacturing Cancer Vaccines

We manufacture our cancer vaccine candidates in our Lexington, MA facility.

We have established, within a single facility, well-defined, cost efficient vaccine manufacturing under GMPs, including bioanalytical, quality control and quality assurance, logistics, distribution and supply chain management. After manufacturing, Prophage and ASV vaccine candidates are tested and released by our analytical and quality systems staff.

QS-21 Stimulon

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. In addition, under the terms of our agreement with GSK, upon request by us, GSK is committed to supply certain quantities of commercial grade QS-21 Stimulon to us and our licensees for a fixed period.

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 approximately 30 issued United States patents and approximately 35 issued foreign patents. We also own, co-own or have exclusive rights to approximately 35 pending United States patent applications and approximately 290 pending foreign patent applications. We may not have rights in all territories where we may pursue regulatory approval for our product candidates.

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. This patent family is projected to expire between 2029 and 2031. We own, co-own, or have exclusive rights to patents and patent applications directed to various methods and compositions, including a patent directed to methods for identifying phosphorylated proteins using mass spectrometry. This patent is projected to expire in 2023. 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 (not including any regulatory exclusivities such as the six-month pediatric extension and/or the granted patent term extension in the U.S. and Japan and Supplementary Patent Certificate in Europe), 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 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 (Projected)**	**E.U. Basic Product Patent Expiration Year (Projected)**
Balstilimab(1)	2037	2036
Zalifrelimab(2)	2037	2036
AGEN1181(3)	2037	2037
AGEN1223(4)	2036	2036
GS-1423(5)	2039	2039
INCAGN1876(6)	2035	2035
INCAGN1949(7)	2037	2036
INCAGN2390(8)	2037	2037
INCAGN2385(9)	2037	2037
MK-4830(10)	2038	2038
AGEN2373	2038	2038

(1) Patents co-owned by Agenus and licensed from Ludwig Institute for Cancer Research.
(2) Patents co-owned by Agenus and licensed from Ludwig Institute for Cancer Research.
(3) Patents co-owned by Agenus and licensed from Ludwig Institute for Cancer Research.
(4) Patents co-owned by Agenus and licensed from Ludwig Institute for Cancer Research.
(5) Patents owned by Agenus and licensed to Gilead.
(6) Patents co-owned by Agenus, licensed from Ludwig Institute for Cancer Research, and licensed to Incyte.
(7) Patents co-owned by Agenus, licensed from Ludwig Institute for Cancer Research, and licensed to Incyte.
(8) Patents co-owned by Agenus and licensed to Incyte.
(9) Patents co-owned by Agenus and licensed to Incyte.
(10) Co-owned by Agenus and Merck.

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

University of Virginia

In connection with our acquisition of PhosImmune in December 2015, we obtained exclusive rights to a portfolio of patent applications and one issued patent relating to PTTs under a patent license agreement with the University of Virginia ("UVA"). The UVA license gives us exclusive rights to develop and commercialize the PTT technology. Under the license agreement, we will pay

low to mid-single digit running royalties on net sales of PTT products, and a modest flat percentage of sublicensing income. In addition, we may be obligated to make milestone payments of up to $2.7 million for each indication of a licensed PTT product to complete clinical trials and achieve certain sales thresholds. The term of the UVA license agreement ends when the last of the licensed patents expires or becomes no longer valid. As of March 2020, the last granted patent that is licensed to us by UVA will expire in late 2033, and there are currently pending patent applications that, if granted, will not expire until mid-2037. The UVA license agreement may be terminated as follows: (i) by UVA in connection with our bankruptcy or cessation of business relating to the licensed technology, (ii) by UVA if we commit a material, uncured breach or (iii) by us for our convenience on 180 days written notice.

Ludwig Institute for Cancer Research

On December 5, 2014, our wholly-owned subsidiary, Agenus Switzerland Inc. (formerly known as 4-Antibody AG) ("4-AB"), entered into a license agreement with the Ludwig Institute for Cancer Research Ltd. ("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 4-AB 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 and 4-AB 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, 4-AB made an upfront payment of $1.0 million to Ludwig. The December 2014 license agreement also obligates 4-AB 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 and/or 4-AB 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. During the year ended December 31, 2017, we paid a percentage of sublicensing income totaling $2.0 million to Ludwig under the license agreements. No payments were made during the years ended December 31, 2018 and 2019. 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 4-AB or us (as applicable) 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 CPM drug landscape is crowded with several competitors developing assets against a number of targets. Our development plans are spread out 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 CPM antibody programs, currently in clinical stage development targeting various pathways (as mono- or multi-specifics) including PD-1, CTLA-4, GITR, OX40, TIM-3, LAG-3, CD73, TGFb and CD137. 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, and nivolumab, an anti-PD-1 antibody, and is developing additional antagonists to LAG-3, TIM-3 and CD73. BMS also has next generation anti-CTLA-4 antibodies in the clinic, which may be competitive to our next generation anti-CTLA-4 program, (2) Merck has an approved anti-PD-1 antibody, as well as anti-CTLA-4 and LAG-3 antagonists recruiting in clinical trials, (3) Regeneron has an approved anti-PD-1 antibody as well as antibodies targeting CTLA-4 and LAG-3 in clinical trials, (4) AstraZeneca has an approved anti PD-L1 antibody, as well as an anti-CTLA-4 targeting antibody in the clinic, (5) Pfizer has an approved anti-PD-L1 (with Merck KgaA) as well as agents targeting PD-1, TGFbR1 CD137 in clinical development, and (6) Roche/Genentech has an approved anti-PD-L1 antibody. Besides these PD-1 and PD-L1 antibodies that were approved in the U.S., we are also aware of competitors with approved PD-1 agents in ex-U.S. geographies such as China. These include Innovent Biologics, Shanghai Junshi Biosciences, Shanghai HengRui Pharmaceuticals and Beigene. We are also aware of other competitors with PD-1/PD-L1 agents in clinical development, including but not limited to AbbVie, Arcus Biosciences, Boehringer Ingelheim, GSK, Macrogenics/Incyte, CytomX, Novartis, Symphogen, Jounce Therapeutics, Gilead Sciences, Janssen, Apollomics/Genor Biopharma, Fortress Biotech, CStone Pharmaceuticals, Suzhou Alphamab, Mabspace Biosciences, Akeso Biopharma, Sichuan Kelun Pharmaceutical, CSPC ZhongQi Pharmaceutical Technology, ImmuneOncia, Lee’s Pharmaceuticals and Sinocelltech. We are also aware of competitors with pre-clinical antibodies against PD-1 or PD-L1. In addition, we are aware of competitors with clinical stage drug candidates against CTLA-4, GITR, OX40, LAG-3, TIM-3, CD73, TGFb, CD137 as well as our earlier stage programs such as TIGIT. As outlined above, some of these include, but are not limited to, BMS, AstraZeneca, Pfizer, Roche, Novartis, Merck, Beigene,

Regeneron, CStone Therapeutics, OncoImmune, Eli Lilly, Innovent Biologics, Boehringer Ingelheim, Arcus Biosciences, Corvus Pharmaceuticals, Potenza, iTeos Therapeutics, GSK, AbbVie, Merck KgaA, Leap Therapeutics, Mereo Biopharma, OncoMed, Symphogen, Alligator Biosciences, Adagene, Lyvgen Biopharma, Compass Therapeutics, MedPacto, Sanofi and Forbius. Additionally, we are aware of competitors developing preclinical assets against these targets, including next generation agents. We are also aware of competitors with clinical or preclinical stage bispecifics targeting PD-1, CTLA-4, GITR, OX40, TIM-3, LAG-3, CD73, TGFb and CD137. There is no guarantee that our antibody product candidates will be able to compete successfully with our competitors' antibody products and product candidates.

We are conducting both monotherapy and combination trials in second line cervical cancer. We are aware that Merck's PD-1 antagonist, Keytruda, has been approved in advanced cervical cancer. We are also aware of industry sponsored clinical trials, including exploratory studies, that are underway in this setting. Clinical stage competitors include, but are not limited to, Regeneron (anti-PD-1), Ono Pharmaceuticals and BMS (anti-PD-1 alone or in combination with CTLA-4), Seattle Genetics and Genmab (antibody drug conjugate targeting Tissue Factor), Iovance Biotherapeutics (autologous TILs), Merck KgaA (PD-L1/TGFb), Genor Biopharma and Lee Pharmaceuticals.

We have autologous vaccine programs in clinical development including our Prophage vaccine in clinical development for GBM. We are aware of other therapeutic options in GBM that could compete with our vaccine, including but not limited to the following: Merck markets temozolomide for treatment of patients with newly diagnosed glioblastoma ("ndGBM") and refractory astrocytoma. Other companies are developing vaccines for the treatment of patients with ndGBM, including, but not limited to, Northwest Biotherapeutics (DC-Vax), Mimivax Inc. (SurVaxM) and Annias Immunotherapeutics (CMV Vaccine). Other companies may begin development programs as well. We are advancing our neoantigen vaccine, AutoSynVax, in solid tumors. There are companies advancing individualized or synthetic vaccine technologies and/or patient-specific medicine techniques that compete with our HSP based vaccines including, but not limited to: Gritstone Oncology, BioNTech, Moderna/Merck, Genocea Biosciences, ISA Pharmaceuticals, Nouscom, EpiVax Inc., and Vaccibody.

In addition, and prior to regulatory approval, if ever, our vaccines and 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.

We are aware of compounds that claim to be comparable to QS-21 Stimulon that are being used in clinical trials. 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 Pfizer, Idera, and Dynavax, (2) MF59, under development by Novartis, (3) IC31, under development by Intercell (now part of Valneva), and (4) MPL, under development by GSK. In the past, we have provided QS-21 Stimulon to other entities under materials transfer arrangements. In at least one instance, it is possible that this material was used without our permission to develop synthetic formulations and/or derivatives of QS-21. In addition, companies such as Adjuvance Technologies, Inc., CSL Limited, and Novavax, Inc., as well as academic institutions and manufacturers of saponin extracts, 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. 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.

We are also aware of a third party that manufactures pre-clinical material purporting to be comparable to QS-21 Stimulon. The claims being made by this third party may create marketplace confusion and have an adverse effect on the goodwill generated by us and our partners with respect to QS-21 Stimulon. We are also aware of other manufacturers of QS-21. Any diminution of this goodwill may have an adverse effect on our ability to commercialize future products, if any, incorporating this technology, either alone or with a third party.

Employees

As of February 29, 2020, we had 328 employees, of whom 86 were PhDs and 7 were MDs. None of our employees are subject to a collective bargaining agreement. We believe that we have good relations with our employees.

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"). The contents of our website are not part of, or incorporated into, this document. 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

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 below. You should consider carefully the following information about risks below in evaluating our business. If any of the following 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, 2019, 2018, and 2017, were $111.6 million, $162.0 million and $120.7 million, respectively. We expect to incur significant losses for the foreseeable future as we continue our research and development of, and seek regulatory approvals for, our product candidates. We anticipate that our expenses will increase substantially if, and as, we:

- conduct clinical trials for our product candidates;
- further develop our antibody programs and platforms, our vaccine programs, and our saponin-based vaccine adjuvants;
- continue to discover and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific manufacturing and commercial personnel;
- expand in-house 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 future commercialization efforts, as well as any additional infrastructure necessary to function as a public company.

To become profitable, we or any current or potential future licensees and collaboration partners must develop 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 and other expenditures to develop and market additional product candidates. 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 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 and commercialization of product candidates, including through our antibody programs and platforms, our vaccine programs, and our saponin-based vaccine adjuvants.

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, 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, 2019, we had $61.8 million of cash and cash equivalents. Based on our current plans and projections, we believe that our cash resources as of December 31, 2019, combined with cash from partnership milestones already triggered and expected later this year, as well as proceeds from financing transactions already completed in the first quarter of 2020, will be sufficient to satisfy our liquidity requirements through the fourth quarter of 2020. We are presently in multiple partnership and out licensing discussions which can extend our cash resources into and beyond next year. 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 any 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 European Medicines Agency (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 supply chain for the development and manufacture of our product candidates;
- the cost and timing of establishing, expanding and scaling 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 and other marketing or distribution arrangements. 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. 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 expect to 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.

We have in the past offered Biotech Electronic Security Tokens, but we are not currently offering such tokens at this time and have not issued any to date.

General economic conditions in the United States and abroad, whether as a result of a public health crisis such as COVID-19, presidential election or otherwise, may have a material adverse effect on 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 and alliances and licensing arrangements. 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, which we do not expect will occur before 2021, if ever, will depend on the successful development 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, 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 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.

Such measures might not be sufficient to enable us to make the principal and interest payments when due on the 2015 Subordinated Notes. In addition, any such financing, refinancing, or sale of assets might not be available on favorable terms, if at all.

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 severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that deterioration in credit and financial markets and confidence in economic conditions will not occur or be sustained, including as a result of the COVID-19 pandemic. Our general business strategy may be adversely affected by any such economic downturn, volatile 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. 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, 2019, we had cash and cash equivalents of $61.8 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, 2019, no assurance can be given that further 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 operations into the third quarter of 2020. Going forward, if we are unable to obtain sufficient funding to support our operations, we could be forced to delay, reduce or eliminate all of our research and development programs, product portfolio expansion or commercialization efforts, and 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 2015 Subordinated Notes could materially and adversely affect our liquidity.

In February 2015, we issued senior subordinated promissory notes in the aggregate principal amount of $14.0 million, of which $13.5 million remain outstanding, with annual interest of 8% (the "2015 Subordinated Notes"). The 2015 Subordinated Notes were previously due February 20, 2020, and in February 2020, we amended the 2015 Subordinate Notes to extend the maturity date to February 20, 2023. 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 $13.5 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. If we default on the 2015 Subordinated Notes and the repayment of such indebtedness is accelerated, our liquidity could be materially and adversely affected.

If we do not have sufficient cash on hand to service our 2015 Subordinated Notes, we may be required to raise additional capital which entails the risks described herein.

Risks Related to the Development of Our Product Candidates

Our business is highly dependent on the success of our balstilimab and zalifrelimab programs targeting second-line cervical cancer, 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 initial product candidates targeting cervical cancer.

Our anti-PD-1 and anti-CTLA-4 programs (balstilimab and zalifrelimab, respectively) are in Phase 2 expansion trials with both balstilimab monotherapy and balstilimab/zalifrelimab combination trials for patients with second-line cervical cancer that are designed to support BLA filings in the second half of 2020 under the FDA's accelerated approval pathway. If approved, we intend to commercialize these assets in 2021. These timelines are aggressive and subject to various factors outside of our control, including regulatory review and approval. In order to file a BLA and seek accelerated approval, we must launch a confirmatory trial and have it be substantially underway at the time of BLA submission. We have not yet initiated a confirmatory trial. There is no guarantee that we will be able to file a BLA in 2020, if at all. If our anti-PD-1 and anti-CTLA-4 programs encounter safety, efficacy, supply or manufacturing problems, developmental delays, regulatory or commercialization issues or other problems, our development plans and business would be significantly harmed.

Even though we have observed positive results to date, they may not necessarily be predictive of the final results of the trials or future clinical trials or otherwise be sufficient to support an accelerated 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.

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

The successful development of immune modulating antibodies, including our balstilimab and zalifrelimab programs, is highly uncertain.

Successful development of immune modulating antibodies, such as our balstilimab and zalifrelimab programs, 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, discussions with the FDA, an FDA request for additional nonclinical or clinical data, or unexpected safety or manufacturing issues;

- 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; and

- failure to initiate or successfully complete confirmation trials for candidates that receive accelerated approval.

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.

Even if we are successful in obtaining market 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 managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors may limit the definition of the target treatment population to one 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 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 one any 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 registration, and will need to continue to comply (or ensure that our third-party providers comply) with cGMPs and good clinical practices (“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.

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, 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 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 and effective for use 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.

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.

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

Positive results from preclinical and 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.

For example, in 2018 we presented early data on our balstilimab and zalifrelimab programs at major oncology conferences that demonstrated a clinical benefit (i.e., complete response, partial response or disease stabilization) in more than 60% of patients treated with balstilimab and zalifrelimab at that time. In February and March 2020, we reported interim data from our registrational trials of these same programs that showed overall response rates of approximately 11.9% with balstilimab monotherapy and approximately 26.5% with balstilimab/zalifrelimab combination therapy. The final data readouts on these programs may not show similar positive results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive 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 or EMA approval.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the 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 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 to monitor patients adequately during and after treatment;
- our ability 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 in such clinical trial site. 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.

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.

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. 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. In February and March 2020, we reported positive interim data from our lead trials of balstilimab and zalifrelimab. These results may not be indicative of the final results from the study, and the final results may not support a marketing approval. There is no guarantee that either balstilimab monotherapy or balstilimab/zalifrelimab combination therapy will receive marketing approval in any jurisdiction, and failure to achieve marketing approval for either of these programs 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 prospects.

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 may prioritize development of certain product candidates, such decisions may prove to be wrong and may adversely affect our business.

We are currently advancing multiple immune modulating antibodies, vaccines and adoptive cell therapies (through our AgenTus subsidiary). Simultaneously advancing so many product candidates creates 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 and commercialization of such product candidate, causing material harm to our business.

If, due to our limited resources and access to capital, we prioritize development of certain product candidates that ultimately prove 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.

We may not be able to advance clinical development or commercialize our cancer vaccine candidates or realize any benefits from these programs.

The probability of future clinical development efforts leading to marketing approval and commercialization of Prophage vaccines is highly uncertain. Prophage vaccines have been in clinical development for over 17 years, including multiple Phase 1 and 2 trials in eight different tumor types as well as randomized Phase 3 trials in metastatic melanoma and adjuvant renal cell carcinoma. To date, the only marketing approval for Prophage is in Russia where commercialization of the approved product was unsuccessful. All of our currently planned trials involving Prophage are intended to be sponsored by third parties, and there is no guarantee that they will occur at all.

Our current clinical trial plans with Prophage vaccines entail one government sponsored IND in which we provide support and product supply. For third-party sponsored trials, we lack the ability to control trial design, timelines, tumor tissue procurement and data availability. For example, in January 2017, we announced a clinical trial collaboration with the NCI, whereby the NCI is conducting a double-blind, randomized controlled Phase 2 trial to evaluate the effect of Prophage vaccine in conjunction with Merck's pembrolizumab on the overall survival rate of patients with ndGBM. In addition, the Phase 2 trial of Prophage vaccine in combination with bevacizumab in patients with surgically resectable recurrent glioma that was being conducted under the sponsorship of the Alliance for Clinical Trials in Oncology, a cooperative group of the NCI, has been closed. Our other cancer vaccine programs (ASV and PSV) are in Phase 1 and pre-clinical development, respectively, and there is no guarantee that they will successfully advance in and through the clinic. ASV also utilizes QS-21 Stimulon, and any inability or delay in securing adequate supplies of the adjuvant could have an adverse impact on the program or otherwise delay timelines. Current and future studies may eventually be terminated due to, among other things, slow enrollment, lack of probability that they will yield useful translational and/or efficacy data, lengthy timelines, or the unlikelihood that results will support timely or successful regulatory filings.

Our synthetic Heat Shock Protein ("HSP") peptide-based platform is in early stage development, and there is no guarantee that a product candidate will progress from this platform.

In June 2014, we reported positive results from a Phase 2 trial with HerpV™, a vaccine candidate for genital herpes from our synthetic HSP peptide-based platform. The Phase 2 trial met its formal endpoints, but subjects were not followed long enough to determine whether the magnitude of the effect on viral load would be sufficient to significantly reduce the incidence, severity, or duration of herpetic lesions or reduce the risk of viral transmission. Although we have not advanced this program into a Phase 3 trial, we initiated our ASV synthetic cancer vaccine program based on our prior findings with this platform. We initiated our first clinical trial for our first AutoSynVax product candidate in 2017 and reported safety and immunogenicity of the vaccine at CIMT2018. Although we have planned to initiate a combination trial with ASV and one or more of our antibodies, the timeline is uncertain and there is no guarantee that we will be able to do so at all. Furthermore, it is possible that research and discoveries by others will render any product candidate from this platform as obsolete or noncompetitive.

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. We, as a company, have limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely in part on third-party contract research organizations ("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 undesirable or unintended 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. 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, Premarket Approval, 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. 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 and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- 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 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 the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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 approval process as well as the unpredictability of future clinical trial results 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.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval may be significantly impacted.

For example, 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 well-controlled, Phase 3 clinical trials of the relevant product candidate in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We intend to utilize 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 also 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.

Moreover, 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. In the future, regulatory agencies may require the development and approval of such tests. Accordingly, the regulatory approval pathway for such product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

In addition, 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, 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.

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.

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 countries. 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 accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for 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 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 undesirable 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.

Undesirable 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 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 undesirable 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;
- 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;
- 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 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 therapeutic vaccines and other products;
- establish superior intellectual property positions;
- discover technologies that may result in medical insights or breakthroughs, which render our drugs or vaccines 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 and marketing 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.

The CPM drug landscape is crowded with several competitors developing assets against a number of targets. Our development plans are spread out 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 CPM antibody programs, currently in clinical stage development targeting various pathways (as mono- or multi-specifics) including PD-1, CTLA-4, GITR, OX40, TIM-3, LAG-3, CD73, TGFb and CD137. 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, and nivolumab, an anti-PD-1 antibody, and is developing additional antagonists to LAG-3, TIM-3 and CD73. BMS also has next generation anti-CTLA-4 antibodies in the clinic, which may be competitive to our next generation anti-CTLA-4 program, (2) Merck has an approved anti-PD-1 antibody, as well as anti-CTLA-4 and LAG-3 antagonists recruiting in clinical trials, (3) Regeneron has an approved anti-PD-1 antibody as well as antibodies targeting CTLA-4 and LAG-3 in clinical trials, (4) AstraZeneca has an approved anti PD-L1 antibody, as well as an anti-CTLA-4 targeting antibody in the clinic, (5) Pfizer has an approved anti-PD-L1 (with Merck KgaA) as well as agents targeting PD-1, TGFbR1 CD137 in clinical development, and (6) Roche/Genentech has an approved anti-PD-L1 antibody. Besides these PD-1 and PD-L1 antibodies that were approved in the U.S., we are also aware of competitors with approved PD-1 agents in ex-U.S. geographies such as China. These include Innovent Biologics, Shanghai Junshi Biosciences, Shanghai HengRui Pharmaceuticals and Beigene. We are also aware of other competitors with PD-1/PD-L1 agents in clinical development, including but not limited to AbbVie, Arcus Biosciences, Boehringer Ingelheim, GSK, Macrogenics/Incyte, CytomX, Novartis, Symphogen, Jounce Therapeutics, Gilead Sciences, Janssen, Apollomics/Genor Biopharma, Fortress Biotech, CStone Pharmaceuticals, Suzhou Alphamab, Mabspace Biosciences, Akeso Biopharma, Sichuan Kelun Pharmaceutical, CSPC ZhongQi Pharmaceutical Technology, ImmuneOncia, Lee's Pharmaceuticals and Sinocelltech. We are also

aware of competitors with pre-clinical antibodies against PD-1 or PD-L1. In addition, we are aware of competitors with clinical stage drug candidates against CTLA-4, GITR, OX40, LAG-3, TIM-3, CD73, TGFb, CD137 as well as our earlier stage programs such as TIGIT. As outlined above, some of these include, but are not limited to, BMS, AstraZeneca, Pfizer, Roche, Novartis, Merck, Beigene, Regeneron, CStone Therapeutics, OncoImmune, Eli Lilly, Innovent Biologics, Boehringer Ingelheim, Arcus Biosciences, Corvus Pharmaceuticals, Potenza, iTeos Therapeutics, GSK, AbbVie, Merck KgaA, Leap Therapeutics, Mereo Biopharma, OncoMed, Symphogen, Alligator Biosciences, Adagene, Lyvgen Biopharma, Compass Therapeutics, MedPacto, Sanofi and Forbius. Additionally, we are aware of competitors developing preclinical assets against these targets, including next generation agents. We are also aware of competitors with clinical or preclinical stage bispecifics targeting PD-1, CTLA-4, GITR, OX40, TIM-3, LAG-3, CD73, TGFb and CD137. There is no guarantee that our antibody product candidates will be able to successfully compete with our competitors' antibody products and product candidates.

We are conducting both monotherapy and combination trials in second line cervical cancer. We are aware that Merck's PD-1 antagonist, Keytruda, has been approved in advanced cervical cancer. We are also aware of industry sponsored clinical trials, including exploratory studies, that are underway in this setting. Clinical stage competitors include, but are not limited to, Regeneron (anti-PD-1), Ono Pharmaceuticals and BMS (anti-PD-1 alone or in combination with CTLA-4), Seattle Genetics and Genmab (antibody drug conjugate targeting Tissue Factor), Iovance Biotherapeutics (autologous TILs), Merck KgaA (PD-L1/TGFb), Genor Biopharma and Lee Pharmaceuticals.

We have autologous vaccine programs in clinical development including our Prophage vaccine in clinical development for GBM. We are aware of other therapeutic options in GBM that could compete with our vaccine, including but not limited to the following: Merck markets temozolomide for treatment of patients with ndGBM and refractory astrocytoma. Other companies are developing vaccines for the treatment of patients with ndGBM, including, but not limited to, Northwest Biotherapeutics (DC-Vax), Mimivax Inc. (SurVaxM) and Annias Immunotherapeutics (CMV Vaccine). Other companies may begin development programs as well. We are advancing our neoantigen vaccine, AutoSynVax, in solid tumors. There are companies advancing individualized or synthetic vaccine technologies and/or patient-specific medicine techniques that compete with our HSP based vaccines including, but not limited to: Gritstone Oncology, BioNTech, Moderna/Merck, Genocea Biosciences, ISA Pharmaceuticals, Nouscom, EpiVax Inc., and Vaccibody.

In addition, and prior to regulatory approval, if ever, our vaccines and 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.

We are aware of compounds that claim to be comparable to QS-21 Stimulon that are being used in clinical trials. 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 Pfizer, Idera, and Dynavax, (2) MF59, under development by Novartis, (3) IC31, under development by Intercell (now part of Valneva), and (4) MPL, under development by GSK. In the past, we have provided QS-21 Stimulon to other entities under materials transfer arrangements. In at least one instance, it is possible that this material was used without our permission to develop synthetic formulations and/or derivatives of QS-21. In addition, companies such as Adjuvance Technologies, Inc., CSL Limited, and Novavax, Inc., as well as academic institutions and manufacturers of saponin extracts, 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. 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.

We are also aware of a third party that manufactures pre-clinical material purporting to be comparable to QS-21 Stimulon. The claims being made by this third party may create marketplace confusion and have an adverse effect on the goodwill generated by us and our partners with respect to QS-21 Stimulon. We are also aware of other manufacturers of QS-21. Any diminution of this goodwill may have an adverse effect on our ability to commercialize future products, if any, incorporating this technology, either alone or with a third party.

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 risk evaluation and mitigation strategy 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 balstilimab and zalifrelimab or any other future 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 doctors could continue to rely on these therapies. If balstilimab and zalifrelimab or any other future 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 balstilimab and zalifrelimab or any future products, if approved for commercial sale, will depend on a number of factors, including:

- 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 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.

Even if we are able to commercialize any product candidates, such products may not receive coverage or may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, 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. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. In the United States, approval and reimbursement decisions are not linked directly, but there is increasing scrutiny from the Congress and regulatory authorities of the pricing of pharmaceutical products. 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. 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.

Significant uncertainty exists as to the coverage and reimbursement status of our product candidates for which we seek regulatory approval. Our ability to commercialize any drugs successfully will depend, in part, on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. 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 does not assure that other payors will also provide coverage and reimbursement for our products, if they are approved, by third-party payors.

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. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek, with respect to an approved product, additional clinical evidence that goes beyond the data required to obtain marketing approval. They may require such evidence to demonstrate clinical benefits and value in specific patient populations or they may call for costly pharmaceutical studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies before covering our products. 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.

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 of the United States. Moreover, 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, sale and distribution. Interim reimbursement levels 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 and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

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. Indeed, the BLAs that we intend to file in the second half of 2020 for balstilimab and zalifrelimab target second-line cervical cancer. This will limit the number of cervical cancer patients who may be eligible to use balstilimab and zalifrelimab, if approved.

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 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. For instance, we expect our product candidates targeting cervical cancer to target the smaller patient populations that suffer from the respective diseases we seek to treat. 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.

We are currently building a marketing and sales organization and have no experience in marketing, selling and distributing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have a small number of employees that are tasked with building our marketing and sales organization, and we currently have no sales, marketing or distribution capabilities and have no experience as a company in marketing, selling or distributing products. Developing an in-house marketing organization and sales force 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 marketing and sales personnel.

In addition to establishing internal sales, marketing and distribution 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 commercialize 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.

The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products 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 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. 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 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.

In 2015, we secured our own internal antibody manufacturing capabilities with the purchase of a manufacturing pilot plant from XOMA Corporation in Berkeley, California, and this facility supplies our antibody drug substance requirements for clinical proof-of-concept studies. Any performance failure on the part of our existing facility could delay clinical development or marketing approval of our antibody programs.

To date, we have manufactured our Prophage vaccines in our Lexington, MA facility. Manufacturing of the Prophage vaccines is complex, and various factors could cause delays or an inability to supply the vaccine. Deviations in the processes controlling manufacture or deficiencies in size or quality of source material could result in production failures. Specific vulnerabilities in the process may exist in tumor types in which quality or quantity of tissue is limited. In addition, regulatory bodies may require us to make our manufacturing facility a single product facility. In such an instance, we may elect to manufacture another product candidate in our current facility and would no longer have the ability to manufacture Prophage vaccines as well.

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. Although we have the right to secure certain quantities of QS-21 from GSK and we have some internal supply in-house, we currently do not have an alternative long-term supply partner for 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. There is no guarantee that we will be successful in these development efforts.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our 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 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. 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. 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. 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 to 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 limit our 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. 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;
- equipment malfunctions, power outages 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.

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 after we submit an BLA and before potential approval of the drug candidate. Similar regulations apply to manufacturers of our drug candidates for use or sale in foreign countries. 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 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. 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 anticipated future dependence upon others for the commercial manufacture of our drug candidates or drugs 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 Gilead to further develop and commercialize certain of our antibody programs. If we or Gilead fail to perform as expected, the potential for us to generate future revenues under the 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.

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, Gilead received (i) worldwide exclusive rights to AGEN1423 (now GS-1423), a bispecific antibody, (ii) the exclusive option to license exclusively AGEN1223, a bispecific antibody, and AGEN2373, a monospecific antibody, and (iii) the right of first negotiation for two additional, undisclosed programs. Gilead has the exclusive right to develop and commercialize GS-1423, and we are eligible to receive potential development and commercial milestones of up to $552.5 million in the aggregate, as well as tiered royalty payments on aggregate net sales ranging from the high single digit to mid-teen percent, subject to certain reductions under certain circumstances. Accordingly, the timely and successful completion by Gilead of clinical development and commercialization activities will significantly affect the timing and amount of any milestones or royalties we may receive for this program. Gilead's activities will be influenced by, among other things, the efforts and allocation of resources by Gilead, which we cannot control. With respect to the option programs, we are responsible for developing

each program up to the option decision point, at which time Gilead may acquire exclusive rights to each program on option exercise. During the option period, we are eligible to receive milestones of up to $30.0 million in the aggregate. If Gilead exercises an option, it would be required to pay an upfront license exercise fee of $50.0 million for each option that is exercised. Following any option exercise, we would be eligible to receive additional development and commercial milestones of up to $520.0 million in the aggregate for each such option program, as well as tiered royalty payments on aggregate net sales ranging from the high single digit to mid-teen percent, subject to certain reductions under certain circumstances. For either, but not both, of the option programs, we will have the right to opt-in to share Gilead's development and commercialization costs in the United State for such option program in exchange for a profit (loss) share on a 50:50 basis and revised milestone payments. There is no guarantee that we will receive any fees, milestones or royalties from Gilead. Similarly, there is no guarantee that we will be able to successfully advance the option programs to the option decision point, and, even if we do, there is no guarantee that Gilead will exercise its option for either program. If Gilead does not exercise its option for either of the option programs, there is no guarantee that we will be able to advance any such program ourselves or with another partner. If we wanted to partner either of the programs that are subject to a right of first negotiation with a third party other than Gilead, such discussions could be delayed and ultimately terminated as a result of Gilead's right of first negotiation. Accordingly, we may not be able to partner either of these programs with a third party other than Gilead on attractive terms, if at all.

In addition, our collaboration with Gilead may be unsuccessful due to other factors, including, without limitation, the following:

- Gilead may terminate any of the agreements for convenience upon 90 days' notice;
- Gilead has control over the development of GS-1423, and it will have control over the option programs if and when it exercises its options;
- Gilead may change the focus of its development and commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to GS-1423 or the option programs (if exercised); and
- Gilead may choose not to develop and commercialize GS-1423 or the option programs (if exercised) in all relevant markets or for one or more indications, if at all.

We are dependent upon our collaboration with Incyte to further develop, manufacture and commercialize antibodies against certain targets. If we or Incyte fail to perform as expected, the potential for us to generate future revenues under the 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.

In February 2017, we amended the terms of our collaboration agreement with Incyte to, among other things, convert the GITR and OX40 programs from profit-share programs, where we and Incyte shared all costs and profits on a 50:50 basis, to royalty-bearing programs, where Incyte funds 100% of the costs and we are eligible for potential milestones and royalties. In addition, the profit-share programs relating to TIGIT and one undisclosed target were removed from the collaboration, with TIGIT reverting to Agenus and the undisclosed target reverting to Incyte, each with a potential 15% royalty to the other party on any global net sales. 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. For each program in the collaboration, we serve as the lead for pre-clinical development activities through the filing of an IND, and Incyte has exclusive rights and all decision-making authority for manufacturing, clinical development and commercialization. Accordingly, the timely and successful completion by Incyte of clinical development and commercialization activities will significantly affect the timing and amount of any royalties or milestones we may receive under the collaboration agreement. In addition, in March 2017 we transferred manufacturing responsibilities to Incyte for antibodies under that collaboration. Any delays or weaknesses in the ability of Incyte to successfully manufacture could have an adverse impact on those programs. Incyte's activities will be influenced by, among other things, the efforts and allocation of resources by Incyte, which we cannot control. If Incyte does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, manufacturing, regulatory approval, and commercialization efforts related to antibodies under the collaboration could be delayed or terminated. There can be no assurance that any of the development, regulatory or sales milestones will be achieved, or that we will receive any future milestone or royalty payments under the collaboration agreement. In September 2018, we sold to XOMA a portion of the royalties and milestones we are entitled to receive from Incyte.

In addition, our collaboration with Incyte may be unsuccessful due to other factors, including, without limitation, the following:

- Incyte may terminate the agreement or any individual program for convenience upon 12 months' notice;
- Incyte has control over the development of assets in the collaboration;
- Incyte may change the focus of its development and commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to our collaboration;

- Incyte may choose not to develop and commercialize antibody products, if any, in all relevant markets or for one or more indications, if at all; and
- If Incyte is acquired during the term of our collaboration, the acquirer may have competing programs or different strategic priorities that could cause it to reduce its commitment to our collaboration.

If Incyte terminates our collaboration agreement, 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.

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, 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, and in December 2018 we entered into a partnership with Gilead relating to five of our antibody programs. Furthermore, we have a collaboration arrangement with Recepta for balstilimab and zalifrelimab, giving Recepta rights to certain South American countries and requiring us to agree upon development plans for these product candidates. Disagreements or the failure of either party to perform satisfactorily could have an adverse impact on these programs.

The Brain Tumor Trials Collaborative, through the NCI, is sponsoring a Phase 2 clinical trial of our Prophage vaccine candidate in combination with Merck’s pembrolizumab in patients with glioma. When our licensees or third-party collaborators sponsor clinical trials using our product candidates, we cannot control the timing of enrollment, data readout, or quality of such trials or related activities.

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, including those with Gilead and Incyte, 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 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 in this Annual Report on Form 10-K also apply to the activities of our therapeutic collaborators.

Additionally, if one of our collaborators, such as Gilead, Incyte or Recepta, terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

Collaborations are complex and time-consuming to negotiate and document. 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 may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials 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. 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, 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 states and other countries. We are not permitted to market any biological product in the United States until we receive a biologics license from the FDA. We have not previously submitted a BLA to the FDA, or similar marketing application to comparable foreign authorities, except for our application related to Prophage. A BLA must include extensive nonclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection. 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 may also 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.

The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

Although the regulatory framework for approving immunotherapy products is evolving, the general approach for FDA approval of a new biologic or drug has historically been to provide dispositive data from two well-controlled, Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We intend to utilize an accelerated approval approach for our product candidates given the limited alternatives for cancer treatments, but the FDA may not agree with our plans.

In addition, our clinical trial results may also not support approval of our product candidates. Our product candidates could 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 our product candidates are safe and effective for any of their proposed indications;

- 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 our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may be deemed by the FDA or comparable foreign regulatory authorities to be insufficient to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes and controls or facilities of third-party manufacturers with which we contract for clinical and commercial supplies or any facilities that we may own in the future; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner that could render our clinical data insufficient for approval.

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 have each expressed interest in further regulating biotechnology products, such as antibodies, vaccines, 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, vaccines, adjuvants or adoptive cell therapies products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. Similarly, the EMA governs the development of antibodies, vaccines, adjuvants and adoptive cell therapies in the European Union and may issue new guidelines concerning the development and marketing authorization for such products and require that we comply with these new guidelines. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we 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. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Breakthrough Therapy Designation, Fast Track Designation or Regenerative Medicine Advanced Therapy 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 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 Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In March 2020, we received Fast Track Designation for investigation of balstilimab in combination with zalifrelimab for the treatment of patients with relapsed or refractory metastatic cervical cancer, and we intend to apply for such designation for our other product candidates in the future. 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. 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 stockholers 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, Fast Track Designation. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

We may seek Regenerative Medicine Advanced Therapy ("RMAT") designation for some of our product candidates including our allogeneic cell therapies. In 2017, the FDA established the RMAT designation as part of its implementation of the 21st Century Cures Act to expedite review of any drug that meets the following criteria: it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like Breakthrough Therapy Designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical trials, patient registries, or other sources of real world evidence, such as electronic health records; through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy. There is no assurance that we will be able to obtain RMAT designation for any of our product candidates. RMAT designation does not change the FDA's standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

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, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. 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. Moreover, a priority review designation does not necessarily result in expedited development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. 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, and only

the first applicant to receive approval will receive the benefits of marketing exclusivity. 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.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act (the "FCA"), which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal anti-inducement law, prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a

person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services ("HHS"), information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- the U.S. Federal Food, Drug, and Cosmetic Act , which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign 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 insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain 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.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's financial resources and management's attention away from the business.

On January 31, 2019, the HHS and HHS Office of Inspector General proposed an amendment to one of the existing Anti- Kickback safe harbors (42 C.F.R. 1001.952(h)) which would prohibit certain pharmaceutical manufacturers from offering rebates to pharmacy benefit managers ("PBMs"), in the Medicare Part D and Medicaid managed care programs. The proposed amendment would remove protection for "discounts" from Anti-Kickback enforcement action and would include criminal and civil penalties for knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or reward the referral of business reimbursable under federal health care programs. At the same time, HHS also proposed to create a new safe harbor to protect point-of-sale discounts that drug manufacturers provide directly to patients, and adds another safe harbor to protect certain administrative fees paid by manufacturers to PBMs. If this proposal is adopted, in whole or in part, it could affect the pricing and reimbursement for any products for which we receive approval in the future.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and

administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

We have adopted a code of business conduct and ethics, 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 will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, 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, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. 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, among other foreign laws.

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 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.

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 risk evaluation and mitigation strategies, or 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 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. For example, certain policies of the current administration may impact our business and industry. Namely, the current administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities, such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict how these executive actions, including any executive orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Healthcare insurance coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably.

The success of our product candidates, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to the treatment of the diseases they target, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

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, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time- consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Further, even if one payor provides coverage for a given product, other payors may not provide coverage for that product. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates may have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Middle Class Tax Relief and Job Creation Act of 2012 required that the Centers for Medicare & Medicaid Services, the agency responsible for administering the Medicare program ("CMS") reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare

payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain pharmaceutical products or additional pricing pressures.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in October 2017, California became the first state to pass legislation requiring pharmaceutical manufacturers to announce planned drug price increases. While this legislation does not directly affect drug prices, it puts further pressure on pharmaceutical manufacturers in setting prices. At least one state, Oregon, has recently passed a similar law, requiring pharmaceutical manufacturers to disclose cost components, and other states are likely to follow. Additionally, the Trump administration recently released a “Blueprint”, or plan, to reduce the cost of drugs. The Trump administrations’ Blueprint contains certain measures that the U.S. Department of Health and Human Services is already working to implement. 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 due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

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

Changes in regulations, statutes or the interpretation of existing regulations 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 legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act (“ACA”), was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. On June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

Moreover, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy. We expect that additional foreign, federal and state

healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

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.

If we begin conducting 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, through our CROs, are conducting clinical trials in countries that Transparency International has identified as "perceived as more corrupt", including, Brazil, Chile, Ukraine and Georgia. 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. If we expand our presence outside of the United States, it will require us to 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, 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 plan to 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.

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, and statutory, regulatory, and policy changes. 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, over the last several years, including most recently from December 22, 2018 to January 25, 2019, 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 a prolonged government shutdown occurs, 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 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 planned or actual withdrawal from the EUor our current political regime, and limitations on the flexibility of our operations and costs imposed by local labor laws.

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.

On January 31, 2020, the UK exited the EU, commonly known as Brexit. Pursuant to the Withdrawal Agreement that has been ratified by both the UK and EU, EU law, including GDPR will continue to apply in the UK until December 31, 2020. The Withdrawal Agreement provides that the UK and EU can elect to extend such transition period by up to two years.

On and after, January 1, 2021, any transfers of personal data to the United Kingdom will then be 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 would 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, Bexit 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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act" (the "TCJA") that significantly reformed the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. Our net deferred tax assets and liabilities were revalued at the newly enacted U.S. corporate rate. We did not recognize any tax expense in the year of enactment as our net deferred tax assets have a full valuation allowance recorded.

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, 2019, we had U.S. federal and state net operating loss, or NOL, carryforwards of $646.3 million and $184.9 million, respectively, which may be available to offset future taxable income. The federal NOLs include $607.7 million which expire at various dates through 2037 and $38.6 million which carryforward indefinitely. The state NOLs expire at various dates through 2038. As of December 31, 2019, we also had U.S. federal and state research and development tax credit carryforwards of $8.8 million and $9.4 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2020 and 2033, respectively. 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 secret protection 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, vaccine, 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, vaccines, 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.

Through our acquisitions of 4-AB, PhosImmune and certain assets of Celexion, 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. This patent family is projected to expire between 2029 and 2031. Through our acquisition of PhosImmune, we own, co-own, or have exclusive rights to patents and patent applications directed to various methods and compositions, including a patent directed to methods for identifying phosphorylated proteins using mass

spectrometry. This patent is projected to expire in 2023. 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 acquisitions of 4-AB, PhosImmune and certain assets of Celexion, 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 acquisitions of 4-AB, PhosImmune and certain assets of Celexion, will result in the issuance of valid and enforceable patents.

Our issued patents covering Prophage vaccine and methods of use thereof, alone or in combination with other agents, expired or will expire at various dates between 2015 and 2024. In particular, our issued U.S. patents covering Prophage composition of matter expired in 2015. In addition, our issued patents covering QS-21 Stimulon composition of matter expired in 2008. We continue to explore means of extending the life cycle of our patent portfolio.

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. With respect to our patent portfolio, as of the date of this filing, we own, co-own or have exclusive rights to approximately 30 issued United States patents and approximately 35 issued foreign patents. We also own, co-own or have exclusive rights to approximately 35 pending United States patent applications and approximately 290 pending foreign patent applications. 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 approximately 35 pending United States patent applications and approximately 290 pending foreign 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 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 may have the right to terminate their respective license agreements, in which event we might not be able to market 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.

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.

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, AIA was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and also affect patent litigation. The USPTO has developed regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-inventor-to- file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This requires us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

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.

As is common in the biopharmaceutical industry, we employ individuals who were previously or concurrently employed at research institutions and/or other biopharmaceutical, biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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 Leahy-Smith America Invents Act, or the American Invents Act (“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 is ways that impair our branding strategy. Recepta has rights to balstilimab and zalifrelimab in certain South American countries and may adopt a marketing strategy, including use of trademarks and tradenames, that could impair our brand identity 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 undergone significant growth across multiple locations over the past few years, and are focusing on further enhancing core areas and capabilities as we move toward commercialization. In addition, 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.

Over the past few years we have more than tripled our headcount, in part through various acquisitions and the expansion of our research and development activities both nationally and internationally. While we have restructured our organization over the past few years, we expect to continue increasing our headcount in certain core areas as we continue to build our development, manufacturing and commercialization capabilities and integrate our acquired technology platforms. 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.

As part of our efforts to optimize efficiency across our organization, we closed our Jena, Germany office in 2016 and consolidated these operations in the UK and Switzerland. In 2017, we completed a reduction in force in our Lexington, MA facility, which included certain members of our management, in line with our prioritization efforts, and we closed our office in Basel, Switzerland and transferred our research and development assets and capabilities there to the UK. In January 2020, our subsidiary AgenTus closed its Waterloo, Belgium office and consolidated those operations in our Lexington, MA facility. If these transition efforts prove to be unsuccessful, or if 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. We are still in the process of liquidating 4-AB and transferring intellectual property rights from Switzerland to the United States or elsewhere. There could be adverse tax consequences resulting from this migration of intellectual property rights, which could have an adverse effect on our business and 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 related litigation;
- substantial monetary awards to plaintiffs; and
- decreased demand for any future products.

We manufacture the Prophage vaccines from a patient’s cancer cells, and medical professionals must inject the vaccines into the same patient from which they were manufactured. A patient may sue us if a hospital, a shipping company, or we fail to receive the removed cancer tissue or deliver that patient’s vaccine. We do not have any other insurance that covers loss of or damage to the Prophage vaccines or tumor material, and we do not know whether such insurance will be available to us at a reasonable price or at all. 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 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.

Both Garo H. Armen, Ph.D., the Chairman of our Board of Directors and our Chief Executive Officer who co-founded the Company in 1994, and Jennifer Buell, Ph.D., our President and Chief Operating Officer, are integral to building our company and developing our technology. If either Dr. Armen or Dr. Buell is unable or unwilling to continue his or her relationship with Agenus, our business may be adversely impacted. We have employment agreements with Dr. Armen and Dr. Buell. They both play an important role in our day-to-day activities, and we do not carry key employee insurance policies for Dr. Armen, Dr. Buell or any other employee. The loss of the services of Dr. Armen or Dr. Buell, 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.

The bulk of our operations are conducted at our facilities in Cambridge,UK, Lexington, MA and Berkeley, CA. The Cambridge, New England 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. 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 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 Health Insurance Portability and Accountability Act of 1996 (“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 could disrupt our business and materially adversely affect our operations.

Our operations, and those of our CROs, CMOs, and other contractors and consultants, 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 from using all or a significant portion of our facilities, 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 lease additional office space in Berkeley, CA. This location is in an area of seismic activity near active earthquake faults and active wildfire activity. In October 2019, Pacific Gas and Electric Company (“PG&E”), the utility supplier for our Berkeley, CA facility provided notice to all residents and businesses in Almeda County (where Berkeley, CA is located) that it would shut off power to the county for a multiday period due to the risk of wildfires. The emergency backup generators located at our Berkeley, CA facility are not able to power the entire facility and only have enough fuel capacity to provide emergency power for a few hours. We have plans in place to maintain the fuel supply of our generators in the event of an extended power interruption, but there is no guarantee that such plans will be adequate to maintain emergency power at our Berkeley, CA facility. In addition, many of our employees reside in Alameda County and may be unable to leave home for the duration of any power shut off. While PG&E did not shut off power to our facility in October 2019, PG&E may do so in the future on short notice.

In March 2020, we put in place a number of protective measures in response to the Coronavirus disease (COVID-19) outbreak that is taking place world-wide and which was recently declared a pandemic by the World Health Organization. These measures include cancelling all commercial business travel, requesting employees to limit non-essential personal travel, asking some employees to self-quarantine at home, adjusting our facilities janitorial and sanitary policies and, most recently, encouraging employees to work from home to the extent their job function enables them to do so. We are revisiting these measures on a daily basis as the situation evolves, and we are likely to take additional action as we learn more and as instruction is provided by national, state and local governmental agencies. Both these existing measures and any future actions are likely to result in a disruption to our business. Our employees are also impacted by the closures of their children’s schools for lengthy periods of time. In Massachusetts, all public and private elementary and secondary schools have been ordered to close for a minimum of three weeks, leaving many of our employees with no choice but to work from home and care for their children at the same time. In addition, in March 2020, the United States government announced that it would suspend air travel between the United States and parts of Europe for a 30-day period and subsequently revised this suspension to include the UK, where we have an office and employees. In the event the governments in Massachusetts, California or the UK mandate a shelter in place or otherwise prohibit employees from going to work for a period of time, our business will be disrupted and our programs and timelines are likely to be delayed, depending on the length and severity of the mandate. Not all of our employees are able to perform their duties or function remotely. We also have a CMO based in the Seattle, WA area, and Washington is one of a few states that has reported extreme outbreak and over 100 cases of infection as of the date of this filing. Please refer to our risk factors related to Manufacturing and Supply and Our Reliance on Third Parties above for the possible impact of a disruption in the production capabilities of our suppliers.

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.

We intend to advance our cell therapy business through our subsidiary, AgenTus Therapeutics, eventually with separate funding. Moving intellectual property assets into AgenTus Therapeutics in foreign jurisdictions could have adverse tax consequences, and there is no guarantee that we will be able to attract external funding. Moreover, even if the business is funded, there is no guarantee that it will be successful.

We are currently in the process of pursuing external funding and partnership opportunities to advance AgenTus Therapeutics, but Agenus is currently funding such operations. There is no guarantee that external funding will be available. If 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, including any potential initial public offering. Similarly, there is no guarantee that partnership opportunities will be available on attractive terms, if at all. If external funding is not available, we may be forced to either retire these programs or continue to use internal resources to advance them. In addition, our cell therapy assets are pre-clinical. Even if adequate funding and partnership opportunities are available, there is no guarantee that we or AgenTus Therapeutics will be successful in advancing one or more product candidates into and through clinical development. In addition, most of the efforts being made on behalf of AgenTus Therapeutics are being led by a separate AgenTus chief executive officer, utilizing several members of Agenus' management team and Agenus' internal general and administrative resources. The current structure could distract management and divert Agenus resources from Agenus' own core pipeline and programs.

The cell therapy assets necessary to enable AgenTus Therapeutics are currently owned or controlled by Agenus in the United States and Switzerland. In connection with capitalizing AgenTus Therapeutics, these assets will be transferred or licensed to new legal entities within the United States and Europe and potentially others. Transferring these assets or licensing them on an exclusive basis would require that taxes be paid based on the fair market value of the assets. We may not have adequate net operating losses to offset any tax liabilities in the relevant jurisdictions. Moreover, we have previously disclosed our interest in potentially issuing a tax-free dividend to Agenus' stockholders in the form of stock of AgenTus Therapeutics. There is no guarantee that any such dividend will be tax-free or that it will be issued at all, or the timing thereof. If we issue a dividend in the form of stock, there could be adverse tax consequences for certain of our stockholders.

Risks Related to our Common Stock

Our stock has historically had low trading volume, and its public trading price has been volatile.

During the period from our initial public offering on February 4, 2000 to December 31, 2019, and the twelve months ended December 31, 2019, the closing price of our common stock has fluctuated between $1.59 (or $0.27 pre-reverse stock split) and $315.78 (or $52.63 pre-reverse stock split) per share and $2.17 and $4.40 per share, respectively. The average daily trading volume for the twelve months ended December 31, 2019 was approximately 1,191,940 shares, while the average daily trading volume for the year ended December 31, 2018 was approximately 1,538,510. The market 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 as we continue our development activities;
- 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.

We are a "Smaller Reporting Company", and the reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We qualify as a Smaller Reporting Company ("SRC") under the SEC rules and are able to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not SRCs, including a shorter look back period for management's discussion and analysis of financial condition and results of operations, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. So long as we meet the definition of SRC, we can maintain our SRC status indefinitely.

We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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, 2018, 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 12, 2020, we had 161,589,924 shares of common stock outstanding. All of these shares are eligible for sale on Nasdaq, although certain of the shares are subject to sales volume and other limitations. We have filed registration statements to permit the sale of approximately 36,000,000 shares of common stock under our equity incentive plans, and to permit the sale of 1,500,000 shares of common stock under our 2015 Inducement Equity Plan. We have also filed registration statements to permit the sale of approximately 667,000 shares of common stock under our Employee Stock Purchase Plan, to permit the sale of 425,000 shares of common stock under our Directors' Deferred Compensation Plan, to permit the sale of approximately 31,100,319 shares of common stock pursuant to various private placement agreements and to permit the sale of up to 50,000,000 shares of our common stock pursuant to our At Market Issuance Sales Agreement. As of March 12, 2020, an aggregate of approximately 48,821,225 of these shares remained available for sale. In October 2018, we completed a private placement of 18,459 shares of Series C-1 convertible preferred stock, convertible into 18,459,000 shares of common stock. The resale of all 18,459,000 shares of common stock underlying the 18,459 shares of Series C-1 convertible preferred stock was registered with the SEC pursuant to a Registration Statement on Form S-3 filed with the SEC on November 8, 2018 and declared effective on December 10, 2018. As part of our collaboration with Gilead, we completed a private placement of 11,111,111 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 connection with our acquisition of 4-AB in February 2014, we are obligated to make contingent milestone payments to the former shareholders of 4-AB, payable in cash or shares of our common stock at our option, as follows (i) $10.0 million upon our market capitalization exceeding $750.0 million for 30 consecutive trading days prior to the earliest of (a) February 12, 2024, (b) the sale of 4-AB or (c) the sale of Agenus and (ii) $10.0 million upon our market capitalization exceeding $1.0 billion for 30 consecutive trading days prior to the earliest of (a) February 12, 2024, (b) the sale of 4-AB or (c) the sale of Agenus. In connection with our acquisition of PhosImmune in December 2015, we issued 1,631,521 shares of our common stock to the shareholders of PhosImmune and other third parties having a fair market value of approximately $7.4 million at closing. 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 $35.0 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, 2019, warrants to purchase approximately 1,400,000 shares of our common stock with a weighted average exercise price per share of $5.10 were outstanding.

As of December 31, 2019, options to purchase 27,164,147 shares of our common stock with a weighted average exercise price per share of $3.67 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, 2019, we had 11,785,971 vested options and 2,119,811 non-vested shares outstanding.

As of December 31, 2019, our outstanding shares of Series A-1 Convertible Preferred Stock were convertible into 333,333 shares of our common stock.

As of December 31, 2019, our outstanding shares of Series C-1 Convertible Preferred Stock were convertible into 12,459,000 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 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 2023 with an option to renew for one additional ten-year period.

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.

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***

We are not party to any material legal proceedings.

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 March 9, 2020, there were 385 holders of record and 24,000 beneficial holders of our common stock.

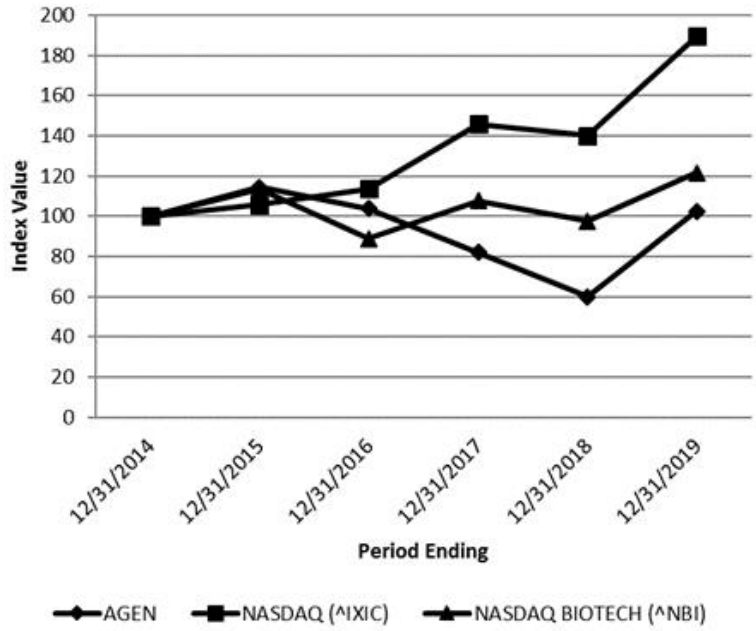
We have never paid cash dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain future earnings, if any, for the future operation and expansion of our business. Any future payment of dividends on our common stock will 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, 2014 to December 31, 2019, 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, 2014. 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**



	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019
Agenus Inc.	100.00	114.36	103.78	82.12	59.95	102.52
Nasdaq Stock Market (U.S. Companies) Index	100.00	105.73	113.66	145.76	140.10	189.45
Nasdaq Biotechnology Index	100.00	113.57	88.94	107.67	97.63	121.46

Item 6. ***Selected Financial Data***

We have derived the condensed consolidated balance sheet data set forth below as of December 31, 2019 and 2018, and the condensed consolidated statement of operations data for each of the years in the three-year period ended December 31, 2019, from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

You should read the selected condensed consolidated financial data in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," our consolidated financial statements, and the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Changes in cash, cash equivalents, and short-term investments, total current assets, total assets, total current liabilities, long-term debt and stockholders' (deficit) equity in the periods presented below include the effects of the receipt of net proceeds from our debt offerings, equity offerings, royalty monetization transactions, the exercise of stock options, and employee stock purchases that totaled approximately $31.6 million, $291.2 million, $81.5 million, $3.4 million, and $220.4 million in the years ended December 31, 2019, 2018, 2017, 2016, and 2015, respectively.

	For the Year Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands except per share data)				
Condensed Consolidated Statement of Operations Data:					
Revenue	$ 150,048	$ 36,784	$ 42,877	$ 22,573	$ 24,817
Operating expenses:					
Research and development	(168,339)	(124,600)	(116,125)	(94,971)	(70,444)
General and administrative	(46,041)	(37,340)	(33,741)	(33,126)	(28,370)
Contingent purchase price consideration fair value adjustment	(5,805)	1,335	3,188	(1,953)	(6,704)
Operating loss	(70,137)	(123,821)	(103,801)	(107,477)	(80,701)
Loss on early extinguishment of debt	—	(10,767)	—	—	—
Non-operating income (expense)	28	(2,183)	1,977	(2,202)	(5,968)
Interest expense, net	(41,451)	(25,273)	(18,868)	(17,316)	(6,599)
Loss before taxes	(111,560)	(162,044)	(120,692)	(126,995)	(93,268)
Income tax benefit (1)	—	—	—	—	5,387
Net loss	(111,560)	(162,044)	(120,692)	(126,995)	(87,881)
Dividends on Series A-1 convertible preferred stock	(208)	(207)	(206)	(204)	(203)
Less: net loss attributable to non-controlling interest	(3,903)	(2,352)	—	—	—
Net loss attributable to Agenus Inc. common stockholders	$ (107,865)	$ (159,899)	$ (120,898)	$ (127,199)	$ (88,084)
Net loss attributable to Agenus Inc. common stockholders per common share, basic and diluted	$ (0.80)	$ (1.44)	$ (1.23)	$ (1.46)	$ (1.13)
Weighted average number of Agenus Inc. common shares outstanding, basic and diluted	134,982	110,772	98,415	87,070	78,212

	As of December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Condensed Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 61,808	$ 53,054	$ 60,187	$ 76,437	$ 171,668
Total current assets	86,536	74,808	73,554	91,312	184,095
Total assets (2)	155,335	136,401	138,402	156,986	242,228
Total current liabilities	122,209	68,062	56,438	40,851	28,934
Long-term debt, less current portion	13,380	13,212	142,385	130,542	114,326
Series C-1 convertible preferred stock	26,917	39,879	—	—	—
Total stockholders' (deficit) equity	(231,337)	(174,546)	(75,816)	(39,126)	70,728

(1) Given our history of incurring operating losses, no income tax benefit has been recognized in our consolidated statements of operations for the years ended December 31, 2019, 2018, 2017, and 2016 because of the loss before income taxes, and the need to recognize a valuation allowance on the portion of our deferred tax assets which will not be offset by the reversal of deferred tax liabilities. For the year ended December 31, 2015, we recognized an income tax benefit as a result of the deferred tax liabilities recognized in connection with the PhosImmune and XOMA antibody manufacturing facility acquisitions.

(2) 2019 total assets reflects the adoption of ASC 842 and includes approximately $7.4 million in operating lease right-of-use assets.

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 immuno-oncology ("I-O") company advancing an extensive pipeline of immune checkpoint antibodies, adoptive cell therapies and neoantigen cancer vaccines, to fight cancer. Our business is designed to drive success in I-O through speed, innovation and effective combination therapies. We believe that combination therapies and a deep understanding of each patient's cancer will drive substantial expansion of the patient 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 good manufacturing practice ("GMP") manufacturing. We believe that these fully integrated capabilities enable us to produce novel candidates on timelines that are shorter than the industry standard. Leveraging from our science and capabilities, we have forged important partnerships to advance our innovation.

We are developing a comprehensive I-O portfolio driven by the following platforms and programs, which we intend to utilize individually and in combination:

- our multiple antibody discovery platforms, including our proprietary display technologies, designed to drive the discovery of future CPM antibody candidates;
- our antibody candidate programs, including our CPM programs;
- our vaccine programs, including Prophage™, AutoSynVax™ and PhosPhoSynVax ™;
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon™ adjuvant, or QS-21 Stimulon; and
- our cell therapy subsidiary, AgenTus Therapeutics, Inc., which is designed to drive the discovery of future adoptive cell therapy, or "living drugs" (Activated, CAR-T and TCR) programs.

We assess development, commercialization and partnering strategies for each of our product candidates periodically based on several factors, including pre-clinical and clinical trial results, competitive positioning and funding requirements and resources. Our most advanced antibody candidates are balstilimab (an anti-PD-1 antibody) and zalifrelimab (an anti-CTLA-4 antibody), which are currently in Phase 2 trials of balstilimab monotherapy and balstilimab/zalifrelimab combination for patients with second-line cervical cancer. Both of these trials are designed to support Biological License Application ("BLA") filings under the U.S. Food and Drug Administration ("FDA") accelerated approval pathway. We announced interim data from these trials in February and March 2020 and expect to file two BLAs in the second half of 2020. We have formed collaborations with companies such as Gilead Sciences, Inc. ("Gilead"), Incyte Corporation ("Incyte"), Merck Sharpe & Dohme ("Merck") and Recepta Biopharma SA ("Recepta"). Through these alliances, as well as our own internal programs, we currently have more than a dozen antibody programs in pre-clinical or clinical development.

In February 2017, we amended our Incyte Collaboration Agreement to, among other things, convert the GITR and OX40 programs from profit-share to royalty-bearing programs, and there are no longer any profit-share programs remaining 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 (anti-GITR agonist) and INCAGN1949 (anti-OX40 agonist). Concurrent with the execution of the amendment, we and Incyte also entered into the Stock Purchase Agreement whereby Incyte purchased an additional 10 million shares of our common stock at $6.00 per share, resulting in additional proceeds of $60.0 million to us. 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"). Pursuant to the terms of the XOMA Royalty Purchase Agreement, XOMA 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 are entitled to receive from Incyte and Merck, net of certain of our obligations to a third party. After taking into account our obligations under the XOMA Royalty Purchase Agreement, as of December 31, 2019, we remain eligible to receive up to $450.0 million and $85.5 million in potential development, regulatory and commercial milestones from Incyte and Merck, respectively.

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 (the "Gilead Collaboration Agreements"). Pursuant to the Gilead Collaboration Agreements, we received an upfront cash payment from Gilead of $120.0 million following the closing in January 2019 as well as milestone payments totaling $22.5 million in 2019. We are eligible to receive up to an additional $1.7 billion in aggregate potential fees and milestones. At closing, Gilead received worldwide exclusive rights to our bispecific antibody, AGEN1423 (now GS-1423). Gilead also received the exclusive option to license exclusively AGEN1223, a bispecific antibody, and AGEN2373, a monospecific antibody. We filed INDs for each of AGEN1423 (now GS-1423), AGEN1223 and AGEN2373 in 2019, and all three assets are now in clinical development. We are responsible for developing the option programs up to the option decision points, at which time Gilead may acquire exclusive rights to the programs on option exercise. For either, but not both, of the option programs, we have the right to opt-in to share Gilead's

development and commercialization costs in the United States in exchange for a profit (loss) share on a 50:50 basis and revised milestone payments. Gilead also received the right of first negotiation for two additional, undisclosed programs. At the closing, Gilead also purchased 11,111,111 shares of Agenus common stock for $30.0 million pursuant to a stock purchase agreement.

Our QS-21 Stimulon adjuvant is partnered with GlaxoSmithKline ("GSK") and is a key component in multiple GSK vaccine programs. These programs are in various stages, with the most advanced being GSK's shingles vaccine, Shingrix. In October 2017, GSK's shingles vaccine was approved in the United States by the FDA. 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 Stimulon 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. GSK's net sales of Shingrix for the twelve months ended December 31, 2019 exceeded $2.0 billion. As a result, we received approximately $12.7 million of the First HCR Milestone in March 2020, and expect to receive the remaining $2.4 million of the First HCR Milestone in the second quarter of 2020.

Our business activities include product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development activities, and support of our collaborations. Our product candidates require 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 by continuing our existing arrangements with academic and corporate collaborators and licensees and by entering into new collaborations.

In October 2017, we announced the launch of a subsidiary that is advancing our cell therapy business, AgenTus Therapeutics. AgenTus is focused on the discovery, development, and commercialization of breakthrough "living drugs" to advance cures for cancer patients, currently advancing allogeneic cell therapies that include unmodified iNKT cells. AgenTus Therapeutics licenses intellectual property assets from Agenus and has its own management and governance.

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, 2019, 2018, and 2017, were $168.3 million, $124.6 million, and $116.1 million, respectively. We have incurred significant losses since our inception. As of December 31, 2019, we had an accumulated deficit of $1.28 billion. We are likely to continue to incur losses until we become a commercial company generating profits. Although we plan to launch our first commercial product in 2021, we do not expect to be profitable in 2021.

Based on our current plans and projections, we believe that our cash resources as of December 31, 2019, combined with cash from partnership milestones already triggered and expected later this year, as well as proceeds from financing transactions already completed in the first quarter of 2020, will be sufficient to satisfy our liquidity requirements through the fourth quarter of 2020. We are presently in multiple partnership and out licensing discussions which can extend our cash resources into and beyond next year. Management continues to address the Company's liquidity position and will adjust spending as needed in order to preserve liquidity. We also continue to monitor the likelihood of success of our key initiatives and have a plan to discontinue funding of such activities if they do not prove to be successful, or, if by the second quarter of 2020 the anticipated additional cash resources are not put into place, restrict funding of non-core programs, restrict capital expenditures and/or reduce the scale of our operations as necessary to ensure sufficient cash resources through the fourth quarter of 2020. Our future liquidity needs will be determined primarily by the success of our operations with respect to the progression of our product candidates and key development and regulatory events in the future. Potential sources of additional funding include: (1) pursuing collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities.

Historical Results of Operations

Year Ended December 31, 2019 Compared to the Year Ended December 31, 2018

Research and development revenue

We recognized research and development ("R&D") revenue of approximately $99.8 million and $19.5 million during the years ended December 31, 2019 and 2018, respectively. R&D revenues for the year ended December 31, 2019, primarily consisted of amounts earned under our Gilead Collaboration Agreement, including $65.5 million related to the recognition of an upfront license fee and $20.6 million related to the recognition of deferred revenue related to research and development services, a $10.0 million upfront license fee from our UroGen License Agreement, as well as amounts earned under our Incyte Collaboration Agreement, including $1.7 million related to the reimbursement of development costs. R&D revenues for the year ended December 31, 2018, primarily consisted of fees earned under our Incyte Collaboration Agreement, including $10.0 million related to the recognition of milestones

and $4.1 million related to the reimbursement of development costs, and $4.0 million related to the recognition of a milestone under our license agreement with Merck. During the years ended December 31, 2019 and 2018, we recorded R&D revenue of $22.7 million and $1.3 million, respectively, from the recognition of deferred revenue.

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. During the years ended December 31, 2019 and 2018, we recognized approximately $30.4 million and $17.3 million in non-cash royalty revenue, respectively, related to our agreement with GSK.

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 increased 35% to $168.3 million for the year ended December 31, 2019 from $124.6 million for the year ended December 31, 2018. Increased expenses in the year ended December 31, 2019 primarily relate to a $28.8 million increase in third-party services and other related expenses largely relating to the advancement of our antibody programs, a $5.7 million increase in personnel related expenses, primarily due to increased headcount and a $11.2 million increase in expenses attributable to the activities of our subsidiary, AgenTus Therapeutics. These increases were partially offset by a $2.0 million decrease in expenses attributable to the activities of our wholly-owned subsidiaries, Agenus UK Limited and Agenus Switzerland.

General and administrative expense

General and administrative ("G&A") expense consists primarily of personnel costs, facility expenses, and professional fees. G&A expense increased 23% to $46.0 million for the year ended December 31, 2019 from $37.3 million for the year ended December 31, 2018. Increased general and administrative expense expenses in the year ended December 31, 2019 primarily relate to a $5.1 million increase in personnel related expenses, primarily due to increased headcount, a $0.5 million increase in professional fees, a $1.7 million increase in other general and administrative expenses and a $1.6 million increase in expenses attributable to the activities of our subsidiaries, AgenTus Therapeutics and our wholly-owned subsidiary, Agenus UK Limited.

Contingent purchase price consideration fair value adjustment

Contingent purchase price consideration fair value adjustment represents the change in the fair value of our contingent purchase price consideration during the year ended December 31, 2019, which resulted from changes in our market capitalization and share price and changes in the credit spread since the prior year end. The fair value of our contingent purchase price consideration is based on estimates from a Monte Carlo simulation of our market capitalization and share price.

Non-operating income (expense)

Non-operating income increased $2.2 million for the year ended December 31, 2019, from expense of $2.2 million for the year ended December 31, 2018, to income of $28,000 for the year ended December 31, 2019, primarily due to our increased foreign currency exchange gains in 2019 compared to losses in 2018.

Interest expense, net

Interest expense, net increased to $41.5 million for the year ended December 31, 2019 from $25.3 million for the year ended December 31, 2018, due to increased non-cash interest recorded in connection with our Royalty Purchase Agreement with HCR.

Year Ended December 31, 2018 Compared to the Year Ended December 31, 2017

Research and development revenue

We recognized R&D revenue of approximately $19.5 million and $42.7 million during the years ended December 31, 2018 and 2017, respectively. R&D revenues for the year ended December 31, 2018, primarily consisted of fees earned under our Incyte Collaboration Agreement, including $10.0 million related to the recognition of milestones and $4.1 million related to the reimbursement of development costs, which have decreased due to the stage of the programs under the collaboration, and $4.0 million related to the recognition of a milestone under our license agreement with Merck. R&D revenues for the year ended December 31, 2017, also primarily consisted of fees earned under our Incyte Collaboration Agreement including $20.0 million related to the acceleration of milestone payments and $14.6 million related to the reimbursement of development costs in addition to $4.0 million related to the recognition of a milestone under our license agreement with Merck, $1.0 million related to the recognition of a milestone under our license agreement with GSK. During the years ended December 31, 2018 and 2017, we recorded revenue of $1.3 million and $3.1 million, respectively, from the amortization of deferred revenue.

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. During the years ended December 31, 2018, we recognized approximately $17.3 million in non-cash royalty revenue related to our agreement with GSK.

Research and development expense

R&D expense increased 7% to $124.6 million for the year ended December 31, 2018 from $116.1 million for the year ended December 31, 2017. Increased expenses in the year ended December 31, 2018 primarily relate to a $7.3 million increase in third-party services and other related expenses largely relating to the advancement of our antibody programs and a $3.0 million increase in expenses attributable to the activities of our subsidiaries, AgenTus Therapeutics and our wholly-owned subsidiary in the United Kingdom, Agenus UK Limited, which increase was partially offset by a decrease in expenses due to the closure of our facility in Basel, Switzerland in 2017. These increases were partially offset by a $1.6 million decrease in personnel related expenses, which consists of a $2.8 million decrease in share based compensation expense partially offset by a $1.2 million increase in other personnel related expenses, and a $0.3 million decrease in other R&D expenses.

General and administrative expense

G&A expenses increased 11% to $37.3 million for the year ended December 31, 2018 from $33.7 million for the year ended December 31, 2017. Increased G&A expense in 2018 primarily relates to a $1.9 million increase in professional fees, a $1.0 million increase in other G&A expenses, and a $1.0 million increase in expenses attributable to the activities of our subsidiaries, AgenTus Therapeutics and our wholly-owned subsidiary in the United Kingdom, Agenus UK Limited, which increase was partially offset by a decrease in expenses due to the closure of our facility in Basel, Switzerland in 2017. These increases were partially offset by a $0.3 million decrease in personnel related expenses, which consists of a $1.9 million decrease in share based compensation expense partially offset by a $1.7 million increase in other personnel related expenses.

Contingent purchase price consideration fair value adjustment

Contingent purchase price consideration fair value adjustment represents the change in the fair value of our contingent purchase price consideration during the year ended December 31, 2018, which resulted from changes in our market capitalization and share price and changes in the credit spread since the prior year end. The fair value of our contingent purchase price consideration is based on estimates from a Monte Carlo simulation of our market capitalization and share price.

Loss on early extinguishment of debt

Loss on early extinguishment of debt of $10.8 million for the year ended December 31, 2018 represents the payment of premiums and the write-off of unamortized debt issuance costs and discounts incurred in connection with the full redemption and termination of Antigenics' $115.0 million principal amount of notes issued pursuant to the Note Purchase Agreement dated September 4, 2015 with Oberland Capital SA Zermatt LLC and the purchasers named therein.

Non-operating income (expense)

Non-operating expense increased by $4.2 million for the year ended December 31, 2018, from income of $2.0 million for the year ended December 31, 2017, to expense of $2.2 million for the year ended December 31, 2018, primarily due to our increased foreign currency exchange losses in 2018 compared to gains in 2017.

Interest expense, net

Interest expense net increased to $25.3 million for the year ended December 31, 2018 from $18.9 million for the year ended December 31, 2017, due to the January 2018 closing of the Royalty Purchase Agreement with HCR and the resulting increase in non-cash interest expense compared to the amount recorded for our Note Purchase Agreement, which was outstanding in the year ended December 31, 2017, and fully redeemed and terminated simultaneously with the closing of the Royalty 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, 2019, our R&D programs consisted largely of our CPM antibody programs as indicated in the following table (in thousands).

Research and Development Program	Product	For the Year Ended December 31, 2019	2018	2017	Prior to 2016	Total
Heat shock proteins for cancer	Prophage and ASV	$ 13,235	$ 13,235	$ 12,499	$ 323,391	$ 362,360
Antibody programs*	Various	126,400	97,011	95,656	160,632	479,699
Vaccine adjuvant	QS-21 Stimulon	872	211	222	13,876	15,181
Other research and development programs		27,832	14,143	7,748	70,594	120,317
Total research and development expenses		$ 168,339	$ 124,600	$ 116,125	$ 568,493	977,557

* Prior to 2014, costs were incurred by 4-AB, which we acquired in February 2014.

R&D 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. Active programs involving QS-21 Stimulon depend on our licensee successfully completing clinical trials, successfully manufacturing QS-21 Stimulon to meet demand, obtaining regulatory approvals and successfully commercializing product candidates containing QS-21 Stimulon.

Product Development Portfolio

Antibody Discovery Platforms and CPM Programs

Checkpoint antibodies regulate immune response against pathogens that invade the body and are achieving positive outcomes in a number of cancers that were untreatable only a few years ago. Two classes of checkpoint targets include:

1. inhibitory checkpoints that help suppress an immune response in order to prevent excessive immune reaction resulting in undesired inflammation and/or auto-immunity, and
2. stimulatory checkpoints that can enhance or amplify an antigen-specific immune response.

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

We and our partners currently have more than fifteen antibody programs in pre-clinical or clinical development, including our anti-CTLA-4, zalifrelimab, and anti-PD-1, balstilimab, programs (both partnered with Recepta for certain South America territories), our next generation anti-CTLA-4 antibody (AGEN1181), an IgG1 anti-CTLA-4 antagonist and anti-GITR, anti-OX40, anti-LAG3 and anti-TIM3 antibody programs (all partnered with Incyte). For additional information regarding our antibody discovery platforms and checkpoint antibody program, please read Part I-Item 1. “Business” of this Annual Report on Form 10-K.

Prophage Vaccine Candidates

Prophage (HSPPC-96), is an autologous cancer vaccine therapy derived from cancer tissues that are surgically removed from an individual patient designed to contain a broad sampling of potentially antigenic mutant proteins to educate the patient’s immune system to seek out and destroy cancer. Prophage in combination with pembrolizumab (Keytruda®) is advancing in a Phase 2 clinical trial collaboration with the National Cancer Institute (“NCI”). The trial is being conducted by the Brain Tumor Trials Collaborative (“BTTC”), led by Dr. Mark Gilbert, Chief of the Neuro-Oncology Branch at the NCI Center for Cancer Research with product provided by Agenus and Merck. The trial is ongoing. For additional information regarding regulatory risks and uncertainties, please read the risks identified under Part I-Item 1A. “Risk Factors” of this Annual Report on Form 10-K.

Neoantigen Vaccine Platforms

Our neoantigen off-the-shelf vaccine platforms include: (i) individualized AutoSynVax™ (ASV™), which targets the unique antigens expressed by a patient’s own tumor, and (ii) off-the-shelf (or pre-manufactured) PhosphoSynVax™ (PSV™), which targets antigens expressed across patients and tumors, potentially enabling us to treat broader categories of patients.

Our neoantigen vaccines are designed with unique features, intending to confer important advantages: (1) proprietary methods to develop an effective and relevant “Blueprint” of immunogenic neoantigens for each patient; (2) HSPs to efficiently deliver neoantigens to the right immune cells to activate an anti-cancer immune response. Our proprietary linker technology is designed to enable efficient neoantigen loading for a robust cancer specific immune response with significantly less peptide; and (3) QS-21 Stimulon® adjuvant, a potent immune stimulator now in GSK’s commercial shingles vaccine, Shingrix. Our vaccines are powered by our proprietary adjuvant, QS-21 Stimulon™ and have demonstrated safety in Phase 1 clinical trials with data reported at the Next Gen Immuno-oncology congress. For additional information regarding regulatory risks and uncertainties, please read the risks identified under Part I-Item 1A. “Risk Factors” 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 Stimulon is a natural product, a triterpene glycoside, or saponin, purified from the bark of the Chilean soapbark tree, Quillaja saponaria. QS-21 Stimulon 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 formulations 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 Stimulon 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. For additional information regarding QS-21 Stimulon, 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 $1.28 billion as of December 31, 2019. 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. To date, we have financed our operations primarily through the sale of equity and debt securities, and interest income earned on cash, cash equivalents, and short-term investment balances. From our inception through December 31, 2019, we have raised aggregate net proceeds of approximately $1.25 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 the offering of up to $250 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 50 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 FBR, Inc. as our sales agent. As of December 31, 2019, approximately 34.1 million shares remained available for sale under the Sales Agreement. During the period between January 1, 2020 and March 13, 2020, we sold approximately 23.8 million shares of our common stock pursuant to the Sales Agreement and received aggregate net proceeds totaling $62.9 million.

As of December 31, 2019, we had debt outstanding of $14.1 million in principal. In February 2015, we issued subordinated notes in the aggregate principal amount of $14.0 million with annual interest at 8% (the “2015 Subordinated Notes”). The 2015 Subordinated Notes were due in February 2020. In February 2020, we amended $13.5 million of the 2015 Subordinated Notes, extending the due date by three years to February 2023. The remaining $0.5 million of the 2015 Subordinated Notes were repaid in February 2020.

Our cash and cash equivalents at December 31, 2019 were $61.8 million, an increase of $8.8 million from December 31, 2018, principally as a result of amounts received under our Gilead Collaboration Agreement.

During the past five years, we have financed our operations primarily through funding from corporate partnerships and novel financing mechanisms. Based on our current plans and projections, we believe that our cash resources of $61.8 million as of December 31, 2019 combined with cash from partnership milestones already triggered and expected later this year, as well as proceeds from financing transactions already completed in the first quarter of 2020, will be sufficient to satisfy our liquidity requirements through the fourth quarter of 2020. We are presently in multiple partnership and out licensing discussions which, if consummated, could extend our cash resources into and beyond next year. Until we are successful in our efforts for capital infusion through these transactions or other financing options, and because the completion of such transactions is not entirely within our control, in accordance with accounting guidance we are required to disclose that substantial doubt exists 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.

Management continues to address the Company’s liquidity position and will adjust spending as needed in order to preserve liquidity. We also continue to monitor the likelihood of success of our key initiatives and have a plan to discontinue funding of such activities if they do not prove to be successful, or, if by the second quarter of 2020 the anticipated additional cash resources are not put into place, restrict funding of non-core programs, restrict capital expenditures and/or reduce the scale of our operations as necessary to ensure sufficient cash resources through the fourth quarter of 2020. Our future liquidity needs will be determined primarily by the success of our operations with respect to the progression of our product candidates and key development and regulatory events in the future. Potential sources of additional funding include: (1) pursuing collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling 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 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 $319.8 million over the term of the related activities. Through December 31, 2019, we have expensed $254.0 million as research and development expenses and $239.6 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 have also entered into sponsored research agreements related to our product candidates that required payments of $9.8 million, $9.0 million of which have been paid as of December 31, 2019. We plan to enter into additional agreements with third party providers as well as sponsored research agreements, and we anticipate significant additional expenditures will be required to initiate and advance our various programs.

Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing collaboration arrangements with academic and collaboration partners and licensees and by entering into new collaborations. As a result of our collaboration agreements, we will not completely control the efforts to attempt to bring those product candidates to market. For example, our collaboration with Incyte for the development, manufacture and commercialization of CPM antibodies against certain targets is managed by a joint steering committee, which is controlled by Incyte.

Net cash used in operating activities for the years ended December 31, 2019 and 2018 was $18.7 million and $131.1 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. 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 contractual obligations as of December 31, 2019 (in thousands).

		Payments by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long-term debt (1)	$ 17,596	$ 1,788	$ 2,160	$ 13,648	$ —
Operating leases (2)	30,646	4,090	7,902	6,257	12,397
Total	$ 48,242	$ 5,878	$ 10,062	$ 19,905	$ 12,397

(1) Includes fixed interest payments and reflects the amendment to our Subordinated Notes entered into on February 18, 2020. See Note 23 of the notes to our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K for further description of the amendment.

(2) The leases and subleases for our properties expire at various times between 2020 and 2030. The amounts include payments for two leases that were signed but had not yet commenced as of December 31, 2019. See Note 15 of the notes to our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K for further description of our leases.

Off-Balance Sheet Arrangements

At December 31, 2019, we had no off-balance sheet arrangements.

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 our critical accounting policies.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes existing revenue recognition guidance. We adopted ASU 2014-09 and its related amendments (collectively known as “ASC 606”) on January 1, 2018 using the modified retrospective method- i.e., by recognizing the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of equity at January 1, 2018. The reported results for 2019 and 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition. The adoption of ASC 606 represented a change in accounting principle that more closely aligned revenue recognition with the delivery of our goods and services and provided financial statement readers with enhanced disclosures.

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. Refer to Note 2 to our consolidated financial statements included within Item 8 of this Annual Report on Form 10-K for a more detailed description of our application of ASC 606.

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

In January 2018 we entered into the HCR Royalty Purchase Agreement with HCR. Pursuant to the terms of the HCR Royalty Purchase Agreement, we sold to HCR 100% of our worldwide rights to receive royalties from GSK on sales of GSK’s vaccines containing our QS-21 Stimulon adjuvant. 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 recorded the proceeds from this transaction as a liability on our consolidated balance sheet that will be amortized using the interest method over the estimated life of the HCR Royalty Purchase Agreement. As a result, we impute interest on the transaction and record non-cash interest expense at the estimated interest rate. Our estimate of the interest rate under the agreement is based on the amount of royalty payments to be received by HCR over the life of the arrangement. We periodically assess the expected royalty payments to HCR from GSK using a combination of historical results and forecasts from market data sources. 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 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.

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 subsidiary and are denominated in local currency. Approximately 2% and 1% of our cash used in operations for the years ended December 31, 2019 and 2018, respectively, was from a foreign subsidiary. Additionally, in the normal course of business, we are exposed to fluctuations in interest rates as we seek debt financing and invest excess cash. We are also 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 Euro, Swiss Franc and British Pound, in large part due to our subsidiaries, AgenTus Therapeutics SA, with operations in Belgium, Agenus Switzerland a company formally with operations in Switzerland and Agenus UK Limited, with operations in England. During the year ended December 31, 2019, there has been no material change with respect to our approach toward those exposures.

We had cash and cash equivalents at December 31, 2019 of $61.8 million, which are exposed to the impact of interest and foreign currency exchange rate changes, and our interest income fluctuates as interest rates change. 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, 2019, 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 annually 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, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the three-year period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, 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, 2019, 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 16, 2020 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Notes 2(s) and 15 to the consolidated financial statements, the Company changed its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update No. 2016-02, Leases (Topic 842), as amended.

As discussed in Notes 2(j) and 13 to the consolidated financial statements, the Company changed its method of revenue recognition as of January 1, 2018 due to the adoption of Accounting Standards Update 2014-09, Revenue from Contracts with Customers (Topic 606), as amended.

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.

/s/ KPMG LLP

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

Boston, Massachusetts
March 16, 2020

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

	December 31, 2019	December 31, 2018
ASSETS		
Cash and cash equivalents	$ 61,808	$ 53,054
Inventories	—	55
Accounts Receivable	16,293	938
Prepaid expenses	7,420	19,265
Other current assets	1,015	1,496
Total current assets	86,536	74,808
Property, plant and equipment, net of accumulated amortization and depreciation of $42,861 and $38,068 at December 31, 2019 and 2018, respectively	26,326	25,116
Operating lease right-of-use assets	7,364	—
Goodwill	23,188	22,925
Acquired intangible assets, net of accumulated amortization of $9,431 and $7,472 at December 31, 2019 and 2018, respectively	10,504	12,338
Other long-term assets	1,417	1,214
Total assets	$ 155,335	$ 136,401
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current portion, long-term debt	$ 646	$ 146
Current portion, liability related to sale of future royalties and milestones	45,961	27,443
Current portion, deferred revenue	29,174	1,814
Current portion, operating lease liabilities	1,347	—
Accounts payable	13,564	13,624
Accrued liabilities	31,332	24,551
Other current liabilities	185	484
Total current liabilities	122,209	68,062
Long-term debt	13,380	13,212
Liability related to sale of future royalties and milestones, net of current portion	175,408	182,817
Deferred revenue, net of current portion	27,705	1,165
Operating lease liabilities, net of current portion	8,020	—
Contingent purchase price consideration	8,843	3,038
Other long-term liabilities	4,190	2,773
Commitments and contingencies (Note 19)		
CONVERTIBLE PREFERRED STOCK		
Preferred stock, par value $0.01 per share; 5,000,000 shares authorized:		
Series C-1 convertible preferred stock; 12,459 shares and 18,459 shares designated, issued, and outstanding at December 31, 2019 and 2018, respectively	26,917	39,879
STOCKHOLDERS' DEFICIT		
Series A-1 convertible preferred stock; 31,620 shares designated, issued, and outstanding at December 31, 2019 and 2018; liquidation value of $33,040 and $32,832 at December 31, 2019, and 2018, respectively	0	0
Common stock, par value $0.01 per share; 400,000,000 shares and 240,000,000 shares authorized; 137,818,068 shares and 119,996,331 shares issued at December 31, 2019 and 2018, respectively	1,378	1,200
Additional paid-in capital	1,059,583	1,005,183
Accumulated other comprehensive loss	(1,324)	(1,539)
Accumulated deficit	(1,284,993)	(1,177,311)
Total stockholders' deficit attributable to Agenus Inc.	(225,356)	(172,467)
Non-controlling interest	(5,981)	(2,078)
Total stockholders' deficit	(231,337)	(174,545)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 155,335	$ 136,401

See accompanying notes to consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
For the Years Ended December 31, 2019, 2018, and 2017
(Amounts in thousands, except per share amounts)

	2019	2018	2017
Revenue:			
Research and development	$ 99,845	$ 19,475	$ 42,709
Royalty sales milestone	15,100	—	—
Other revenues	4,679	—	168
Non-cash revenue related to the sale of future royalties and milestones	30,424	17,309	—
Total revenues	150,048	36,784	42,877
Operating expenses:			
Research and development	(168,339)	(124,600)	(116,125)
General and administrative	(46,041)	(37,340)	(33,741)
Contingent purchase price consideration fair value adjustment	(5,805)	1,335	3,188
Operating loss	(70,137)	(123,821)	(103,801)
Other income (expense):			
Loss on early extinguishment of debt	—	(10,767)	—
Non-operating income (expense)	28	(2,183)	1,977
Interest expense, net	(41,451)	(25,273)	(18,868)
Net loss	(111,560)	(162,044)	(120,692)
Dividends on Series A-1 convertible preferred stock	(208)	(207)	(206)
Less: net loss attributable to non-controlling interest	(3,903)	(2,352)	—
Net loss attributable to Agenus Inc. common stockholders	$ (107,865)	$ (159,899)	$ (120,898)
Per common share data:			
Basic and diluted net loss attributable to Agenus Inc. common stockholders	$ (0.80)	$ (1.44)	$ (1.23)
Weighted average number of Agenus Inc. common shares outstanding:			
Basic and diluted	134,982	110,772	98,415
Other comprehensive income (loss):			
Foreign currency translation gain (loss)	$ 215	$ 630	$ (615)
Pension liability	—	—	(25)
Other comprehensive income (loss)	215	630	(640)
Comprehensive loss	$ (107,650)	$ (159,269)	$ (121,538)

See accompanying notes to consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
For the Years Ended December 31, 2019, 2018, and 2017
(Amounts in thousands)

	Series C-1 Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Common Stock			Treasury Stock					
	Number of Shares	Amount	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, 2016	—	—	32	0	87,795	878	866,854	—	—	(1,529)	—	(905,329)	$ (39,126)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(120,692)	(120,692)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(640)	—	—	(640)
Impact of accounting change	—	—	—	—	—	—	1,211	—	—	—	—	(1,293)	(82)
Shares sold under Stock Purchase Agreement	—	—	—	—	10,000	100	59,900	—	—	—	—	—	60,000
Share-based compensation	—	—	—	—	—	—	10,924	—	—	—	—	—	10,924
Reclassification of liability	—	—	—	—	—	—	2,016	—	—	—	—	—	2,016
Vesting of nonvested shares	—	—	—	—	1,097	11	(11)	(156)	(527)	—	—	—	(527)
Shares sold at the market	—	—	—	—	1,315	13	5,547	—	—	—	—	—	5,560
Amendment to 2013 warrants	—	—	—	—	—	—	731	—	—	—	—	—	731
Retirement of treasury shares	—	—	—	—	(156)	(2)	(1,364)	156	527	—	—	839	—
Issuance of shares for milestone	—	—	—	—	373	4	1,482	—	—	—	—	—	1,486
Issuance of stock for acquisition of SECANT yeast display technology	—	—	—	—	999	10	3,538	—	—	—	—	—	3,548
Exercise of stock options and employee share purchases	—	—	—	—	283	3	984	—	—	—	—	—	987
Balance at December 31, 2017	—	$ —	32	$ 0	101,706	$ 1,017	$ 951,812	—	$ —	$ (2,169)	$ —	$ (1,026,475)	$ (75,815)

See accompanying notes to consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Continued)
For the Years Ended December 31, 2019, 2018, and 2017
(Amounts in thousands)

	Series C-1 Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Common Stock			Treasury Stock					
	Number of Shares	Amount	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	—	—	—	—	—	—	—	—	—	—	(2,352)	(159,692)	$ (162,044)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	630	—		630
Adoption of ASC 606	—	—	—	—	—	—	—	—	—	—	—	8,856	8,856
AgenTus share distribution	—	—	—	—	—	—	—	—	—	—	274	—	274
Share-based compensation	—	—	—	—	—	—	7,351	—	—	—	—	—	7,351
Vesting of nonvested shares	—	—	—	—	53	1	(1)	—	—	—	—	—	—
Shares sold at the market	—	—	—	—	17,799	178	44,741	—	—	—	—	—	44,919
Issuance of Series C-1 convertible preferred stock, net of issuance costs of $122	18	39,879	—	—	—	—	—	—	—	—	—	—	—
Payment of consultant in shares	—	—	—	—	26	0	50	—	—	—	—	—	50
Exercise of stock options and employee share purchases	—	—	—	—	413	4	1,230	—	—	—	—	—	1,234
Balance at December 31, 2018	18	$ 39,879	32	$ 0	119,997	$ 1,200	$ 1,005,183	—	$ —	$ (1,539)	$ (2,078)	$ (1,177,311)	$ (174,545)

See accompanying notes to consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Continued)
For the Years Ended December 31, 2019, 2018, and 2017
(Amounts in thousands)

	Series C-1 Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Common Stock			Treasury Stock					
	Number of Shares	Amount	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	—	—	—	—	—	—	—	—	—	—	(3,903)	(107,657)	(111,560)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	215	—	—	215
Adoption of ASC 842	—	—	—	—	—	—	—	—	—	—	—	(25)	(25)
Share-based compensation	—	—	—	—	—	—	9,892	—	—	—	—	—	9,892
Vesting of nonvested shares	—	—	—	—	130	1	(1)	—	—	—	—	—	—
Shares sold under stock purchase agreement	—	—	—	—	11,111	111	29,889	—	—	—	—	—	30,000
Conversion of Series C-1 convertible preferred stock	(6)	(12,962)	—	—	6,000	60	12,902	—	—	—	—	—	12,962
Payment of consultant in shares	—	—	—	—	29	0	81	—	—	—	—	—	81
Exercise of stock options and employee share purchases	—	—	—	—	552	6	1,637	—	—	—	—	—	1,643
Balance at December 31, 2019	12	$ 26,917	32	$ 0	137,819	$ 1,378	$ 1,059,583	—	$ —	$ (1,324)	$ (5,981)	$ (1,284,993)	$ (231,337)

See accompanying notes to consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2019, 2018, and 2017
(Amounts in thousands, except per share amounts)

	2019	2018	2017
Cash flows from operating activities:			
Net loss	$ (111,560)	$ (162,044)	$ (120,692)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	6,662	6,288	6,006
Share-based compensation	9,892	7,625	12,429
Non-cash royalty revenue	(30,424)	(17,309)	—
Non-cash interest expense	42,201	24,599	18,242
Loss on disposal of assets	58	145	24
Change in fair value of contingent obligations	5,805	(1,335)	(3,188)
Gain on issuance of stock for settlement of milestone obligation	—	—	(566)
Loss on extinguishment of debt	—	10,767	—
Changes in operating assets and liabilities:			
Accounts receivable	(15,355)	196	10,217
Inventories	55	24	9
Prepaid expenses	11,792	(8,210)	(8,453)
Accounts payable	(234)	5,366	1,646
Deferred revenue	53,900	(397)	(2,722)
Accrued liabilities and other current liabilities	7,097	3,303	(4,849)
Other operating assets and liabilities	1,429	(113)	(2,329)
Net cash used in operating activities	(18,682)	(131,095)	(94,226)
Cash flows from investing activities:			
Proceeds from sale of plant and equipment	—	6	120
Purchases of plant and equipment	(4,657)	(3,597)	(3,120)
Purchases of available-for-sale securities	—	—	(14,936)
Proceeds from sale of available-for-sale securities	—	—	20,000
Net cash provided by (used in) investing activities	(4,657)	(3,591)	2,064
Cash flows from financing activities:			
Net proceeds from sale of equity	30,000	44,919	65,560
Net proceeds from sale of C-1 Preferred Stock	—	39,879	—
Proceeds from employee stock purchases and option exercises	1,643	1,234	987
Purchase of treasury shares to satisfy tax withholdings	—	—	(527)
Proceeds from issuance of long-term debt	—	—	15,000
Debt issuance costs	—	—	(150)
Proceeds from sale of future royalties	—	204,878	—
Transaction costs from sale of future royalties and milestones	—	(494)	—
Repayments of debt	—	(161,847)	—
Payment of finance lease obligation	(320)	(283)	(331)
Net cash provided by (used in) financing activities	31,323	128,286	80,539
Effect of exchange rate changes on cash	770	(733)	362
Net decrease in cash and cash equivalents	8,754	(7,133)	(11,261)
Cash and cash equivalents, beginning of period	53,054	60,187	71,448
Cash and cash equivalents, end of period	$ 61,808	$ 53,054	$ 60,187
Supplemental cash flow information:			
Cash paid for interest	$ 1,224	$ 1,171	$ 1,120
Supplemental disclosures - non-cash activities:			
Purchases of plant and equipment in accounts payable and accrued liabilities	$ 1,242	$ 300	$ 968
Issuance of common stock, $0.01 par value, issued in connection with the settlement of milestone obligation	—	—	1,486
Issuance of common stock, $0.01 par value, in connection with the acquisition of the SECANT yeast display technology	—	—	3,548

Issuance of common stock, $0.01 par value, in connection with payment to consultant	81	50	—
Lease right-of-use assets obtained in exchange for new operating lease liabilities	3,017	—	—

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 immuno-oncology ("I-O") company advancing an extensive pipeline of immune checkpoint antibodies, adoptive cell therapies and neoantigen cancer vaccines, to fight cancer. Our business is designed to drive success in I-O through speed, innovation and effective combination therapies. We believe that combination therapies and a deep understanding of each patient's cancer will drive substantial expansion of the patient 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 good manufacturing practice ("GMP") manufacturing. We believe that these fully integrated capabilities enable us to produce novel candidates on timelines that are shorter than the industry standard. Leveraging from our science and capabilities, we have forged important partnerships to advance our innovation.

We are developing a comprehensive I-O portfolio driven by the following platforms and programs, which we intend to utilize individually and in combination:

- our multiple antibody discovery platforms, including our proprietary display technologies, designed to drive the discovery of future CPM antibody candidates;
- our antibody candidate programs, including our CPM programs;
- our vaccine programs, including Prophage™, AutoSynVax™ and PhosPhoSynVax ™;
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon™ adjuvant, or QS-21 Stimulon; and
- our cell therapy subsidiary, AgenTus Therapeutics, Inc., which is designed to drive the discovery of future adoptive cell therapy, or "living drugs" (Activated, CAR-T and TCR) programs.

Our business activities include product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development activities, and support of our collaborations. Our product candidates require 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 by continuing our existing arrangements with academic and corporate collaborators and licensees and by entering into new collaborations.

Our cash and cash equivalents at December 31, 2019 were $61.8 million, an increase of $8.8 million from December 31, 2018.

We have incurred significant losses since our inception. As of December 31, 2019, we had an accumulated deficit of $1.28 billion. Although we plan to launch our first commercial product in 2021, we do not expect to be profitable in 2021.

During the past five years, we have financed our operations primarily through funding from corporate partnerships and novel financing mechanisms. Based on our current plans and projections, we believe that our cash resources of $61.8 million as of December 31, 2019 combined with cash from partnership milestones already triggered and expected later this year, as well as proceeds from financing transactions already completed in the first quarter of 2020, will be sufficient to satisfy our liquidity requirements through the fourth quarter of 2020. We are presently in multiple partnership and out licensing discussions which, if consummated, could extend our cash resources into and beyond next year. Until we are successful in our efforts for capital infusion through these transactions or other financing options, and because the completion of such transactions is not entirely within our control, in accordance with accounting guidance we are required to disclose that substantial doubt exists 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.

Management continues to address the Company's liquidity position and will adjust spending as needed in order to preserve liquidity. We also continue to monitor the likelihood of success of our key initiatives and have a plan to discontinue funding of such activities if they do not prove to be successful, or, if by the second quarter of 2020 the anticipated additional cash resources are not put into place, restrict funding of non-core programs, restrict capital expenditures and/or reduce the scale of our operations as necessary to ensure sufficient cash resources through the fourth quarter of 2020. Our future liquidity needs will be determined primarily by the success of our operations with respect to the progression of our product candidates and key development and regulatory events in the future. Potential sources of additional funding include: (1) pursuing collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling 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 and neoantigen vaccine programs are early stage, and because any further development of HSP-based vaccines 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 AgenTus Therapeutics not owned by Agenus.

(b) Segment Information

We are managed and currently operate as two segments. However, we have concluded that our two operating segments meet all three criteria required by Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 280, *Segment Reporting* to be aggregated into one reportable segment. The aggregation of our two operating segments into one reportable segment is consistent with the objectives and basic principles of ASC 280. Our two operating segments have similar economic characteristics and are both 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.

(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) Inventories

Inventories are stated at the lower of cost or net realizable value. Cost has been determined using standard costs that approximate the first-in, first-out method. We had no inventory as of December 31, 2019 and inventory as of December 31, 2018 consisted solely of finished goods.

(g) Accounts Receivable

Accounts receivable are amounts due from our collaboration partners as a result of research and development and manufacturing services provided and milestones achieved. We considered the need for an allowance for doubtful accounts and have concluded that no allowance was needed as of December 31, 2019 and 2018, as the estimated risk of loss on our accounts receivable was determined to be minimal.

(h) 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 $4.8 million, $4.3 million, and $3.8 million, for the years ended December 31, 2019, 2018, and 2017, respectively.

(i) 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 $14.1 million at December 31, 2019 and 2018, respectively.

(j) Revenue Recognition

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes existing revenue recognition guidance. We adopted ASU 2014-09 and its related amendments (collectively known as “ASC 606”) on January 1, 2018 using the modified retrospective method- i.e., by recognizing the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of equity at January 1, 2018. The reported results for 2019 and 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition (“ASC 605”).

The adoption of ASC 606 resulted in a cumulative adjustment to decrease our accumulated deficit by $8.9 million at January 1, 2018, which included a $3.0 million decrease in current portion, deferred revenue and a $5.9 million decrease in deferred revenue, net of current portion. As a result of the adoption of ASC 606, research and development revenue on our consolidated statement of operations for the year ended December 31, 2018 was decreased by $3.2 million and on our December 31, 2018 consolidated balance sheet, deferred revenue, current portion, deferred revenue, net of current portion and accumulated deficit were decreased by $1.0 million, $4.7 million and $5.7 million, respectively. The change in revenue was primarily attributable to the change in recognition of an upfront fee related to the GSK License and Amended Supply Agreements. While the change in deferred revenue and accumulated deficit is mainly attributable to the change in the timing of revenue recognition for amounts received under the Incyte Collaboration Agreement and the reversal of the cumulative transition adjustment, respectively.

For the years ended December 31, 2019, 2018 and 2017, 60%, 43% and 87%, 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 judgement, 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.

(k) 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 do not currently use derivative financial instruments to manage the risks associated with foreign currency fluctuations. We recorded a foreign currency gain of $0.1 million for the year ended December 31, 2019, a foreign currency loss of $2.2 million for the year ended December 31, 2018, and a foreign currency gain of $1.9 million for the year ended December 31, 2017.

(l) 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 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.

(m) 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 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.

(n) 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 are recognized when they are more likely than not expected to be realized.

(o) Net Loss Per Share

Basic income and loss per common share is 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, 2019, 2018, and 2017, as they would be anti-dilutive:

	Year Ended		
	2019	2018	2017
Warrants	1,400	2,900	4,351
Stock options	27,164	18,614	14,367
Nonvested shares	2,120	2,214	1,314
Series A-1 convertible preferred stock	333	333	333
Series C-1 convertible preferred stock	12,459	18,459	-

(p) 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 indicator of impairment. We operate as two reporting units. ASC 350, *Intangibles, Goodwill and Other* states that if the carrying value of a reporting unit is negative, the second step of the impairment test shall be performed to measure the amount of impairment loss, if any, if qualitative factors indicate that it is more likely than not that a goodwill impairment exists. No goodwill impairment has been recognized for the periods presented.

(q) In-process Research and Development

Acquired in-process research and development ("IPR&D") represents the fair value assigned to research and development assets that have not reached technological feasibility. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value. The revenue and cost projections used to value acquired IPR&D are, as applicable, reduced based on the probability of success of developing a new drug. Additionally, the projections consider the relevant market sizes and growth factors, expected trends in technology, and the nature and expected timing of new product introductions by us and our competitors. The rates utilized to discount the net cash flows to their present value are commensurate with the stage of development of the projects and uncertainties in the economic estimates used in the projections. Upon the acquisition of IPR&D, we complete an assessment of whether our acquisition constitutes the purchase of a single asset or a group of assets. We consider multiple factors in this assessment, including the nature of the technology acquired, the presence or absence of separate cash flows, the development process and stage of completion, quantitative significance and our rationale for entering into the transaction.

If we acquire an asset or group of assets that do not meet the definition of a business under applicable accounting standards, then the acquired IPR&D is expensed on its acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

We review amounts capitalized as acquired IPR&D for impairment at least annually, as of October 31, or whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. When performing our impairment assessment, we have the option to first assess qualitative factors to determine whether it is necessary to estimate the fair value of our acquired IPR&D. If we elect this option and believe, as a result of the qualitative assessment, that it is more-likely-than-not that the fair value of our acquired IPR&D is less than its carrying amount, we estimate the fair value using the same methodology as described above. If the carrying value of our acquired IPR&D exceeds its fair value, then the intangible asset is written-down to its fair value. Alternatively, we may elect to not first assess qualitative factors and immediately estimate the fair value of our acquired IPR&D. No IPR&D impairments were recognized for the years presented.

(r) 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.

(s) Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, Leases (Topic 842) ("ASC 842") which supersedes Topic 840, Leases ("ASC 840"). We adopted ASC 842 on January 1, 2019 using the alternative transition method and recorded a cumulative effect adjustment to beginning retained earnings without restating prior periods. Accordingly, all financial information and disclosures for periods before January 1, 2019 continue to be presented under the requirements of ASC 840. We elected the package of practical expedients, which allowed us to carry forward our historical lease classification, our assessment of whether a contract is or contains a lease and our initial direct costs for any leases that existed prior to adoption of the new standard.

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.

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 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 condensed 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 account for the sublease of space in our main Lexington, Massachusetts facility from the perspective of a lessor. Our sublease is classified as an operating lease. We record 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 condensed consolidated balance sheet.

Impact of Adopting ASC 842 on the Condensed Consolidated Financial Statements

We recorded the following adjustments to our condensed consolidated balance sheet on the date of adoption (in thousands):

	As Reported December 31, 2018	ASC 842 Adjustment	Adjusted January 1, 2019
Condensed Consolidated Balance Sheet Data:			
Operating lease right-of-use assets	$ —	$ 5,687	$ 5,687
Current portion, operating lease liabilities	—	1,510	1,510
Other current liabilities	484	(95)	389
Operating lease liabilities, net of current portion	—	6,216	6,216
Other long-term liabilities	2,773	(1,921)	852
Accumulated deficit	$ (1,177,311)	$ (25)	$ (1,177,336)

The adoption did not have an impact on our condensed consolidated statement of operations or our condensed consolidated statement of cash flows. See Note 15 for additional information regarding our leases.

(t) Recent Accounting Pronouncements

Recently Issued and Adopted

In February 2016, the FASB issued ASC 842 which supersedes ASC 840, Leases. ASC 842 requires lessees to recognize a right-of-use asset and a lease liability on their balance sheets for all leases with terms greater than twelve months. We adopted the new standard on January 1, 2019 and have used the effective date as our date of initial application. See Note 2 (s) and Note 15.

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting (“ASU 2018-07”). The amendments in ASU 2018-07 simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. We adopted the new standard on January 1, 2019. The adoption did not have a material impact on our consolidated financial statements.

Recently Issued, Not Yet Adopted

In January 2017, the FASB issued ASU 2017-04, Intangibles – Goodwill and Other (Topic 350) (“ASU 2017-04”) that will eliminate the requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Instead, an impairment charge will be based on the excess of a reporting unit’s carrying amount over its fair value. The guidance is effective for the Company in the first quarter of fiscal 2023. Early adoption is permitted. We do not anticipate the adoption of this guidance to have a material impact on our consolidated financial statements, absent any goodwill impairment.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"). The amendments in ASU 2018-13 modify the disclosure requirements of fair value measurements. The standard will be effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, with early adoption permitted. Certain disclosures are required to be applied on a retrospective basis and others on a prospective basis. We are currently evaluating the impact of adoption of ASU 2018-13 on our financial statement disclosures.

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606, Revenue from Contracts with Customers, (“ASC 606”) (“ASU 2018-18”). ASU 2018-18 (1) clarifies that certain transactions between collaborative arrangement participants should be accounted for under ASC 606, when the collaborative arrangement participant is a customer in the context of a unit of account, (2) adds unit-of-account guidance in ASC 808 to align with ASC 606 when an entity is assessing whether the collaborative arrangement, or a part of the arrangement, is within the scope of ASC 606, (3) precludes presenting transactions together with revenue when those transactions involve collaborative

arrangement participants that are not directly related to third parties and are not customers. The standard will be effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of adoption of ASU 2018-18 on our consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"). ASU 2019-12 enhances and simplifies multiple aspects of the income tax accounting guidance in ASC 740. The standard will be effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of adoption of ASU 2019-12 on our consolidated financial statements.

No other new accounting pronouncement issued or effective during the year ended December 31, 2019 had or is expected to have a material impact on our consolidated financial statements or disclosures.

(3) Business Acquisitions

4-Antibody

On January 10, 2014, we entered into a Share Exchange Agreement (the "Share Exchange Agreement") providing for our acquisition of all of the outstanding capital stock of Agenus Switzerland Inc. (formerly known as 4-Antibody AG) ("4-AB"), from the shareholders of 4-AB (the "4-AB Shareholders"). The transaction closed on February 12, 2014 (the "Closing Date"). In exchange for their shares, the 4-AB Shareholders received an aggregate of 3,334,079 shares of our common stock paid upon closing and valued at $10.1 million. Contingent milestone payments of up to $40.0 million (the "contingent purchase price consideration"), payable in cash or shares of our common stock at our option, are due to the 4-AB Shareholders as follows: (i) $20.0 million upon our market capitalization exceeding $300.0 million for 10 consecutive trading days prior to the earliest of (a) the fifth anniversary of the Closing Date (b) the sale of the 4-AB or (c) the sale of Agenus; (ii) $10.0 million upon our market capitalization exceeding $750.0 million for 30 consecutive trading days prior to the earliest of (a) the tenth anniversary of the Closing Date (b) the sale of 4-AB, or (c) the sale of Agenus, and (iii) $10.0 million upon our market capitalization exceeding $1.0 billion for 30 consecutive trading days prior to the earliest of (a) the tenth anniversary of the Closing Date, (b) the sale of 4-AB, or (c) the sale of Agenus. We assigned an acquisition date fair value of $9.7 million to the contingent purchase price consideration. During January 2015, the first milestone noted above was achieved. This acquisition provided us with the Retrocyte Display technology platform for the rapid discovery and optimization of fully-human and humanized monoclonal antibodies against a wide array of molecular targets and a portfolio of CPM antibodies.

PhosImmune Inc.

On December 23, 2015 (the "PhosImmune Closing Date"), we entered into a Purchase Agreement with PhosImmune Inc., a privately-held Virginia corporation ("PhosImmune"), the securityholders of PhosImmune (the "PhosImmune Securityholders") and Fanelli Haag PLLC, as representative of the PhosImmune Securityholders providing for the acquisition of all outstanding securities of PhosImmune. On the PhosImmune Closing Date, in exchange for their shares, the PhosImmune Securityholders received $2.5 million in cash and an aggregate of 1,631,521 of our common stock paid upon closing and valued at $7.4 million. Contingent milestone payments up to $35.0 million payable in cash and/or stock at our option are due as follows: (i) $5.0 million upon the closing trading price of our common stock equals or exceeds $8.00 for 60 consecutive trading days prior to the earlier of (a) the fifth anniversary of the PhosImmune Closing Date or (b) the sale of Agenus; (ii) $15.0 million if the closing trading price of our common stock equals or exceeds $13.00 for 60 consecutive trading days prior to the earlier of (a) the tenth anniversary of the PhosImmune Closing Date or (b) the sale of Agenus; and (iii) $15.0 million if the closing trading price of our common stock equals or exceeds $19.00 for 60 consecutive trading days prior to the earlier of (a) the tenth anniversary of the PhosImmune Closing Date or (b) the sale of Agenus. We assigned an acquisition date fair value of $2.5 million to the contingent purchase price consideration.

(4) Goodwill and Acquired Intangible Assets

The following table sets forth the changes in the carrying amount of goodwill for year ended December 31, 2019 (in thousands):

Balance, December 31, 2018	$	22,925
Effect of foreign currency		263
Balance, December 31, 2019	$	23,188

Acquired intangible assets consisted of the following at December 31, 2019 and 2018 (in thousands):

	As of December 31, 2019			
	Amortization period (years)	Gross carrying amount	Accumulated amortization	Net carrying amount
Intellectual Property	7-15 years	$ 16,584	$ (8,044)	$ 8,540
Trademarks	4.5 years	834	(834)	-
Other	2-6 years	572	(553)	19
In-process research and development	Indefinite	1,945	—	1,945
Total		$ 19,935	$ (9,431)	$ 10,504

	As of December 31, 2018			
	Amortization period (years)	Gross carrying amount	Accumulated amortization	Net carrying amount
Intellectual Property	7-15 years	$ 16,509	$ (6,147)	$ 10,362
Trademarks	4.5 years	820	(820)	—
Other	2-6 years	569	(505)	64
In-process research and development	Indefinite	1,912	—	1,912
Total		$ 19,810	$ (7,472)	$ 12,338

The weighted average amortization period of our finite-lived intangible assets is approximately 9 years. Amortization expense for the years ended December 31, 2019, 2018, and 2017 was $2.0 million, $2.0 million and $2.3 million, respectively. Amortization expense related to acquired intangibles is estimated at $1.9 million for each of 2020, 2021 and 2022, $1.4 million for 2023 and $0.3 million for 2024.

The acquired IPR&D asset relates to the six pre-clinical antibody programs acquired in the Agenus Switzerland transaction. 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.

(5) Investments

Cash Equivalents

Cash equivalents consisted of the following as of December 31, 2019 and 2018 (in thousands):

	December 31, 2019		December 31, 2018	
	Cost	Estimated Fair Value	Cost	Estimated Fair Value
Institutional Money Market Funds	$ 55,258	$ 55,258	$ 29,948	$ 29,948

As a result of the short-term nature of our investments, there were minimal unrealized holding gains or losses as of December 31, 2019, 2018 and 2017.

All the investments listed above have been classified as cash equivalents on our consolidated balance sheet as of December 31, 2019 and 2018, respectively.

(6) Property, Plant and Equipment

Property, plant and equipment, net as of December 31, 2019 and 2018 consist of the following (in thousands):

	2019	2018	Estimated Depreciable Lives
Land	$ 2,230	$ 2,230	Indefinite
Building and building improvements	5,624	5,451	35 years
Furniture, Fixtures, and other	6,394	3,984	3 to 10 years
Laboratory and manufacturing equipment	20,880	18,993	4 to 10 years
Leasehold improvements	25,350	24,525	2 to 12 years
Software and computer equipment	8,709	8,001	3 years
	69,187	63,184	
Less accumulated depreciation and amortization	(42,861)	(38,068)	
Total	$ 26,326	$ 25,116	

(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 2016 through 2019. 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 2015 and prior. However, net operating losses from the tax year 2015 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, 2019, we had available net operating loss carryforwards of $646.3 million and $184.9 million for Federal and state income tax purposes, respectively, which are available to offset future Federal and state taxable income, if any, $38.6 million of these Federal net operating loss carryforwards do not expire, while the remaining net operating loss carryforwards expire between 2021 and 2038. Our ability to use these net operating losses is limited by change of control provisions under Internal Revenue Code Section 382 and may expire unused. In addition, we have $8.8 million and $9.4 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 2020 and 2033 and 2020 and 2029, respectively. Additionally, we have $214,000 of state investment tax credits, available to offset future taxable income and expire between 2020 and 2022. We also have foreign income tax net operating loss carryforwards of approximately $1.9 million generated in Switzerland which are available to offset future foreign taxable income, if any, and expire between 2024 and 2026. We also have foreign net operating loss carryforwards, which do not expire, available to offset future foreign taxable income of $7.5 million in the United Kingdom, $8.0 million in Belgium, $55,000 in Ireland, and $289,000 in Hong Kong. The potential impacts of such provisions are among the items considered and reflected in management’s assessment of our valuation allowance requirements.

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, 2019 and 2018 are presented below (in thousands).

	2019	2018
Deferred tax assets:		
U.S. Federal and State net operating loss carryforwards	$ 143,126	$ 182,557
Foreign net operating loss carryforwards	4,096	1,524
Research and development tax credits	16,364	18,507
Share-based compensation	4,774	4,824
Intangible Assets	38,710	36,217
Interest expense carryforward	3,893	6,555
Deferred Revenue	47,456	—
Lease Liability	2,002	—
Other	3,974	4,882
Total deferred tax assets	264,395	255,066
Less: valuation allowance	(262,228)	(254,315)
Net deferred tax assets	2,167	751
Foreign intangible assets	(1,009)	(1,063)
Right of use asset	(1,599)	—
Other	(165)	(406)
Deferred tax liabilities	(2,773)	(1,469)
Net deferred tax liability	$ (606)	$ (718)

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 $7.9 million during the year ended December 31, 2019, while the valuation allowance decreased by $21.9 during the year ended December 31, 2018, respectively.

Income tax benefit was nil for the years ended December 31, 2019, 2018 and 2017. Income taxes recorded differed from the amounts computed by applying the U.S. Federal income tax rate of 21% in 2019 and 2018 and 34% in 2017 to loss before income taxes as a result of the following (in thousands).

	2019	2018	2017
Computed “expected” Federal tax benefit	$ (23,413)	$ (34,029)	$ (41,035)
(Increase) reduction in income taxes benefit resulting from:			
Change in valuation allowance	7,913	24,233	(63,868)
(Decrease) increase due to uncertain tax positions	(64)	7	—
Foreign income inclusion	—	11,089	—
State and local income benefit, net of Federal income tax benefit	4,144	(11,708)	(4,561)
Change in federal tax rate	—	—	104,764
Foreign rate differential	(564)	956	2,084
Change in fair value contingent consideration	1,219	(280)	(1,084)
Other, net	10,765	9,732	3,700
Income tax benefit	$ —	$ —	$ —

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

	2019	2018	2017
Balance, January 1	$ 4,356	$ 4,349	$ 5,278
Increase related to current year positions	122	—	—
Increase (decrease) related to previously recognized positions	(186)	7	—
Decrease related to change in federal tax rate	—	—	(929)
Balance, December 31	$ 4,292	$ 4,356	$ 4,349

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 Liabilities

Accrued liabilities consist of the following as of December 31, 2019 and 2018 (in thousands):

	December 31, 2019	December 31, 2018
Payroll	$ 9,575	$ 8,770
Professional fees	4,314	3,528
Contract manufacturing costs	8,768	5,947
Research services	6,675	5,348
Other	2,000	958
Total	$ 31,332	$ 24,551

(9) Equity

Effective June 19, 2019, our certificate of incorporation was amended to increase the number of authorized shares of common stock from 240,000,000 to 400,000,000.

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 $94.86 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 both our Series C-1 Convertible Preferred Stock and 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 $1.4 million or $44.92 per share, and $1.2 million, or $38.33 per share, at December 31, 2019 and 2018, respectively.

During September 2013, we sold approximately 3,333,000 shares of our common stock and warrants to purchase 1,000,000 shares of our common stock in a registered direct public offering raising net proceeds of approximately $9.5 million, after deducting offering expenses. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase 0.3 of a share of common stock. Subject to certain ownership limitations, the warrants became exercisable beginning 6 months following issuance and will expire five years from the date they become exercisable, at an exercise price of $3.75 per share. The number of shares issuable upon exercise of the warrants and the exercise price of the warrants are adjustable in the event of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The warrants expired unexercised in March 2019.

On February 14, 2017, we entered into an additional Stock Purchase Agreement (the "Additional Stock Purchase Agreement") with Incyte, pursuant to which Incyte purchased 10 million shares of our common stock (the "Additional Shares") at a purchase price of $6.00 per share. Immediately following the transaction, Incyte owned approximately 18.1% of our outstanding shares. Under the Additional Stock Purchase Agreement, Incyte agreed not to dispose of any of the Additional Shares for a period of 12 months and to vote the Additional Shares in accordance with the recommendations of the Company's board of directors in connection with certain

equity incentive plan or compensation matters for a period of 18 months, both provisions have expired. We also agreed to certain registration rights with respect to the Additional Shares. The parties also revised the existing standstill provision to permit Incyte's acquisition of the Additional Shares, but Incyte was precluded from acquiring any additional shares of our voting stock until December 31, 2019.

In March 2017, we issued an additional 373,351 shares of our common stock, valued at approximately $1.5 million, to Iontas in accordance with the terms of the Technology Transfer and License Agreement. Subsequently, we filed, and the SEC declared effective, a registration statement covering the resale of the 530,864 shares of our common stock issued.

On November 9, 2017 we made the final payment under the Asset Purchase Agreement with Celexion, LLC ("Celexion") and each of the members of Celexion. We issued to Celexion 999,317 shares of our common stock based on the preceding 20 trading day average of approximately $4.10 per share. The closing price of our common stock on November 9, 2017 was $3.55 per share. As such, we recorded a gain of approximately $550,000 at issuance. Also, on November 9, 2017, we filed a registration statement covering the sale of the 999,317 shares issued to Celexion. The SEC declared the registration statement effective in January 2018.

In October 2017, we filed, and the SEC declared effective, a Registration Statement on Form S-3 (the "2017 Registration Statement"), covering the offering of up to $250 million of common stock, preferred stock, warrants, debt securities and units. The 2017 Registration Statement included a prospectus covering the offering, issuance and sale of up to 15 million shares of our common stock from time to time in "at-the-market offerings" pursuant to a Controlled Equity Offering℠ sales agreement (the "Sales Agreement") entered into with Cantor Fitzgerald & Co. (the "Sales Agent") on October 30, 2017. Pursuant to the Sales Agreement, sales will be made only upon instructions by us to the Sales Agent, and we cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. On October 18, 2017, we exercised our right under that certain At Market Issuance Sales Agreement by and between us and MLV & Co. LLC, dated as of October 10, 2014 (the "2014 ATM Program") to terminate the 2014 ATM Program, which termination took effect upon the effectiveness of the 2017 Registration Statement. We terminated the Sales Agreement with Cantor Fitzgerald & Co. in May 2018.

In May 2018, we entered into an At Market Issuance Sales Agreement (the "Agreement") with B. Riley FBR, Inc. ("BRFBR") with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, up to 20 million shares of our common stock through BRFBR as our sales agent. The issuance and sale of the shares under the Agreement are made pursuant to our 2017 Registration Statement. In December 2018, we filed a prospectus supplement with the SEC in connection with the offer and sale of up to an additional 30 million shares from time to time pursuant to the Agreement. During the year ended December 31, 2019, no shares of our common stock were sold in at-the-market offerings under the Agreement.

On December 20, 2018, in connection of the Gilead Collaboration Agreement we also entered into the Stock Purchase Agreement (the "Gilead Stock Purchase Agreement") with Gilead Sciences, Inc. ("Gilead"), pursuant to which Gilead purchased approximately 11.11 million shares of our common stock (the "Shares") for an aggregate purchase price of $30.0 million, or $2.70 per Share. Gilead owned approximately 8.5% of the outstanding shares of our common stock after such purchase. Under the Stock Purchase Agreement, Gilead has agreed (i) not to dispose of any of the Shares for a period of 12 months, (ii) to certain standstill provisions that generally preclude it from acquiring more than 15% of our outstanding voting stock after taking into account the purchase of the Shares and (iii) to vote the Shares in accordance with the recommendations of our board of directors in connection with certain equity incentive plan or compensation matters for a period of 12 months. In the Gilead Stock Purchase Agreement, we agreed to register the Shares for resale under the Securities Act of 1933, and in October 2019 we filed a registration statement with the SEC accordingly.

(10) Series C-1 Convertible Preferred Stock

In October 2018, we entered into a Stock Purchase Agreement with certain institutional investors (the "Purchasers"), pursuant to which we issued and sold an aggregate of 18,459 shares of Series C-1 Convertible Preferred Stock (the "C-1 Preferred Shares"), at a purchase price of $2,167 per share. Each C-1 Preferred Share is convertible into 1,000 shares of our common stock at an initial conversion price of $2.167 per share of common stock, which represents a 10% premium over the prior day's closing price on Nasdaq. The aggregate purchase price paid by the Purchasers C-1 Preferred Shares was approximately $40,000,000. We received net proceeds of $39.9 million after offering expenses.

The Stock Purchase Agreement requires us to register the resale of the Common Stock underlying the C-1 Preferred Shares (the "Conversion Shares"), which occurred in the fourth quarter of 2018.

The C-1 Preferred Shares have been classified as temporary or mezzanine equity on our Consolidated Balance Sheets in accordance with U.S. GAAP as the C-1 Convertible Preferred Shares contain deemed liquidation rights that are a contingent redemption feature not solely in the Company's control.

Conversion

The C-1 Preferred Shares are convertible at the option of the stockholder into the number of shares of Common Stock determined by dividing the stated value of the C-1 Preferred Shares being converted by the conversion price of $2.167, subject to adjustment for stock splits, reverse stock splits and similar recapitalization events. We will not effect any conversion of the C-1 Preferred Shares, and a stockholder shall not have the right to convert any portion of the C-1 Preferred Shares, to the extent that, after giving effect to the conversion such stockholder would beneficially own in excess of 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock pursuant to a notice of conversion (the "Beneficial Ownership Limitation"). By written notice to us, a Purchaser may from time to time increase or decrease the Beneficial Ownership Limitation percentage not in excess of 19.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of the shares of Common Stock pursuant to a notice of conversion; provided that any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the us.

In the year ended December 31, 2019, holders of shares of Series C-1 Preferred Stock converted a portion of such shares into 6.0 million shares of our common stock. As of December 31, 2019, 12,459 shares of Series C-1 Convertible Preferred Stock remained outstanding.

Voting

The C-1 Preferred Shares do not have voting rights. However, as long as any Preferred Shares are outstanding, we may not, without the affirmative vote of the holders of a majority of the then-outstanding C-1 Preferred Shares, (i) alter or change adversely the powers, preferences or rights given to the C-1 Preferred Shares or alter or amend the Certificate of Designation, amend or repeal any provision of, or add any provision to, our Certificate of Incorporation or bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the C-1 Preferred Shares, regardless of whether any of the foregoing actions shall be by means of amendment to the Certificate of Incorporation or by merger, consolidation or otherwise, (ii) issue further C-1 Preferred Shares or increase or decrease (other than by conversion) the number of authorized C-1 Preferred Shares, or (iii) enter into any agreement with respect to any of the foregoing.

Dividends

The C-1 Preferred Shares are entitled to receive dividends equal (on an as-if-converted-to-Common-Stock-basis, without regard to the Beneficial Ownership Limitation) to and in the same form, and in the same manner, as dividends (other than dividends in the form of Common Stock) actually paid on shares of Common Stock when, and if paid.

Liquidation

In any liquidation or dissolution of the Company, the C-1 Preferred Shares are entitled to participate in the distribution of assets, to the extent legally available for distribution, on a pari passu basis with the Common Stock.

Redemption

If at any time while the C-1 Preferred Shares are outstanding, a) the Company effects any merger, consolidation, stock sale or other business combination (other than such a transaction in which the Company is the surviving or continuing entity and its common stock is not exchanged for or converted into other securities, cash or property), b) the Company effects any sale of all or substantially all of its assets in one transaction or a series of related transactions, c) any tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which more than 50% of the common stock not held by the Company or is exchanged for or converted into other securities, cash or property, or d) the Company effects any reclassification of the common stock or any compulsory share exchange pursuant (other than as a result of a dividend, subdivision or combination covered above) to which the common stock is effectively converted into or exchanged for other securities, cash or property, (in any such case, a "Fundamental Transaction") then, upon any subsequent conversion of the C-1 Preferred Shares, the holder shall have the right to receive, in lieu of the right to receive shares of common stock, for each share of common stock that would have been issued upon such conversion immediately prior to the occurrence of such Fundamental Transaction, the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the equivalent amount of common stock.

Registration Payment Arrangement

We were required to file a registration statement covering the resale of the full number of shares no later than 30 days after the closing of the agreement and must use commercially reasonable efforts to cause the registration statement to be declared effective no later than 90 days after the closing date (no review by the SEC) or in the event of a review by the SEC, 120 days after the closing date. We filed, and the SEC declared effective this registration statement during 2018. If the registration statement is not maintained we must pay to each holder 1.0% of the holder's ratable interest in the aggregate purchase price on the day of the filing/maintenance failure and on every thirtieth day thereafter until the filing/maintenance failure is cured, up to a maximum of 6% (six months). We

currently deem the likelihood that we will ever be required to make payments under this arrangement to be remote, and as such no contingent liability has been recorded in our Consolidated Balance Sheets.

(11) Share-based Compensation Plans

Our 1999 Equity Incentive Plan, as amended (the "1999 EIP") authorized awards of incentive stock options within the meaning of Section 422 of the Internal Revenue Code (the "Code"), non-qualified stock options, non-vested (restricted) stock, and unrestricted stock for up to 2.0 million shares of common stock (subject to adjustment for stock splits and similar capital changes and exclusive of options exchanged at the consummation of mergers) to employees and, in the case of non-qualified stock options, non-vested (restricted) stock, and unrestricted stock, to consultants and directors as defined in the 1999 EIP. The plan terminated on November 15, 2009.

On March 12, 2009, our Board of Directors adopted, and on June 10, 2009, our stockholders approved, our 2009 Equity Incentive Plan (the "2009 EIP"). The 2009 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, for up to 29.2 million shares of our common stock (subject to adjustment in the event of stock splits and other similar events). As of December 31, 2019, no shares remain available for issuance under the 2009 EIP.

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"). 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 40.2 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 1999 EIP, the 2009 EIP and the 2019 EIP. No awards will be granted under the 2019 EIP after June 19, 2029.

On March 12, 2009, our Board of Directors adopted, and on June 10, 2009, our stockholders approved, the 2009 Employee Stock Purchase Plan (the "2009 ESPP") to provide eligible employees the opportunity to acquire our common stock in a program designed to comply with Section 423 of the Code. There were 166,666 shares of common stock reserved for issuance under the 2009 ESPP. Rights to purchase common stock under the 2009 ESPP were granted at the discretion of the Compensation Committee, which determined the frequency and duration of individual offerings under the plan and the dates when stock may have been purchased. Eligible employees participated voluntarily and may have withdrawn from any offering at any time before the stock is purchased. Participation terminated automatically upon termination of employment. The purchase price per share of common stock in an offering was 85% of the lesser of its fair value at the beginning of the offering period or on the applicable exercise date and may have been paid through payroll deductions, periodic lump sum payments, the delivery of our common stock, or a combination thereof. Unless otherwise permitted by the Board of Directors, no participant may have acquired more than 3,333 shares of stock in any offering period. No participant was allowed to purchase shares under the 2009 ESPP if such employee would own or would have been deemed to own stock possessing 5% or more of the total combined voting power or value of the Company. The 2009 ESPP plan terminated on June 10, 2019.

In the second quarter of 2019, our Board of Directors adopted 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. There are 500,000 shares reserved for issuance under the 2019 ESPP. The 2019 ESPP is subject to approval by our stockholders.

Our Director's 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. There are 425,000 shares of our common stock reserved for issuance under this plan. As of December 31, 2019, 72,081 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 412,435 units, each representing a share of our common stock at a weighted average common stock price of $4.52, had been credited to participants' stock accounts as of December 31, 2019. 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. There are 1,500,000 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:

	2019	2018	2017
Expected volatility	64%	64%	65%
Expected term in years	5	6	4
Risk-free interest rate	1.8%	2.8%	1.7%
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 2019 is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	18,613,822	$ 4.15		
Granted	11,579,119	3.00		
Exercised	(466,940)	3.15		
Forfeited	(1,186,465)	3.20		
Expired	(1,375,389)	5.08		
Outstanding at December 31, 2019	27,164,147	3.67	7.65	$ 19,782,605
Vested or expected to vest at December 31, 2019	27,164,147	3.67	7.65	$ 19,782,605
Exercisable at December 31, 2019	11,785,971	$ 4.33	5.83	$ 3,677,098

The weighted average grant-date fair values of options granted during the years ended December 31, 2019, 2018, and 2017, was $1.77, $1.23, and $1.97, respectively.

The aggregate intrinsic value in the table above represents the difference between our closing stock price on the last trading day of fiscal 2019 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, 2019 (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, 2019, 2018, and 2017, determined on the dates of exercise, was $385,000, $399,000, and $132,000, respectively.

During 2019, 2018, and 2017, 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 March 2, 2018, August 6, 2018 and December 31, 2018. In March 2018, our Board of Directors approved certain awards subject to forfeiture in the event stockholder approval was not obtained to increase the shares available under our 2009 EIP. This approval was obtained in June 2018. Accordingly, these awards have a grant date of June 2018, with an exercise price as of the date the Board of Director's approved the awards in March 2018. In August 2018, our Board of Directors approved certain awards. However, the awards were not communicated until October 2018. Accordingly, these awards have a grant date of October 2018 with an exercise price as of the date the Board of Director's approved the awards in August 2018. In December 2018, our Board of Directors approved certain awards subject to forfeiture in the event stockholder approval was not obtained for our 2019 EIP. This approval was obtained in June 2019. Accordingly, these awards have a grant date of June 2019, with an exercise price as of the date the Board of Director's approved the awards in December 2018.

As of December 31, 2019, there was $20.3 million of unrecognized share-based compensation expense related to stock options granted to employees, consultants and directors for which, if all milestones are achieved, will be recognized over a weighted average period of 2.3 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 2019 is presented below:

	Nonvested Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2018	2,213,967	$ 3.20
Granted	737,682	2.98
Vested	(129,675)	2.76
Forfeited	(702,163)	4.14
Outstanding at December 31, 2019	2,119,811	$ 2.84

As of December 31, 2019, there was $3.9 million of unrecognized share-based compensation expense related to these non-vested shares for which, if all milestones are achieved, will be recognized over a period of 1.7 years. The total intrinsic value of shares vested during the years ended December 31, 2019, 2018, and 2017, was $357,000, $242,000, and $3.8 million, respectively.

Cash received from option exercises and purchases under our 2009 ESPP for the years ended December 31, 2019, 2018, and 2017, was $1.6 million, $1.2 million, and $1.0 million, respectively. We issue new shares upon option exercises, purchases under our 2009 ESPP and 2019 ESPP, vesting of non-vested stock and under the Director's Deferred Compensation Plan. During the years ended December 31, 2019, 2018, and 2017, 84,703 shares, 140,313 shares, and 121,183 shares, were issued under the 2009 ESPP, respectively. During the years ended December 31, 2019, 2018, and 2017, 129,675 shares, 53,050 shares, and 1.1 million shares, respectively, were issued as a result of the vesting of non-vested stock.

The impact on our results of operations from share-based compensation for the years ended December 31, 2019, 2018, and 2017, was as follows (in thousands).

	Year Ended		
	2019	2018	2017
Research and development	$ 3,873	$ 3,498	$ 6,159
General and administrative	6,019	4,127	6,270
Total share-based compensation expense	$ 9,892	$ 7,625	$ 12,429

(12) License, Research, and Other Agreements

On December 5, 2014, Agenus Switzerland, 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 Agenus Switzerland 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 and Agenus Switzerland 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, Agenus Switzerland made an upfront payment of $1.0 million to Ludwig. The December 2014 license agreement also obligates Agenus Switzerland 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 and/or Agenus Switzerland 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. During the year ended December 31, 2017, we paid a percentage of sublicensing income totaling $2.0 million to Ludwig under the license agreements. No payments were made during the years ended December 31, 2018 and 2019, respectively. 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 Agenus Switzerland or us (as applicable) for convenience upon 90 days' prior written notice. The license agreements also contain customary representations and warranties, mutual indemnification, confidentiality and arbitration provisions.

In connection with the December 2015 acquisition of PhosImmune, we obtained exclusive rights to a portfolio of patent applications and one issued patent relating to phosphopeptide tumor targets (PTTs) under a patent license agreement with the University of Virginia ("UVA"). The UVA license gives us exclusive rights to develop and commercialize the PTT technology and an exclusive option to license any further PTT technology arising from ongoing research at UVA until December 2018. Under the license agreement, we will pay low to mid-single digit running royalties on net sales of PTT products, and a modest flat percentage of sublicensing income. In addition, we may be obligated to make milestone payments of up to $2.7 million for each indication of a licensed PTT product to complete clinical trials and achieve certain sales thresholds. If we fail to meet certain diligence milestones, we may also be required to pay penalties in excess of $150,000. The term of the UVA license agreement ends when the last of the licensed patents expires or becomes no longer valid. As of March 2020, the last granted patent that is licensed to us by UVA will expire in late 2033, and there are currently pending patent applications that, if granted, will not expire until mid-2037. The UVA license agreement may be terminated as follows: (i) by UVA in connection with our bankruptcy or cessation of business relating to the licensed technology, (ii) by UVA if we commit a material, uncured breach or (iii) by us for our convenience on 180 days written notice.

We have entered into various 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 $319.8 million over the term of the studies. For the years ended December 31, 2019, 2018, and 2017, $87.7 million, $41.5 million, and $35.8 million, respectively, have been expensed in the accompanying consolidated statements of operations related to these third-party providers. Through December 31, 2019, we have expensed $254.0 million as research and development expenses and $239.6 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

Gilead Collaboration Agreement

On December 20, 2018, we entered into a series of agreements with Gilead focused on the development and commercialization of up to five novel immuno-oncology therapies. Pursuant to the terms of the license agreement, the option and license agreements and the stock purchase agreement we entered into with Gilead (each defined below and, collectively, the "Gilead Collaboration Agreements"), at the closing of the transaction on January 23, 2019 (the "Effective Date"), we received an upfront cash payment from Gilead of $120.0 million and Gilead made a $30.0 million equity investment in Agenus. We are also eligible to receive up to $1.7 billion in aggregate potential milestones.

License Agreement

Pursuant to the terms of a license agreement between the parties (the "License Agreement"), we granted Gilead an exclusive, worldwide license under certain of our intellectual property rights to develop, manufacture and commercialize our preclinical bispecific antibody, AGEN1423 (now GS-1423), in all fields of use. Pursuant to the License Agreement, Gilead is responsible for all of the development, manufacturing and commercialization costs for any products that Gilead may develop under the License Agreement. In addition, Gilead also received the right of first negotiation for two of our undisclosed antibody programs. The License Agreement will continue until all of Gilead's applicable payment obligations under the License Agreement have been performed or have expired, or the agreement is earlier terminated. Under the terms of the License Agreement, each party has the right to terminate the agreement for material breach by, or insolvency of, the other party. Gilead may also terminate the License Agreement in its entirety, or on a product-by-product or country-by-country basis, for convenience upon ninety (90) days' notice. Pursuant to the terms of the License Agreement, we are eligible to receive potential development and commercial milestones of up to $552.5 million in the aggregate, as well as tiered royalty payments on aggregate net sales ranging from the high single digit to mid-teen percent, subject to certain reductions under certain circumstances as described in the License Agreement. We filed an investigational new drug ("IND") application for AGEN1423 (now GS-1423) in February 2019, and the IND was accepted by the FDA in March 2019.

Option and License Agreements

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. Gilead is 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 are responsible for the costs and expenses related to the development of the Option Programs. After Gilead's exercise of a License Option, if at all, Gilead would be responsible for all development, manufacturing and commercialization activities relating to the relevant Option Program at Gilead's cost and expense.

During the Option Period, we are eligible to receive milestones of up to $30.0 million in the aggregate. If Gilead exercises a License Option, it would be required to pay an upfront license exercise fee of $50.0 million for each License Option that is exercised. Following any exercise of a License Option, we would be eligible to receive additional development and commercial milestones of up to $520.0 million in the aggregate for each such Option Program, as well as tiered royalty payments on aggregate net sales. For either, but not both, of the Option Programs, we will have the right to opt-in to share Gilead's development and commercialization costs in the United States for such Option Program in exchange for a profit (loss) share on a 50:50 basis and revised milestone payments. If we opt-in under one Option and License Agreement, our right to opt-in under the other Option and License Agreement automatically terminates. We filed INDs for each of AGEN1223 and AGEN2373 in 2019, and both assets are now in clinical development.

Unless earlier terminated, each Option and License Agreement will continue until the earlier of (i) the expiration of the Option Period, without Gilead's exercise of the License Option; and (ii) the date all of Gilead's applicable payment obligations under the Option and License Agreement have been performed or have expired. Under the terms of each Option and License Agreement, we and Gilead each have the right to terminate the agreement for material breach by, or insolvency of, the other party. Gilead may also terminate an Option License Agreement in its entirety, or on a product-by-product or country-by-country basis for convenience upon ninety (90) days' notice.

Stock Purchase Agreement

Pursuant to the terms of a stock purchase agreement between the parties (the "Stock Purchase Agreement"), Gilead purchased 11,111,111 shares of Agenus common stock (the "Shares") for an aggregate purchase price of $30.0 million, or $2.70 per share. Gilead owned approximately 8.5% of the outstanding shares of Agenus common stock after such purchase. Under the Stock Purchase Agreement, Gilead has agreed (i) not to dispose of any of the Shares for a period of 12 months, (ii) to certain standstill provisions that generally preclude it from acquiring more than 15% of Agenus' outstanding voting stock after taking into account the purchase of the Shares and (iii) to vote the Shares in accordance with the recommendations of the Agenus board of directors in connection with certain equity incentive plan or compensation matters for a period of 12 months. In the Stock Purchase Agreement we agreed to register the Shares for resale under the Securities Act of 1933, and in October 2019 we filed a registration statement with the SEC accordingly.

Collaboration Revenue

We identified the following performance obligations under the Gilead Collaboration Agreements: (1) the license that we granted to Gilead pursuant to the License Agreement (the "AGEN1423 License"), (2) our obligation to complete manufacturing and know-how tech transfer activities to Gilead pursuant to the License Agreement to enable Gilead or its third party contract manufacturing organization to manufacture the licensed antibody (the "AGEN1423 Technology Transfer"), (3) our obligation to advance development of AGEN1223 to the option exercise point pursuant to the AGEN1223 Option and License Agreement (such development activities, the "AGEN1223 R&D Services"), and (4) our obligation to advance development of AGEN2373 to the option exercise point pursuant to the AGEN2373 Option and License Agreement (such development activities, the "AGEN2373 R&D Services").

We determined that the AGEN1423 License was both capable of being distinct and distinct within the context of the contract given both the advanced stage of development and that the IND was anticipated to be accepted within a short period of time after the Effective Date. Gilead can begin deriving benefit from the license prior to the AGEN1423 Technology Transfer being completed. The technology transfer plan includes an extensive list of items to be transferred over time and is separate from the transfer of the AGEN1423 License which occurred at contract inception. As a result, we concluded that the AGEN1423 License and AGEN1423 Technology Transfer are separate performance obligations.

We considered whether the AGEN1223 R&D Services and AGEN2373 R&D Services were distinct from one another and from the performance obligations related to AGEN1423. We determined that the research and development services related to each antibody were both capable of being distinct and distinct within the context of the contract given that each program is governed by a separate option agreement with a separate development plan. The services performed to develop each program are independent of one

another, and the antibodies are in different stages of development. We concluded that the AGEN1223 R&D Services and AGEN2373 R&D Services 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 license and research and development fees totaling $120.0 million would be included in the total transaction price. In addition to the fixed consideration, the variable consideration milestones related to IND acceptance for each of the three antibodies was also included in the transaction price. We determined that based on the likelihood of the triggering event occurring for the acceptance of each IND filling, the most likely amount for each of the three milestones was the stated value, totaling $22.5 million. The variable consideration related to each performance obligation will be allocated entirely to that specific performance obligation. The remaining fixed consideration will be allocated using the relative standalone selling price method.

We determined the estimated standalone selling price of the AGEN1423 License by applying a risk adjusted, net present value, estimate of future cash flow approach. We determined the estimated standalone selling price of the AGEN1423 Technology Transfer, and AGEN1223 R&D Services and AGEN2373 R&D Services by using the estimated costs of satisfying these performance obligations, plus an appropriate margin for such services.

Revenue attributable to the AGEN1423 License was recognized at a point-in-time, upon delivery of the license to Gilead at the Effective Date. The AGEN1423 Technology Transfer, AGEN1223 R&D Services and AGEN2373 R&D Services are satisfied over time and revenue attributable to these performance obligations 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 our performance obligations to Gilead. A cost-based input method of revenue recognition requires management to make estimates of costs to complete our performance obligations. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete our performance obligations will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

For the year ended December 31, 2019, we recognized $86.1 million of license and collaboration revenue related to the Gilead Collaboration Agreement. This amount included $20.6 million of the transaction price recognized based on the partial satisfaction of the over time performance obligations as of period end.

We expect to recognize deferred research and development revenue of $28.7 million and $27.7 million in 2020 and 2021, respectively, related to performance obligations that are unsatisfied or partially unsatisfied as of December 31, 2019.

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 determined that the license of AGEN1884 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 AGEN1884. We also determined that the clinical supply of AGEN1884 was both capable of being distinct and distinct within the context of the contract as it was considered a readily available resource in the market.

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 the license totaling $10.0 million would be included in the total transaction price. We concluded that the combined standalone selling price of the license approximated the $10.0 million upfront fee and as such the full amount will be recognized at a point-in-time, upon delivery of the license to UroGen at contract inception. We will not estimate the transaction price in order to recognize the revenue related to the AGEN1884 supply due to the “as invoiced” practical expedient.

For the year ended December 31, 2019, we recognized $10.0 million of license and collaboration revenue related to the UroGen License Agreement.

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, but we sold these royalty rights to HCR in January 2018 pursuant to the HCR Royalty Purchase Agreement (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.

We assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, GSK, is a customer. We identified the following performance obligations under the contract: (1) an exclusive license to QS-21 in the specified field and related technology transfer; and (2) and exclusive license to QS-21 in an additional field.

We determined that the fixed payments of $19.3 million constituted all of the consideration to be included in the transaction price and to be allocated to the performance obligations based on their relative stand-alone selling prices. The fixed upfront consideration is recognized under ASC 606 based on when control of the combined performance obligation is transferred to the customer, which corresponds with the service period (through December 2014). At contract inception, the milestones of $5.0 million had been excluded from the transaction price, as we could not conclude that it was probable a significant reversal would not occur. Event driven milestones are a form of variable consideration as the payments are variable based on the occurrence of future events. As part of its estimation of the amount, we considered numerous factors, including that receipt of the milestones is outside of our control and contingent upon success in future clinical trials and the licensee's efforts. Recognition of event driven milestones should be recognized when the variable consideration is able to be estimated. As of December 31, 2017, all milestones had been received, and therefore recognized.

Any consideration related to royalties will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to GSK and therefore have also been excluded from the transaction price.

For the year ended December 31, 2019, we recognized $15.1 million in royalty sales milestone revenue and $30.4 million in non-cash royalty revenue. For the year ended December 31, 2018, we recognized $17.3 million in non-cash royalty revenue. For the year ended December 31, 2017, we recognized $1.0 million in research and development revenue related to the achievement of a milestone.

The cumulative impact of changing the timing of revenue recognition for the GSK License and Amended GSK Supply Agreements as of January 1, 2018 was a decrease to stockholders' deficit of approximately $2.5 million and a corresponding decrease in deferred revenue of $2.5 million for the portion of the upfront fee creditable toward future royalties, as described above. This amount was included in the transition adjustment, as under ASC 606 it would have been recognized as revenue in March 2012, at the time of the amendment.

Merck Collaboration and License Agreement

During the quarter ended June 30, 2014, we entered into a collaboration and license agreement with Merck to discover and optimize fully-human antibodies against two undisclosed cancer targets using the Retrocyte Display®. Under this agreement, Merck is responsible for the clinical development and commercialization of antibodies generated under the collaboration. There are no unsatisfied performance obligations relating to this contract. Pursuant to the XOMA Royalty Purchase Agreement (see Note 17), we sold to XOMA 33% of the future royalties and 10% of the future milestones that we are entitled to receive from Merck, and we remain

eligible to receive from Merck approximately $85.5 million in potential payments associated with the completion of certain clinical, regulatory and commercial milestones, as well as 67% of all future royalties on worldwide product sales.

For the year ended December 31, 2019, no revenue was recognized. For each of the years ended December 31, 2018 and 2017, we recognized $4.0 million in research and development revenue related to the achievement of milestones.

The adoption of ASC 606 did not have an impact on the Merck collaboration and license agreement.

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 CPM 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.

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. As of December 31, 2018, we remain eligible to receive up to $450.0 million in future potential development, regulatory and commercial milestones across all programs in the collaboration, as well as 67% of all future royalties on worldwide product sales.

On January 9, 2015, we also entered into the Stock Purchase Agreement with Incyte Corporation whereby, for an aggregate purchase price of $35.0 million, Incyte purchased approximately 7.76 million shares of our common stock.

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. Incyte is 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 are 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 will also have 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. For each additional program beyond GITR, OX40, TIM-3 and LAG-3 that the parties elect to bring into the collaboration, we will have the option to designate it as a profit-share product or a royalty-bearing product.

The Collaboration Agreement will continue as long as (i) any product is being developed or commercialized or (ii) the discovery period remains in effect. Incyte may terminate the Collaboration Agreement or any individual program for convenience upon 12 months' notice. The Collaboration Agreement may also be terminated by either party upon the occurrence of an uncured material breach of the other party or by us if Incyte challenges patent rights controlled by us. In addition, either party may terminate the Collaboration Agreement as to any program if the other party is acquired and the acquiring party controls a competing program.

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. Should any of those programs be successfully developed by a party, the other party will be eligible to receive the same milestone payments as the royalty-bearing programs and royalties at a 15% rate on global net sales. 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 gives 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.

In February 2017, we also entered into an Additional Stock Purchase Agreement with Incyte, pursuant to which Incyte purchased 10 million shares of our common stock at a purchase price of $6.00 per share.

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

Collaboration Revenue

We identified the following performance obligations under the Incyte Collaboration Agreement, as amended: (1) combined license and related research and development ("R&D") services to a GITR antibody, (2) combined license and related R&D services to an OX40 antibody, (3) combined license and related R&D services to a TIM-3 antibody, (4) combined license and related R&D services to a LAG-3 antibody, (5) combined license and related R&D services to a TIGIT antibody, (6) combined license and related R&D services to a first undisclosed target, (7) combined license and related R&D services to a second undisclosed target, and (8) the option to license certain other mutually agreed-upon antibodies combined with related R&D Services ("Assumed Project Options Development"). Each of these performance obligations consists of a license or option to a license and related R&D services through the filing of an IND for each antibody candidate.

We concluded that the licenses could be used with other readily available resources if the know-how was also transferred with the license; however, our knowledge and experience is necessary for further development of the licensed antibodies. Therefore, we determined that each of the licensed antibodies and the related developmental R&D services should be treated as a combined performance obligation. We also evaluated whether the Assumed Project Options Development was a material right. At contract inception Incyte paid us a nonrefundable access fee for the ability to exercise the option and bring additional targets into the program. Both we and Incyte have the ability to explore targets and, if mutually agreed upon, convert those targets into assumed projects for no additional license fee. We concluded that Assumed Project Options Development represents a material right and is therefore a performance obligation.

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 the $10.0 million license fee and $15.0 million project access fee would be included in the total transaction price of $25.0 million. This amount was then allocated to the performance obligations on a relative stand-alone selling price basis.

The estimated variable consideration to be recognized for developmental R&D services and related reimbursable expenses ("Development Costs") was determined based on the forecasted amounts in the research plan that had been approved by the both parties via the joint steering committee ("JSC"). Under the Agreement, Development Costs related to Profit-Sharing products are split equally between us and Incyte. Therefore, our expected revenue is 50% of the costs of these programs. Based on review of the budgets presented at the JSC meetings, as well as costs of previous R&D projects, we expected the total development costs over the term of the contract would be $43.4 million. This amount was allocated entirely to the distinct R&D services that forms part of each performance obligation.

We determined that the transaction price of the Collaboration Agreement was $75.2 million as of December 31, 2019, a decrease of $3.4 million from the transaction price of $78.6 million as of December 31, 2018. In order to determine the transaction price, we evaluated all the payments to be received during the duration of the contract. We determined that the fixed upfront license fee and project access fee of $10.0 million and $15.0 million, respectively, and the $50.2 million of actual and estimated variable consideration for development costs (including R&D services) and milestones constituted consideration to be included in the transaction price, which is allocated among the performance obligations.

For payments made to Incyte related to their work performed on profit-sharing programs, we considered that we will receive a benefit through the performance of a series of distinct R&D services by Incyte. Additionally, the R&D services are being provided by Incyte at fair value. Therefore, the amount paid to Incyte represents the fair value of the services performed, and no excess will be

allocated as a reduction of the transaction price. We will record any consideration paid to Incyte in the same manner that we would purchases for other vendors, classified as R&D expense.

In summary, each of the performance obligations includes a license or option to a license, and respective R&D services that will be performed over time from program initiation through the filing of an IND with respect to each antibody candidate. We have determined that the combined performance obligation is satisfied over time, and that the input method should be applied for all performance obligations that have consideration allocated to them. The cost-cost measure will be applied based on the percentage of completion of R&D services provided during the period compared to the respective budget. We believe this is the best measure of progress because other measures do not reflect how we transfer our performance obligation to Incyte. We will recognize the fixed consideration allocated to each performance obligation over time as the related R&D services are being performed using the input of R&D costs incurred over total R&D costs expected to be incurred through IND filing, beginning on the date a license is granted. A cost-based input method of revenue recognition requires management to make estimates of costs to complete our performance obligations. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete our performance obligations will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

We considered the nature of the arrangement between Incyte and us in evaluating the classification of the payments to be received under the cost-sharing arrangement. We do not currently have any commercial products available for sale. Our primary operations to date have included research and development activities, licensing intellectual property and performing R&D services for external parties. Accordingly, arrangements such as this represent our ongoing business operations. Therefore, we have concluded that payments received from Incyte under the cost-sharing arrangement represent payments made to us as part of our on-going operations and should be classified as revenue as such amounts are earned.

For the year ended December 31, 2019, we recognized approximately $3.7 million of license and collaboration revenue. This amount included $2.0 million of the transaction price for the Incyte Collaboration Agreement recognized based on proportional performance and $1.7 million for research and development services. For the year ended December 31, 2018, we recognized approximately $15.5 million of license and collaboration revenue. This amount included $1.3 million of the transaction price for the Incyte Collaboration Agreement recognized based on proportional performance, $10.0 million for the achievement of milestones and $4.2 million for research and development services. For year ended December 31, 2017, we recognized approximately $37.3 million of research and development revenue.

The cumulative impact of the adoption of ASC 606 for the Incyte Collaboration Agreement as of January 1, 2018 was a decrease to stockholders' deficit of approximately $6.4 million and a corresponding decrease in deferred revenue of $6.4 million.

Disaggregation of Revenue

The following table presents revenue (in thousands) for years ended December 31, 2019, 2018 and 2017, 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, 2019		
	United States	Europe	Total
Revenue Type			
Research and development services	$ 1,707	$ —	$ 1,707
License fees	75,500	—	75,500
Royalty sales milestone	15,100	—	15,100
Manufacturing services	3,337	—	3,337
Recognition of deferred research and development revenue	22,638	—	22,638
Recognition of deferred grant revenue	652	690	1,342
Non-cash royalties and milestones	30,424	—	30,424
	$ 149,358	$ 690	$ 150,048

	Year ended December 31, 2018		
Revenue Type			
Research and development services	$ 4,150	$ —	$ 4,150
License and collaboration milestones	10,000	4,000	14,000
Recognition of deferred research and development revenue	1,325	—	1,325
Non-cash royalty revenue	17,309	—	17,309
	$ 32,784	$ 4,000	$ 36,784

	Year ended December 31, 2017		
Revenue Type			
Research and development services	$ 14,615	$ —	$ 14,615
License and collaboration milestones	21,000	3,994	24,994
Recognition of deferred research and development revenue	3,100	—	3,100
Grant revenue	168	—	168
	$ 38,883	$ 3,994	$ 42,877

Contract Balances

Contract assets primarily relate to our rights to consideration for work completed in relation to our R&D services performed but not billed at the reporting date. The contract assets are transferred to the 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. The 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 R&D 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 assets and contract liabilities from contracts with customers (in thousands):

Year ended December 31, 2019	Balance at beginning of period	Additions	Deductions	Balance at end of period
Contract assets:				
Unbilled receivables from collaboration partners	$ -	$ -	$ -	$ -
Contract liabilities:				
Deferred revenue	$ 2,052	$ 77,000	$ (22,638)	$ 56,414

The change in contract liabilities is primarily related to the addition of $77.0 million of deferred revenue from the Gilead Collaboration Agreement, offset by the recognition of $20.6 million of revenue related to this same agreement and $2.0 million of revenue related to the Incyte Collaboration Agreement during the year ended December 31, 2019. Deferred revenue related to the Gilead Collaboration Agreement of $56.4 million as of December 31, 2019, which was comprised of the $142.5 million initial transaction price, less $86.1 million of license and collaboration revenue recognized from the effective date of the contract, will be recognized as the combined performance obligation is satisfied.

We also recorded a $1.2 million receivable as of December 31, 2019 for research and development and manufacturing services provided.

In the year ended December 31, 2019, 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

Our Audit and Finance Committee approved a charitable contribution to the Children of Armenia Fund ("COAF") of up to $125,000 for 2019. Dr. Garo H. Armen, our CEO, is the founder and chairman of COAF. The 2019 charitable contribution was comprised of a cash component and a non-cash component. The cash component was $43,000, which we paid in quarterly installments. The non-cash component was $50,000, which was the estimated value of a portion of office space made available to COAF employees.

We also consider our transactions with Incyte and Gilead, as disclosed in Note 13, to be related party transactions.

(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, facilities in Berkeley, California, for manufacturing and corporate offices and facilities in Charlottesville, Virginia and Cambridge, United Kingdom for research and development and corporate offices. We have subleased a small portion of the space in our main Lexington facility for part of the associated head lease. These agreements expire at various times between 2020 and 2030, with options to extend certain of the leases.

We also have finance lease agreements for equipment used in our research and development and manufacturing activities which expire in 2020.

Lease information related to the adoption of ASC 842

The components of lease cost recorded in our condensed consolidated statement of operations were as follows (in thousands):

	Year ended December 31, 2019
Operating lease cost	$ 2,551
Finance lease cost	221
Variable lease cost	1,414
Sublease income	(561)
Net lease cost	$ 3,625

Variable lease cost for the year ended December 31, 2019, primarily related to common area maintenance, taxes, utilities and insurance associated with our operating leases. Short-term lease cost for the year ended December 31, 2019 was immaterial.

Cash paid for amounts included in the measurement of operating lease liabilities for the year ended December 31, 2019 was approximately $1.4 million. Cash paid for amounts included in the measurement of finance lease liabilities for the year ended December 31, 2019 was immaterial.

The following table presents supplemental balance sheet information related to our leases as of December 31, 2019 (in thousands):

	As of December 31, 2019
Operating Leases	
Operating lease right-of-use assets	$ 7,364
Total operating lease right-of-use assets	7,364
Current portion, operating lease liabilities	1,347
Operating lease liabilities, net of current portion	8,020
Total operating lease liabilities	9,367
Finance Leases	
Property, plant and equipment, net	796
Total finance lease right-of-use assets	796
Other current liabilities	148
Total finance lease liabilities	$ 148

Maturities of our operating lease liabilities in accordance with ASC 842 as of December 31, 2019 were as follows (in thousands):

Year	Operating Leases	Finance leases	Expected sublease receipts	Net future lease commitments
2020	$ 2,788	$ 159	$ (578)	$ 2,369
2021	2,566			2,566
2022	2,614			2,614
2023	2,162			2,162
2024	1,207			1,207
Thereafter	4,384			4,384
Total	$ 15,721	$ 159	$ (578)	$ 15,302
Less imputed interest	(6,354)	(11)		
Present value of lease liabilities	$ 9,367	$ 148		

Total future minimum lease payments of approximately $14.9 million for operating leases that had not yet commenced as of December 31, 2019, as we did not control the underlying assets, are not included in the consolidated financial statements. These leases commenced in January 2020 with a term of 10 years.

The weighted-average remaining lease terms and discount rates related to our operating leases were as follows:

	December 31, 2019
Weighted average remaining lease term (in years)	6.2
Weighted average discount rate	16.6%

(16) Debt

Debt obligations consisted of the following as of December 31, 2019 and 2018 (in thousands):

Debt instrument	Principal at December 31, 2019	Unamortized Debt Discount	Balance at December 31, 2019
Current Portion:			
Debentures	$ 146	$ —	$ 146
2015 Subordinated Notes	500	—	500
Long-term Portion:			
2015 Subordinated Notes	13,500	(120)	13,380
Total	$ 14,146	$ (120)	$ 14,026

Debt instrument	Principal at December 31, 2018	Unamortized Debt Discount	Balance at December 31, 2018
Current Portion:			
Debentures	$ 146	$ —	$ 146
Long-term Portion:			
2015 Subordinated Notes	14,000	(788)	13,212
Total	$ 14,146	$ (788)	$ 13,358

Subordinated Notes

On February 20, 2015, we, certain existing investors and certain additional investors entered into an Amended and Restated Note Purchase Agreement, pursuant to which we (i) canceled our senior subordinated promissory notes issued in April 2013 (the "2013 Notes") in exchange for new senior subordinated promissory notes (the "2015 Subordinated Notes") in the aggregate principal amount of $5.0 million, (ii) issued additional 2015 Subordinated Notes in the aggregate principal amount of $9.0 million and (iii) issued five year warrants (the "2013 Warrants") to purchase 1,400,000 shares of our common stock at an exercise price of $5.10 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. The 2015 Subordinated Notes are not convertible into shares of our common stock and were to mature on February 20, 2020, at which point we would have been required to repay the full outstanding balance in cash. In February 2020, we amended $13.5 million of the 2015 Subordinated Notes, extending the due date by three years to February 2023, the remaining $0.5 million of the 2015 Subordinated Notes were repaid in February 2020. As a result, the obligation has been classified as non-current in the accompanying consolidated balance sheet. Refer to Note 23, Subsequent Events for further detail. The Company may prepay the 2015 Subordinated Notes at any time, in part or in full, without premium or penalty.

The warrants to purchase 500,000 shares of the Company's common stock issued in connection with the 2013 Notes (the "2013 Warrants") had an exercise price of $4.41 per share; and expired on April 15, 2019.

In March 2017, we and the holders of the 2015 Subordinated Notes entered into an Amendment to Notes and Warrants, pursuant to which we (i) extended the term of the 2013 Warrants by two years from April 15, 2017 to April 15, 2019 and (ii) extended the maturity date of the 2015 Notes by two years from February 20, 2018 to February 20, 2020. This resulted in an additional debt discount of $0.7 million, which will be amortized using the effective interest method over three years, the expected life of the 2015 Subordinated Notes. The 2013 Warrants and 2015 Notes were otherwise unchanged. The Amendment to Notes and Warrants was accounted for as a debt modification.

Note Purchase Agreement Related to Future Royalties

In January 2018, we through our wholly-owned subsidiary, Antigenics, entered into a Royalty Purchase Agreement (the "HCR Royalty Purchase Agreement") with Healthcare Royalty Partners III, L.P., and certain of its affiliates (collectively "HCR"), and we used $161.9 million of the upfront proceeds from HCR to redeem all of our limited recourse notes (the "Notes") dated September 8, 2015, accordingly, the related note purchase agreement and the Notes issued thereunder were redeemed in full and terminated. In connection with this redemption, we recorded a $10.8 million loss on early extinguishment of debt which primarily reflects the payment of premiums to fully redeem the notes and the write-off of unamortized debt issuance costs and discounts. See Note 18 for additional information on the Royalty Purchase Agreement.

The Notes accrued interest at a rate of 13.5% per annum, compounded quarterly, computed on the basis of a 360-day year and the actual number of days elapsed. The Notes had limited recourse and were secured solely by a first priority security interest in the royalties and accounts and payment intangibles relating thereto plus various rights of Antigenics related to the royalties under its contracts with GSK.

The redemption price was equal to the outstanding principal amount of the Notes, plus all accrued and unpaid interest thereon, plus a premium payment that would yield an aggregate internal rate of return ("IRR") for the purchasers of 17.5% in accordance with the terms of the NPA.

No non-cash interest expense related to the Notes was recorded for the year ended December 31, 2019. We recorded $849,000 and $17.4 million in non-cash interest expense related to the Notes for the years ended, December 31, 2018 and 2017, respectively, within our consolidated statement of operations and comprehensive loss.

Other

At December 31, 2019, approximately $146,000 of debentures we assumed in our merger with Aquila Biopharmaceuticals are outstanding. These debentures carry interest at 7% and are callable by the holders. Accordingly, they are classified as short-term debt.

(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, 2019 and for the period from the inception of the royalty transactions to December 31, 2019 (in thousands):

	Year ended December 31, 2019	Period from inception to December 31, 2019
Liability related to sale of future royalties and milestones - beginning balance	$ 210,795	$ —
Proceeds from sale of future royalties and milestones	—	205,000
Non-cash royalty revenue	(30,424)	(47,733)
Non-cash interest expense recognized	41,474	64,578
Liability related to sale of future royalties and milestones - ending balance	221,845	221,845
Less: unamortized transaction costs	(476)	(476)
Liability related to sale of future royalties and milestones, net	$ 221,369	$ 221,369

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 GSK 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, we are required to account for these royalties as revenue when earned, and we recorded the $190.0 million in proceeds from this transaction as a liability on our consolidated balance sheet that will be amortized using the interest method 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 recognition of the royalty payments to be received by HCR in the next 12 months from the financial statement reporting date.

In the years ended December 31, 2019 and 2018, we recognized $30.4 million and $17.3 million, respectively, of non-cash royalty revenue and we recorded $41.5 million and $23.1 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 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. Since the inception of the HCR Royalty Purchase Agreement our estimate of the effective annual interest rate over the life of the agreement increased to 23.3%, which results in a retrospective interest rate of 21.6%.

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 are 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. As such, we recognized $15.1 million in royalty sales milestone revenue in the year ended December 31, 2019.

Additionally, pursuant to the HCR Royalty Purchase Agreement, we were obligated to pay HCR approximately $25.9 million in 2021 (the "Rebate Payment") if neither of the following sales milestones are achieved: (i) 2019 sales exceed $1.0 billion or (ii) 2020 sales exceed $1.75 billion. However, we were released from this obligation in the fourth quarter of 2019 when GSK announced that Shingrix sales for the first nine months of 2019 reached 1.28 billion pounds (or approximately $1.6 billion).

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"). Pursuant to the terms of the XOMA Royalty Purchase Agreement, XOMA 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 are entitled to receive from Incyte Corporation ("Incyte") and Merck Sharpe & 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 fail to repay the amount received by us at closing we would have no further obligation to XOMA.

(18) Fair Value Measurements

We measure our contingent purchase price consideration at fair value. The fair values of our Agenus Switzerland and PhosImmune contingent purchase price consideration, $6.7 million and $2.1 million, respectively, 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 the liabilities uses assumptions we believe would be made by a market participant. The fair value of our Agenus Switzerland and PhosImmune contingent purchase price consideration is based on estimates from a Monte Carlo simulation of our market capitalization and share price, respectively, and other factors impacting the probability of triggering the milestone payments. Market capitalization and share price were evolved using a geometric brownian motion, calculated daily for the life of the contingent purchase price consideration.

Assets and liabilities measured at fair value are summarized below (in thousands):

Description	December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities:				
Contingent purchase price consideration	8,843	—	—	8,843
Total	$ 8,843	$ —	$ —	$ 8,843

Description	December 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities:				
Contingent purchase price consideration	3,038	—	—	3,038
Total	$ 3,038	$ —	$ —	$ 3,038

The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3), as of December 31, 2019 (amounts in thousands):

Balance, December 31, 2018	$ 3,038
Change in fair value of contingent purchase price consideration during the period	5,805
Balance, December 31, 2019	$ 8,843

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, 2019 and 2018 was $14.2 million and $14.2 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, 2019 and 2018 was $14.1 million and $14.1, respectively.

(19) Contingencies

We may currently be, or may become, a party to legal proceedings. While we currently believe that the ultimate outcome of any of these proceedings will not have a material adverse effect on our financial position, results of operations, or liquidity, litigation is subject to inherent uncertainty. Furthermore, litigation consumes both cash and management attention.

(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, 2019, 2018, and 2017 we made discretionary contributions to the Plans of $922,000, $617,000, and $487,000, respectively. For the years ended December 31, 2019, 2018, and 2017, we expensed $922,000, $617,000, and $487,000, respectively, related to the discretionary contribution to the Plans.

(21) Geographic Information

The following is geographical information regarding our revenues for the years ended December 31, 2019, 2018 and 2017 and our long-lived assets as of December 31, 2019 and 2018 (in thousands):

	2019	2018	2017
Revenue:			
United States	$ 149,358	$ 32,784	$ 38,883
Europe	690	4,000	3,994
	$ 150,048	$ 36,784	$ 42,877

In the table above, revenue by geographic region is allocated based on the domicile of our respective business operations.

	2019	2018
Long-lived Assets:		
United States	$ 23,822	$ 22,681
Europe	3,921	3,649
Total	$ 27,743	$ 26,330

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) Quarterly Financial Data (Unaudited)

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
2019				
Revenue	$ 79,891	$ 15,715	$ 19,940	$ 34,502
Net income (loss)	17,435	(51,867)	(46,277)	(30,851)
Net income (loss) attributable to Agenus Inc. common shareholders	18,454	(50,686)	(45,526)	(30,107)
Per common share, basic and diluted:				
Basic net income (loss) attributable to Agenus Inc. common stockholders	0.14	(0.38)	(0.33)	(0.22)
Diluted net income (loss) attributable to Agenus Inc. common stockholders	0.12	(0.38)	(0.33)	(0.22)
2018				
Revenue	$ 1,636	$ 15,895	$ 12,802	$ 6,451
Net loss	(54,261)	(25,204)	(33,731)	(48,848)
Net loss attributable to Agenus Inc. common shareholders	(54,192)	(24,723)	(33,177)	(47,807)
Per common share, basic and diluted:				
Basic and diluted net loss attributable to Agenus Inc. common stockholders	(0.53)	(0.24)	(0.37)	(0.40)

Net loss attributable to common stockholders per share is calculated independently for each of the quarters presented. Therefore, the sum of the quarterly net loss per share amounts will not necessarily equal the total for the full fiscal year.

(23) Subsequent Events

Subordinated Note Amendment

On February 18, 2020, we entered into an amendment (the "Amendment") with the holders of the 2015 Subordinated Notes, pursuant to which we:

- extended the maturity date of $13.5 million of the 2015 Subordinated Notes by three years from February 20, 2020 to February 20, 2023;
- extended the exercise period of the warrants to purchase 1,400,000 shares of the Company's common stock previously issued in 2015 by three years from February 20, 2020 to February 20, 2023; and
- issued new warrants to purchase 675,000 shares of the Company's common stock with a term of five years and an exercise price of $4.48 per share, which represented a 20% premium over the 30-day average trailing closing price of the Company's common stock.

A description of the terms and conditions of the 2015 Subordinated Notes can be found in Note 16.

At the Market Offerings

During the period of January 1, 2020 through March 13, 2020, we received net proceeds of approximately $62.9 million from the sale of approximately 23.8 million shares of our common stock in At Market Issuance Sales Agreement with B. Riley FBR, Inc.

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, 2019.

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 2019 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, 2019, 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, 2019, 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, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements), and our report dated March 16, 2020 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 16, 2020

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

Information regarding our executive officers is incorporated herein by reference to the information contained in Part I of this Annual Report on Form 10-K under the heading "Executive Officers of the Registrant." The balance of 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 2020 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 2020 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 2020 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 2020 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***

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 2020 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.
3.2	Fifth Amended and Restated By-laws of Agenus Inc. Filed as Exhibit 3.2 to our Current Report on Form 8-K (File No. 0-29089) filed on January 6, 2011 and incorporated herein by reference.
3.3	Certificate of Designation, Preferences and Rights of the Series A Convertible Preferred Stock of Agenus Inc. filed with the Secretary of State of the State of Delaware on September 24, 2003. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 25, 2003 and incorporated herein by reference.
3.4	Certificate of Designations, Preferences and Rights of the Class B 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 September 5, 2007 and incorporated herein by reference.
3.5	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
3.6	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 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 4.4 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2015 and incorporated herein by reference.
4.6	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.
4.7	Amendment to Notes and Warrants dated as of February 18, 2020 by and among Agenus Inc. and the Investors listed therein. Filed herewith.
4.8	Form of Warrant under the Amended and Restated Note Purchase Agreement dated as of February 18, 2020. Filed herewith.
4.9	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.
4.10	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	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.
4.12	Description of Securities. Filed herewith.
	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.

Exhibit No.	Description
10.2	Agenus Inc. Directors' Deferred Compensation Plan, as amended to date. Filed as Exhibit 10.4 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2012 and incorporated herein by reference.
10.2.1	Seventh Amendment to Agenus Directors' Deferred Compensation Plan. Filed as Appendix C to our Definitive Proxy Statement on Schedule 14A filed on April 30, 2015 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.
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*	Executive Employment Agreement dated August 8, 2019 between Agenus Inc. and Jennifer Buell. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q (File No. 0-29089) filed on August 9, 2019 and incorporated herein by reference.
10.9	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.
10.10*	Agenus Inc. 2019 Equity Incentive Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed on April 26, 2019 and incorporated herein by reference.
10.10.1*	Form of Incentive Stock Option Agreement for the Agenus Inc. 2019 Equity Incentive Plan. Filed herewith.
10.10.2*	Form of Non-Qualified Stock Option Agreement for the Agenus Inc. 2019 Equity Incentive Plan. Filed herewith.
10.10.3*	Form of Restricted Stock Unit Award Agreement for the Agenus Inc. 2019 Equity Incentive Plan. Filed herewith.
	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.

Exhibit No.	Description
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.
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, 2019 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, 2019 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, 2019 and incorporated herein by reference.
	Real Estate Leases
10.22	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.
10.22.1	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.
10.22.2	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.

Exhibit No.	Description
10.22.3	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.
10.22.4	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.
10.22.5	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.
	Sales Agreement
10.23	Sales Agreement dated May 11, 2018 by and between Agenus Inc. and B. Riley FBR, Inc. Filed as Exhibit 1.1 to the Current Report on Form 8-K filed by the Company on May 11, 2018 and incorporated by reference.
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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase 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 16, 2020

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. **Garo H. Armen, Ph.D.**	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 16, 2020
/S/ CHRISTINE M. KLASKIN **Christine M. Klaskin**	Vice President Finance (Principal Financial and Accounting Officer)	March 16, 2020
/S/ ULF WIINBERG **Ulf Wiinberg**	Director	March 16, 2020
/S/ BRIAN CORVESE **Brian Corvese**	Director	March 16, 2020
/S/ WADIH JORDAN **Wadih Jordan**	Director	March 16, 2020
/S/ ALLISON JEYNES-ELLIS **Allison Jeynes-Ellis**	Director	March 16, 2020
/S/ TIMOTHY R. WRIGHT **Timothy R. Wright**	Director	March 16, 2020

Name:	[_____]
Number of Shares of Stock subject to the Stock Option:	[_____]
Exercise Price Per Share:	$[_____]
Date of Grant:	[_____]
Vesting:	[_____]

AGENUS INC.
2019 EQUITY INCENTIVE PLAN
INCENTIVE STOCK OPTION

STOCK OPTION AWARD AGREEMENT

This agreement (this "**Agreement**") evidences a stock option granted by Agenus Inc. (the "**Company**") to the individual named above (the "**Participant**"), pursuant to and subject to the terms of the Agenus Inc. 2019 Equity Incentive Plan (as from time to time amended and in effect, the "**Plan**"). Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan.

1.Grant of Stock Option. The Company grants to the Participant on the date set forth above (the "**Date of Grant**") an option (the "**Stock Option**") to purchase, pursuant to and subject to the terms and conditions set forth in this Agreement and in the Plan, up to the number of shares of Stock set forth above (the "**Shares**"), with an exercise price per Share as set forth above, in each case, subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

This Stock Option is intended to qualify as an "incentive stock option" under Section 422 of the Code, but the Company does not represent or warrant that this Stock Option qualifies as such. The Participant should consult with his or her own tax advisors regarding the tax effects of this Stock Option and the requirements necessary to obtain favorable income tax treatment under Section 422 of the Code, including, but not limited to, holding period requirements. To the extent any portion of this Stock Option does not so qualify as an "incentive stock option," such portion shall be deemed to be a non-qualified stock option. If the Participant intends to dispose or does dispose (whether by sale, gift, transfer or otherwise) of any Shares within the one-year period beginning on the date after the transfer of such shares to him or her, or within the two-year period beginning on the day after the grant of this Stock Option, he or she will so notify the Company within 30 days after such disposition.

2.Vesting. The term "**vest**" as used herein with respect to the Stock Option (or any portion thereof) means to become exercisable and the term "**vested**" with respect to the Stock Option (or any portion thereof) means that the Stock Option (or portion thereof) is then exercisable. Unless earlier terminated, forfeited, relinquished or expired, the Stock Option will vest as set forth in the table above, subject, in each case, to the Participant remaining in continuous Employment from the Date of Grant through such vesting date.

3.Exercise of the Stock Option. No portion of the Stock Option may be exercised until such portion vests. Each election to exercise any vested portion of the Stock Option will be subject to the terms and conditions of the Plan and must be in written or electronic form acceptable to the

Administrator, signed (including by electronic signature) by the Participant or, if at the relevant time the Stock Option has passed to a Beneficiary or permitted transferee, the Beneficiary or permitted transferee. Each such written or electronic exercise election must be received by the Company at its principal office or by such other party as the Administrator may prescribe and be accompanied by payment in full of the exercise price by cash or check or as otherwise provided in the Plan. The Participant acknowledges that in the event a broker-assisted cashless exercise is used to pay any portion of the exercise price, the Participant may lose the favorable tax treatment afforded to incentive stock options under the Code with respect to the Stock Option. The latest date on which the Stock Option or any portion thereof may be exercised is the tenth (10th) anniversary of the Date of Grant (the "**Final Exercise Date**") and, if not exercised by such date, the Stock Option or any remaining portion thereof will thereupon immediately terminate.

4.Cessation of Employment. If the Participant's Employment ceases, except as expressly provided for in an employment agreement between the Participant and the Company that is in effect at the time of such termination, the Stock Option, to the extent not then vested, will be immediately forfeited for no consideration, and any vested portion of the Stock Option that is then outstanding will remain exercisable for the period described in Section 6(a)(4) of the Plan.

5.Restrictions on Transfer; Disqualifying Dispositions. The Stock Option may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

6.Forfeiture; Recovery of Compensation. By accepting the Stock Option, the Participant expressly acknowledges and agrees that the Participant's rights, and those of any permitted transferee, with respect to the Stock Option, including the right to any Shares acquired under the Stock Option or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). The Participant further agrees to be bound by the terms of any clawback or recoupment policy of the Company that applies to incentive compensation that includes Awards such as the Stock Option. Nothing in the preceding sentence will be construed as limiting the general application of Section 8 of this Agreement.

7.Withholding. The Participant expressly acknowledges and agrees that the Participant's rights hereunder, including the right to be issued Shares upon exercise of the Stock Option, are subject to the Participant promptly paying to the Company in cash or by check (or by such other means as may be acceptable to the Administrator) all taxes required to be withheld, if any. No Shares will be issued pursuant to the exercise of the Stock Option unless and until the person exercising the Stock Option has remitted to the Company an amount in cash sufficient to satisfy any federal, state, or local withholding tax requirements, or has made other arrangements satisfactory to the Company with respect to such taxes. The Participant authorizes the Company and its subsidiaries to withhold such amount from any amounts otherwise owed to the Participant, but nothing in this sentence will be construed as relieving the Participant of any liability for satisfying his or her obligation under the preceding provisions of this Section 7.

8.Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been made available to the Participant. By accepting the Stock Option, the Participant agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

9.Acknowledgements. The Participant acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument; (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder; and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Participant.

[Signature page follows.]

The Company, by its duly authorized officer, and the Participant have executed this Agreement as of the Date of Grant.

AGENUS INC.

By: _____

Name: _____

Title: _____

Agreed and Accepted:

By_____
[Participant's Name]

[*Signature Page to Stock Option Award Agreement*]

Name:	[_____]
Number of Shares of Stock subject to the Stock Option:	[_____]
Exercise Price Per Share:	$[_____]
Date of Grant:	[_____]
Vesting:	[_____]

AGENUS INC.
2019 EQUITY INCENTIVE PLAN
NON-QUALIFIED STOCK OPTION

STOCK OPTION AWARD AGREEMENT

This agreement (this "**Agreement**") evidences a stock option granted by Agenus Inc. (the "**Company**") to the individual named above (the "**Participant**"), pursuant to and subject to the terms of the Agenus Inc. 2019 Equity Incentive Plan (as from time to time amended and in effect, the "**Plan**"). Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan.

1.Grant of Stock Option. The Company grants to the Participant on the date set forth above (the "**Date of Grant**") an option (the "**Stock Option**") to purchase, pursuant to and subject to the terms and conditions set forth in this Agreement and in the Plan, up to the number of shares of Stock set forth above (the "**Shares**"), with an exercise price per Share as set forth above, in each case, subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

The Stock Option evidenced by this Agreement is a non-statutory option (that is, an option that is not intended to qualify as an ISO) and is granted to the Participant in connection with the Participant's Employment.

2.Vesting. The term "**vest**" as used herein with respect to the Stock Option (or any portion thereof) means to become exercisable and the term "**vested**" with respect to the Stock Option (or any portion thereof) means that the Stock Option (or portion thereof) is then exercisable. Unless earlier terminated, forfeited, relinquished or expired, the Stock Option will vest as set forth in the table above, subject, in each case, to the Participant remaining in continuous Employment from the Date of Grant through such vesting date.

3.Exercise of the Stock Option. No portion of the Stock Option may be exercised until such portion vests. Each election to exercise any vested portion of the Stock Option will be subject to the terms and conditions of the Plan and must be in written or electronic form acceptable to the Administrator, signed (including by electronic signature) by the Participant or, if at the relevant time the Stock Option has passed to a Beneficiary or permitted transferee, the Beneficiary or permitted transferee. Each such written or electronic exercise election must be received by the Company at its principal office or by such other party as the Administrator may prescribe and be accompanied by payment in full of the exercise price by cash or check or as otherwise provided in the Plan. The latest date on which the Stock Option or any portion thereof may be exercised is the tenth (10th) anniversary of the Date of Grant (the "**Final Exercise Date**") and, if not exercised by such date, the Stock Option or any remaining portion thereof will thereupon immediately terminate.

4.Cessation of Employment. If the Participant's Employment ceases, except as expressly provided for in an employment agreement between the Participant and the Company that is in effect at

the time of such termination, the Stock Option, to the extent not then vested, will be immediately forfeited for no consideration, and any vested portion of the Stock Option that is then outstanding will remain exercisable for the period described in Section 6(a)(4) of the Plan.

5.Restrictions on Transfer; Disqualifying Dispositions. The Stock Option may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

6.Forfeiture; Recovery of Compensation. By accepting the Stock Option, the Participant expressly acknowledges and agrees that the Participant's rights, and those of any permitted transferee, with respect to the Stock Option, including the right to any Shares acquired under the Stock Option or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). The Participant further agrees to be bound by the terms of any clawback or recoupment policy of the Company that applies to incentive compensation that includes Awards such as the Stock Option. Nothing in the preceding sentence will be construed as limiting the general application of Section 8 of this Agreement.

7.Withholding. The Participant expressly acknowledges and agrees that the Participant's rights hereunder, including the right to be issued Shares upon exercise of the Stock Option, are subject to the Participant promptly paying to the Company in cash or by check (or by such other means as may be acceptable to the Administrator) all taxes required to be withheld, if any. No Shares will be issued pursuant to the exercise of the Stock Option unless and until the person exercising the Stock Option has remitted to the Company an amount in cash sufficient to satisfy any federal, state, or local withholding tax requirements, or has made other arrangements satisfactory to the Company with respect to such taxes. The Participant authorizes the Company and its subsidiaries to withhold such amount from any amounts otherwise owed to the Participant, but nothing in this sentence will be construed as relieving the Participant of any liability for satisfying his or her obligation under the preceding provisions of this Section 7.

8.Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been made available to the Participant. By accepting the Stock Option, the Participant agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

9.Acknowledgements. The Participant acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument; (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder; and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Participant.

[Signature page follows.]

The Company, by its duly authorized officer, and the Participant have executed this Agreement as of the Date of Grant.

AGENUS INC.

By: _____

Name: _____

Title: _____

Agreed and Accepted:

By_____
[Participant's Name]

[*Signature Page to Stock Option Award Agreement*]

Exhibit 10.10.3

Name:	[_____]
Number of Restricted Stock Units:	[_____]
Date of Grant:	[_____]
Vesting:	[_____]

AGENUS INC.
2019 EQUITY INCENTIVE PLAN

RESTRICTED STOCK UNIT AWARD AGREEMENT

This agreement (this "**Agreement**") evidences an award (the "**Award**") of restricted stock units granted by Agenus Inc. (the "**Company**") to the individual named above (the "**Participant**"), pursuant to and subject to the terms of the Agenus Inc. 2019 Equity Incentive Plan (as from time to time amended and in effect, the "**Plan**"). Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan.

1. Grant of Restricted Stock Unit Award. The Company grants to the Participant on the date set forth above (the "**Date of Grant**") the number of restricted stock units (the "**RSUs**") set forth above giving the Participant the conditional right to receive, without payment and pursuant to and subject to the terms and conditions set forth in this Agreement and in the Plan, one share of Stock (a "**Share**") with respect to each RSU forming part of the Award, subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

2. Vesting; Cessation of Employment.

(a) Vesting. Unless earlier terminated, forfeited, relinquished or expired, the RSU will vest as set forth in the table above, subject, in each case, to the Participant remaining in continuous Employment from the Date of Grant through such vesting date.

(b) Cessation of Employment. Automatically and immediately upon the cessation of the Participant's Employment any then unvested RSUs and, if such termination is for Cause or occurs in circumstances that in the determination of the Administrator would have constituted grounds for the Participant's Employment to be terminated for Cause (in each case, without regard to the lapsing of any required notice or cure periods in connection therewith), any vested RSUs will terminate and be forfeited for no consideration.

3. Delivery of Shares. Subject to Section 4 below, the Company shall, as soon as practicable upon the vesting of any RSUs subject to this Award (but in no event later than 30 days following the date on which such RSUs vest), effect delivery of the Shares with respect to such vested RSUs to the Participant (or, in the event of the Participant's death, to the person to whom the Award has passed by will or the laws of descent and distribution). No Shares will be issued pursuant to this Award unless and until all legal requirements applicable to the issuance or transfer of such Shares have been complied with to the satisfaction of the Administrator.

4. Forfeiture; Recovery of Compensation. The Administrator may cancel, rescind, withhold or otherwise limit or restrict this Award at any time if the Participant is not in compliance

with all applicable provisions of this Agreement and the Plan. By accepting, or being deemed to have accepted, this Award, the Participant expressly acknowledges and agrees that his or her rights, and those of any permitted transferee of this Award, under this Award, including the right to any Shares acquired under this Award or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). The Participant further agrees to be bound by the terms of any clawback or recoupment policy of the Company that applies to incentive compensation that includes Awards such as the RSUs. Nothing in the preceding sentence may be construed as limiting the general application of Section 9 of this Agreement.

5. **Dividends; Other Rights.** This Award may not be interpreted to bestow upon the Participant any equity interest or ownership in the Company or any subsidiary prior to the date on which the Company delivers Shares to the Participant. The Participant is not entitled to vote any Shares by reason of the granting of this Award or to receive or be credited with any dividends declared and payable on any Share prior to the date on which any such Share is delivered to the Participant hereunder. The Participant will have the rights of a shareholder only as to those Shares, if any, that are actually delivered under this Award.

6. **Nontransferability.** This Award may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

7. **Taxes.** The Participant expressly acknowledges and agrees that the Participant's rights hereunder, including the right to be issued Shares in settlement of the RSUs subject to this Award, are subject to the Participant promptly paying to the Company in cash or by check (or by such other means as may be acceptable to the Administrator) all taxes required to be withheld, if any. No Shares will be delivered in settlement of the RSUs subject to this Award unless and until the Participant has remitted to the Company an amount in cash sufficient to satisfy any federal, state, or local withholding tax requirements, or has made other arrangements satisfactory to the Company with respect to such taxes. The Participant authorizes the Company and its subsidiaries to withhold such amount from any amounts otherwise owed to the Participant, but nothing in this sentence will be construed as relieving the Participant of any liability for satisfying his or her obligation under the preceding provisions of this Section 7. Subject to Section 11(b) of the Plan, this Award is intended to be exempt from Section 409A as a short-term deferral thereunder and shall be construed and administered in accordance with that intent.

8. **Effect on Employment.** Neither the grant of this Award, nor the issuance of Shares upon the vesting of this Award, will give the Participant any right to be retained in the employ or service of the Company or any of its subsidiaries, affect the right of the Company or any of its subsidiaries to discharge the Participant at any time, or affect any right of the Participant to terminate his or her Employment at any time.

9. **Provisions of the Plan.** This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been made available to the Participant. By accepting this Award, the Participant agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

10. **Acknowledgements.** The Participant acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument; (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder; and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Participant.

[Signature page follows.]

The Company, by its duly authorized officer, and the Participant have executed this Agreement as of the date first set forth above.

AGENUS INC.

By: _____

Name: _____

Title: _____

Agreed and Accepted:

By_____
[Participant's Name]

Exhibit 4.7

AMENDMENT TO NOTES AND WARRANTS
AND SALE OF NEW WARRANTS

This Amendment to Notes and Warrants and Sale of New Warrants (this "**Amendment**") is entered into this 18th day of February 2020 by and between (a) Agenus Inc., a Delaware corporation, having an address at 3 Forbes Road, Lexington, MA 02421 (the "**Borrower**"), and (b) Mark Berg and Nicole Berg, Nicky V LLC and MSB Research Inc. (collectively, the "**Signing Purchasers**").

WITNESSETH

WHEREAS, the Borrower and the Required Purchases are parties to that certain Amended and Restated Note Purchase Agreement dated February 20, 2015, as amended (the "**2015 Purchase Agreement**"), pursuant to which the Borrower issued to the Purchasers, among other things, 8% senior subordinated notes that mature on February 20, 2020 (the "**2015 Notes**") and warrants to purchase an aggregate of 1,400,000 shares of Borrower common stock at a price of $5.10 per share that expire on February 20, 2020 (the "**2015 Warrants**");

WHEREAS, the parties now wish to (i) extend the term of the 2015 Notes and 2015 Warrants by three years from February 20, 2020 to February 20, 2023 and (ii) issue additional Warrants to the Purchasers as set forth herein; and

WHEREAS, Section 5.13(a) of the 2015 Purchase Agreement provides that the 2015 Notes and 2015 Warrants may be amended by the Purchasers of Notes (as defined therein) representing at least a majority of the aggregate principal amount outstanding under all of the 2015 Notes (the "**Required Purchasers**"), and the undersigned Signing Purchasers constitute the Required Purchasers.

NOW, THEREFORE, the parties hereby agree as follows:

1. Defined Terms. Terms used, but not defined here, shall have the meaning assigned such terms in the 2015 Purchase Agreement.

2. Amendment to 2015 Warrants. Section 2 of each of the 2015 Warrants is hereby deleted in its entirety and replaced with the following:

> "Term of Warrant. Subject to the terms and conditions hereof, at any time or from time to time after the date hereof and prior to 5:00 p.m., New York City time, on the eight (8th) anniversary of the date hereof or, if such day is not a Business Day, on the next preceding Business Day (the "**Exercise Period**"), the Holder of this Warrant may exercise this Warrant for all or any part of the Warrant Shares purchasable hereunder (subject to adjustment as provided herein)."

3. Amendment to 2015 Notes. The maturity date for each of the 2015 Notes is hereby extended by three years from February 20, 2020 to February 20, 2023.

4. No other Amendments. The parties acknowledge and agree that, except as set forth in this Amendment, the 2015 Notes and 2015 Warrants shall remain in full force and effect.

5. New Warrants. In consideration of the amendments hereunder, the Borrower shall issue to the Purchasers warrants to purchase that number of shares of Common Stock of the Borrower (collectively, the "**2020 Warrants**") in accordance with such Purchaser's individual allocation set forth opposite such Purchaser's name on Schedule 1 under the heading "Allocation of 2020 Warrants" which warrants shall be in the form attached hereto as Exhibit I. The 2020 Warrants are deemed to be issued by, and governed in accordance with, the Purchase Agreement as if they are Warrants issued thereunder.

6. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of New York irrespective of any conflicts of law principles thereof.

7. Counterparts. This Amendment may be executed in counterparts, which, when taken together, shall constitute one agreement. If any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed by their respective authorized officers as of the day and year first above written.

BORROWER:

AGENUS INC.

By: /s/ Garo H. Armen
Name: Garo H. Armen
Title: Chairman and CEO

PURCHASERS:

/s/ Mark Berg /s/ Nicole Berg
Mark Berg and Nicole Berg

NICKY V LLC

By: /s/ Nicole Berg
Name: Nicole Berg
Title: Owner

MSB RESEARCH INC.

By: /s/ Mark Berg
Name: Mark Berg
Title: President

Exhibit 4.8

WARRANT

THIS WARRANT AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS WARRANT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"), OR QUALIFIED UNDER ANY STATE OR FOREIGN SECURITIES LAWS AND MAY NOT BE OFFERED FOR SALE, SOLD, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED OR ASSIGNED UNLESS (I) A REGISTRATION STATEMENT COVERING SUCH SHARES IS EFFECTIVE UNDER THE ACT AND IS QUALIFIED UNDER APPLICABLE STATE AND FOREIGN LAW OR (II) THE TRANSACTION IS EXEMPT FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS UNDER THE ACT AND THE QUALIFICATION REQUIREMENTS UNDER APPLICABLE STATE AND FOREIGN LAW AND, IF THE CORPORATION REQUESTS, AN OPINION SATISFACTORY TO THE CORPORATION TO SUCH EFFECT HAS BEEN RENDERED BY COUNSEL.

Warrant Certificate No.: _____ Original Issue Date: February 18, 2020

FOR VALUE RECEIVED, Agenus Inc., a Delaware corporation (the "**Company**"), hereby certifies that _____, or [his]/[her]/their registered assigns (the "**Holder**") is entitled to purchase from the Company _____ duly authorized, validly issued, fully paid and nonassessable shares of Common Stock at a purchase price per share of $4.48 (subject to adjustment as provided herein, the "**Exercise Price**"), all subject to the terms, conditions and adjustments set forth below in this Warrant. Certain capitalized terms used herein are defined in Section 1 hereof.

This Warrant has been issued pursuant to the terms of the Amended and Restated Note Purchase Agreement, dated as of February 20, 2015, as amended (the "**Purchase Agreement**"), between the Company and the Holder.

1. Definitions. As used in this Warrant, the following terms have the respective meanings set forth below:

"**Aggregate Exercise Price**" means an amount equal to the product of (a) the number of Warrant Shares in respect of which this Warrant is then being exercised pursuant to Section 3 hereof, multiplied by (b) the Exercise Price in effect as of the Exercise Date in accordance with the terms of this Warrant.

"**Board**" means the board of directors of the Company.

"**Business Day**" means any day other than (i) a Saturday or Sunday or (ii) a day on which banking institutions located in New York City are closed.

"**Common Stock**" means the common stock, par value $0.01 per share, of the Company, and any capital stock into which such Common Stock shall have been converted, exchanged or reclassified following the date hereof.

"**Common Stock Deemed Outstanding**" means, at any given time, the number of shares of Common Stock actually outstanding at such time, less shares owned or held by or for the account of the Company or any of its wholly owned subsidiaries.

"**Company**" has the meaning set forth in the preamble.

"**Exercise Agreement**" has the meaning set forth in Section 3(a)(i).

"**Exercise Date**" means, for any given exercise of this Warrant, the date on which the conditions to such exercise as set forth in Section 3 shall have been satisfied at or prior to 5:00 p.m., New York City time, on a Business Day, including, without limitation, the receipt by the Company of the Exercise Agreement, the Warrant and the Aggregate Exercise Price.

"**Exercise Period**" has the meaning set forth in Section 2.

"**Exercise Price**" has the meaning set forth in the preamble.

"**Fair Market Value**" means, as of any particular date: (a) the volume weighted average of the closing sales prices of the Common Stock for such day on all domestic securities exchanges on which the Common Stock may at the time be listed; (b) if there have been no sales of the Common Stock on any such exchange on any such day, the average of the highest bid and lowest asked prices for the Common Stock on all such exchanges at the end of such day; (c) if on any such day the Common Stock is not listed on a domestic securities exchange, the closing sales price of the Common Stock as quoted on Nasdaq, the OTC Bulletin Board or similar quotation system or association for such day; or (d) if there have been no sales of the Common Stock on Nasdaq, the OTC Bulletin Board or similar quotation system or association on such day, the average of the highest bid and lowest asked prices for the Common Stock quoted on Nasdaq, the OTC Bulletin Board or similar quotation system or association at the end of such day; in each case, averaged over twenty (20) consecutive Business Days ending on the Business Day immediately prior to the day as of which "Fair Market Value" is being determined; provided, that if the Common Stock is listed on any domestic securities exchange, the term "Business Day" as used in this sentence means Business Days on which such exchange is open for trading. If at any time the Common Stock is not listed on any domestic securities exchange or quoted on Nasdaq, the OTC Bulletin Board or similar quotation system or association, the "Fair Market Value" of the Common Stock shall be the fair market value per share as determined jointly by the Board and the Holder.

"**Holder**" has the meaning set forth in the preamble.

"**Nasdaq**" means The Nasdaq Stock Market, Inc.

"**Original Issue Date**" means February 18, 2020, the date on which the Warrant was issued by the Company pursuant to the Purchase Agreement.

"**Person**" means any individual, sole proprietorship, partnership, limited liability company, corporation, joint venture, trust, incorporated organization or government or department or agency thereof.

"**Purchase Agreement**" has the meaning set forth in the preamble.

"**Warrant**" means this Warrant and all warrants issued upon division or combination of, or in substitution for, this Warrant.

"**Warrant Shares**" means the shares of Common Stock or other capital stock of the Company then purchasable upon exercise of this Warrant in accordance with the terms of this Warrant.

2. Term of Warrant. Subject to the terms and conditions hereof, at any time or from time to time after the date hereof and prior to 5:00 p.m., New York City time, on the fifth (5th) anniversary of the date hereof or, if such day is not a Business Day, on the next preceding Business Day (the "**Exercise Period**"), the Holder of this Warrant may exercise this Warrant for all or any part of the Warrant Shares purchasable hereunder (subject to adjustment as provided herein).

3. Exercise of Warrant.

(a) **Exercise Procedure**. This Warrant may be exercised from time to time on any Business Day during the Exercise Period, for all or any part of the unexercised Warrant Shares, upon:

(i) surrender of this Warrant to the Company at its then principal executive offices (or an indemnification undertaking with respect to this Warrant in the case of its loss, theft or destruction), together with an Exercise Agreement in the form attached hereto as **Exhibit A** (each, an "**Exercise Agreement**"), duly completed (including specifying the number of Warrant Shares to be purchased) and executed; and

(ii) payment to the Company of the Aggregate Exercise Price in accordance with Section 3(b).

(b) **Payment of the Aggregate Exercise Price**. At the option of the Holder, payment of the Aggregate Exercise Price for any exercise of this Warrant shall be made (i) by delivery to the Company of a certified or official bank check payable to the order of the Company or (ii) by wire transfer of immediately available funds to an account designated in writing by the Company.

(c) **[Intentionally Omitted]**.

(d) **Delivery of Stock Certificates**. Upon receipt by the Company of the Exercise Agreement, surrender of this Warrant and payment of the Aggregate Exercise Price (in accordance with Section 3(a) hereof), the Company shall, as promptly as practicable, execute (or cause to be executed) and deliver (or cause to be delivered) the Warrant Shares represented by book-entry credits with the Company's transfer agent together with cash in lieu of any fraction of a share, as provided in Section 3(e) hereof. The book-entry credits so delivered shall be, to the extent possible, in such denomination or denominations as the exercising Holder shall reasonably request in the Exercise Agreement and shall be registered in the name of the Holder or, subject to compliance with Section 5 below, such other Person's name as shall be designated in the

Exercise Agreement. This Warrant shall be deemed to have been exercised and such Warrant Shares shall be deemed to have been issued, and the Holder or any other Person so designated to be named therein shall be deemed to have become a holder of record of such Warrant Shares for all purposes, as of the Exercise Date.

(e) **Fractional Shares**. The Company shall not be required to issue a fractional Warrant Share upon exercise of any Warrant. As to any fraction of a Warrant Share that the Holder would otherwise be entitled to purchase upon such exercise, the Company shall pay to such Holder an amount in cash (by delivery of a certified or official bank check or by wire transfer of immediately available funds) equal to the product of (i) such fraction multiplied by (ii) the Fair Market Value of one Warrant Share on the Exercise Date.

(f) **Valid Issuance of Warrant and Warrant Shares; Payment of Taxes**. With respect to the exercise of this Warrant, the Company hereby represents, covenants and agrees:

(i) This Warrant is, and any Warrant issued in substitution for or replacement of this Warrant shall be, upon issuance, duly authorized and validly issued.

(ii) All Warrant Shares issuable upon the exercise of this Warrant pursuant to the terms hereof shall be, upon issuance, and the Company shall take all such actions as may be necessary or appropriate in order that such Warrant Shares are, validly issued, fully paid and non-assessable, issued without violation of any preemptive or similar rights of any stockholder of the Company and free and clear of all taxes, liens and charges.

(iii) The Company shall take all such actions as may be necessary to ensure that all such Warrant Shares are issued without violation by the Company of any applicable law or governmental regulation or any requirements of any domestic securities exchange upon which shares of Common Stock or other securities constituting Warrant Shares may be listed at the time of such exercise (except for official notice of issuance which shall be immediately delivered by the Company upon each such issuance).

(iv) The Company shall pay all expenses in connection with, and all taxes and other governmental charges that may be imposed with respect to, the issuance or delivery of Warrant Shares upon exercise of this Warrant; provided, that the Company shall not be required to pay any tax or governmental charge that may be imposed with respect to any applicable withholding or the issuance or delivery of the Warrant Shares to any Person other than the Holder, and no such issuance or delivery shall be made unless and until the Person requesting such issuance has paid to the Company the amount of any such tax, or has established to the satisfaction of the Company that such tax has been paid.

(g) **Conditional Exercise**. Notwithstanding any other provision hereof, if an exercise of any portion of this Warrant is to be made in connection with a public offering or a sale of the Company (pursuant to a merger, sale of stock, or otherwise), such exercise may at the election of the Holder be conditioned upon the consummation of such transaction, in which case such exercise shall not be deemed to be effective until immediately prior to the consummation of such transaction.

(h) **Reservation of Shares**. During the Exercise Period, the Company shall at all times reserve and keep available out of its authorized but unissued Common Stock or other securities constituting Warrant Shares, solely for the purpose of issuance upon the exercise of this Warrant, the maximum number of Warrant Shares issuable upon the exercise of this Warrant, and the par value per Warrant Share shall at all times be less than or equal to the applicable Exercise Price. The Company shall not increase the par value of any Warrant Shares receivable upon the exercise of this Warrant above the Exercise Price then in effect, and shall take all such actions as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable shares of Common Stock upon the exercise of this Warrant.

4. Adjustment to Exercise Price and Number of Warrant Shares. In order to prevent dilution of the purchase rights granted under this Warrant, the Exercise Price and the number of Warrant Shares issuable upon exercise of this Warrant shall be subject to adjustment from time to time as provided in this Section 4.

(a) **Adjustment to Exercise Price and Warrant Shares Upon Dividend, Subdivision or Combination of Common Stock**. If the Company shall, at any time or from time to time after the Original Issue Date, (i) pay a dividend or make any other distribution upon the Common Stock or any other capital stock of the Company payable in shares of Common Stock, or (ii) subdivide (by any stock split, recapitalization or otherwise) its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to any such dividend, distribution or subdivision shall be proportionately reduced and the number of Warrant Shares issuable upon exercise of this Warrant shall be proportionately increased. If the Company at any time combines (by combination, reverse stock split or otherwise) its outstanding shares of Common Stock into a smaller number of shares, the Exercise Price in effect immediately prior to such combination shall be proportionately increased and the number of Warrant Shares issuable upon exercise of this Warrant shall be proportionately decreased. Any adjustment under this Section 4(a) shall become effective at the close of business on the date the dividend, subdivision or combination becomes effective.

(b) **Adjustment to Exercise Price and Warrant Shares Upon Reorganization, Reclassification, Consolidation or Merger**. In case the Company after the date hereof (a) shall consolidate with or merge into any other Person and shall not be the continuing or surviving corporation of such consolidation or merger, or (b) shall permit any other Person to consolidate with or merge into the Company and the Company shall be the continuing or surviving Person but, in connection with such consolidation or merger, the Common Stock shall be changed into or exchanged for stock or other securities of any other Person or cash or any other property, or (c) shall transfer all or substantially all of its properties or assets to any other Person, then, and in the case of each such transaction, proper provision shall be made so that, upon the basis and the terms and in the manner provided in this Warrant, this Warrant shall be terminated upon the consummation of the transaction and the holder of this Warrant shall be entitled to receive upon such consummation, in the same form of consideration as received by the shareholders, the excess, if any, of (i) the fair market value of the securities, cash or other property to which such holder would actually have been entitled as a shareholder upon such consummation if such holder had exercised the rights represented by this Warrant immediately prior thereto, less (ii) the aggregate exercise price payable upon exercise in full of this Warrant.

(c) **Certificate as to Adjustment**.

(i) As promptly as reasonably practicable following any adjustment of the Exercise Price, the Company shall furnish to the Holder a certificate of an executive officer setting forth in reasonable detail such adjustment and the facts upon which it is based and certifying the calculation thereof.

(ii) As promptly as reasonably practicable following the receipt by the Company of a written request by the Holder, the Company shall furnish to the Holder a certificate of an executive officer certifying the Exercise Price then in effect and the number of Warrant Shares or the amount, if any, of other shares of stock, securities or assets then issuable upon exercise of the Warrant.

(d) **Notices**. In the event:

(i) that the Company shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon exercise of the Warrant) for the purpose of entitling or enabling them to receive any dividend or other distribution, to vote at a meeting (or by written consent), to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or

(ii) of any capital reorganization of the Company, any reclassification of the Common Stock of the Company, any consolidation or merger of the Company with or into another Person, or sale of all or substantially all of the Company's assets to another Person; or

(iii) of the voluntary or involuntary dissolution, liquidation or winding-up of the Company;

then, and in each such case, the Company shall send or cause to be sent to the Holder at least fifteen (15) days prior to the applicable record date or the applicable expected effective date, as the case may be, for the event, a written notice specifying, as the case may be, (A) the record date for such dividend, distribution, meeting or consent or other right or action, and a description of such dividend, distribution or other right or action to be taken at such meeting or by written consent, or (B) the effective date on which such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up is proposed to take place, and the date, if any is to be fixed, as of which the books of the Company shall close or a record shall be taken with respect to which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon exercise of the Warrant) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to the Warrant and the Warrant Shares.

5. Transfer of Warrant. Subject to the transfer conditions referred to in the legend endorsed hereon and the terms and conditions of this Warrant and all rights hereunder are transferable, in whole or in part, by the Holder without charge to the Holder, upon surrender of this Warrant to the Company at its then principal executive offices with a properly completed and duly executed Assignment in the form attached hereto as **Exhibit B**, together with funds

sufficient to pay any transfer taxes described in Section 3(f)(iv) in connection with the making of such transfer. Upon such compliance, surrender and delivery and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees and in the denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant, if any, not so assigned and this Warrant shall promptly be cancelled.

6. Holder Not Deemed a Stockholder; Limitations on Liability. Except as otherwise specifically provided herein, prior to the issuance to the Holder of the Warrant Shares to which the Holder is then entitled to receive upon the due exercise of this Warrant, the Holder shall not be entitled to vote or receive dividends or be deemed the holder of shares of capital stock of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, as such, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

7. Replacement on Loss; Division and Combination.

(a) **Replacement of Warrant on Loss**. Upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and upon delivery of an indemnity reasonably satisfactory to it (it being understood that a written indemnification agreement or affidavit of loss of the Holder shall be a sufficient indemnity) and, in case of mutilation, upon surrender of such Warrant for cancellation to the Company, the Company at its own expense shall execute and deliver to the Holder, in lieu hereof, a new Warrant of like tenor and exercisable for an equivalent number of Warrant Shares as the Warrant so lost, stolen, mutilated or destroyed; provided, that, in the case of mutilation, no indemnity shall be required if this Warrant in identifiable form is surrendered to the Company for cancellation.

(b) **Division and Combination of Warrant**. Subject to compliance with the applicable provisions of this Warrant as to any transfer or other assignment which may be involved in such division or combination, this Warrant may be divided or, following any such division of this Warrant, subsequently combined with other Warrants, upon the surrender of this Warrant or Warrants to the Company at its then principal executive offices, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the respective Holders or their agents or attorneys. Subject to compliance with the applicable provisions of this Warrant as to any transfer or assignment which may be involved in such division or combination, the Company shall at its own expense execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants so surrendered in accordance with such notice. Such new Warrant or Warrants shall be of like tenor to the surrendered Warrant or Warrants and shall be exercisable in the aggregate for an equivalent number of Warrant Shares as the Warrant or Warrants so surrendered in accordance with such notice.

8. No Impairment. The Company shall not, by amendment of its Certificate of Incorporation or Bylaws, or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities, or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed by it hereunder, but shall at all times in good faith assist in the carrying out of all the provisions of this Warrant and in the taking of all such action as may reasonably be requested by the Holder in order to protect the exercise rights of the Holder against dilution or other impairment, consistent with the tenor and purpose of this Warrant.

9. Compliance with the Securities Act.

(a) **Agreement to Comply with the Securities Act; Legend**. The Holder, by acceptance of this Warrant, agrees to comply in all respects with the provisions of this Section 9 and the restrictive legend requirements set forth on the face of this Warrant and further agrees that such Holder shall not offer, sell or otherwise dispose of this Warrant or any Warrant Shares to be issued upon exercise hereof except under circumstances that will not result in a violation of the Securities Act of 1933, as amended (the "**Securities Act**"). This Warrant and all Warrant Shares issued upon exercise of this Warrant (unless registered under the Securities Act) shall be stamped or imprinted with a legend in substantially the following form:

> "THIS WARRANT AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS WARRANT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR QUALIFIED UNDER ANY STATE OR FOREIGN SECURITIES LAWS AND MAY NOT BE OFFERED FOR SALE, SOLD, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED OR ASSIGNED UNLESS (I) A REGISTRATION STATEMENT COVERING SUCH SHARES IS EFFECTIVE UNDER THE ACT AND IS QUALIFIED UNDER APPLICABLE STATE AND FOREIGN LAW OR (II) THE TRANSACTION IS EXEMPT FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS UNDER THE ACT AND THE QUALIFICATION REQUIREMENTS UNDER APPLICABLE STATE AND FOREIGN LAW AND, IF THE CORPORATION REQUESTS, AN OPINION SATISFACTORY TO THE CORPORATION TO SUCH EFFECT HAS BEEN RENDERED BY COUNSEL."

(b) **Representations of the Holder**. In connection with the issuance of this Warrant, the Holder specifically represents, as of the date hereof, to the Company by acceptance of this Warrant as follows:

(i) The Holder is an "accredited investor" as defined in Rule 501 of Regulation D promulgated under the Securities Act. The Holder is acquiring this Warrant and the Warrant Shares to be issued upon exercise hereof for investment for its own account and not with a view towards, or for resale in connection with, the public sale or distribution of this Warrant or the Warrant Shares, except pursuant to sales registered or exempted under the Securities Act.

(ii) The Holder understands and acknowledges that this Warrant and the Warrant Shares to be issued upon exercise hereof are "restricted securities" under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that, under such laws and applicable regulations, such securities may be resold without registration under the Securities Act only in certain limited circumstances. In addition, the Holder represents that it is familiar with Rule 144 under the Securities Act, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act.

(iii) The Holder acknowledges that it can bear the economic and financial risk of its investment for an indefinite period, and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Warrant and the Warrant Shares. The Holder has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of the Warrant and the business, properties, prospects and financial condition of the Company.

10. Warrant Register. The Company shall keep and properly maintain at its principal executive offices books for the registration of the Warrant and any transfers thereof. The Company may deem and treat the Person in whose name the Warrant is registered on such register as the Holder thereof for all purposes, and the Company shall not be affected by any notice to the contrary, except any assignment, division, combination or other transfer of the Warrant effected in accordance with the provisions of this Warrant.

11. Notices. Any and all notices or other communications or deliveries hereunder (including without limitation any Exercise Notice) shall be in writing and shall be mailed by certified mail, return receipt requested, or by a nationally recognized courier service or delivered (in person or by facsimile), against receipt to the party to whom such notice or other communication is to be given. Any notice or other communication given by means permitted by this Section 11 shall be deemed given at the time of receipt thereof. The address for such notices or communications shall be as set forth below (or at such other address for a party as shall be specified in a notice given in accordance with this Section 11):

If to the Company:	Agenus Inc. 3 Forbes Road Lexington, MA 02421 Facsimile:781-674-4200 Attention:Vice President of Finance
with a copy to:	Agenus Inc. 3 Forbes Road Lexington, MA 02421 Facsimile:781-674-4200 Attention:Legal Department
If to the Holder:	*(As indicated on the signature page hereto)*

12. Cumulative Remedies. Except to the extent expressly provided in Section 6 to the contrary, the rights and remedies provided in this Warrant are cumulative and are not exclusive of, and are in addition to and not in substitution for, any other rights or remedies available at law, in equity or otherwise.

13. Equitable Relief. Each of the Company and the Holder acknowledges that a breach or threatened breach by such party of any of its obligations under this Warrant would give rise to irreparable harm to the other party hereto for which monetary damages would not be an adequate remedy and hereby agrees that in the event of a breach or a threatened breach by such party of any such obligations, the other party hereto shall, in addition to any and all other rights and remedies that may be available to it in respect of such breach, be entitled to equitable relief, including a restraining order, an injunction, specific performance and any other relief that may be available from a court of competent jurisdiction.

14. Entire Agreement. This Warrant, together with the Purchase Agreement, constitutes the sole and entire agreement of the parties to this Warrant with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings and agreements, both written and oral, with respect to such subject matter. In the event of any inconsistency between the statements in the body of this Warrant and the Purchase Agreement, the statements in the body of this Warrant shall control.

15. Successor and Assigns. This Warrant and the rights evidenced hereby shall be binding upon and shall inure to the benefit of the parties hereto and the successors of the Company and the successors and permitted assigns of the Holder. Such successors and/or permitted assigns of the Holder shall be deemed to be a Holder for all purposes hereunder.

16. No Third-Party Beneficiaries. This Warrant is for the sole benefit of the Company and the Holder and their respective successors and, in the case of the Holder, permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other Person any legal or equitable right, benefit or remedy of any nature whatsoever, under or by reason of this Warrant.

17. Headings. The headings in this Warrant are for reference only and shall not affect the interpretation of this Warrant.

18. Amendment and Modification; Waiver. To the extent that (i) the terms of this Warrant require the Company to obtain the consent or approval of the Purchasers (as defined in the Purchase Agreement) or (ii) the Company seeks an amendment to or modification or waiver of any of the terms of this Warrant, such Approval (as defined in the Purchase Agreement) shall be made by the Required Purchasers (as defined in the Purchase Agreement). Notwithstanding the foregoing, the Holder may, in its sole discretion, agree to any consent, approval, action, termination, amendment or waiver that solely effects the rights of the Holder under this Warrant. No failure or delay by any party in exercising any power or right arising from this Warrant shall operate as a waiver thereof nor shall any single or partial exercise of any such right or power, or any abandonment or discontinuance of steps to enforce such a right or power, preclude any other or further exercise thereof or the exercise of any other right or power. The rights and remedies

of each party under this Warrant are cumulative and are not exclusive of any rights or remedies that they would otherwise have.

19. Severability. If any term or provision of this Warrant is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Warrant or invalidate or render unenforceable such term or provision in any other jurisdiction.

20. Governing Law. THIS WARRANT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL BE CONSTRUED IN ACCORDANCE WITH AND GOVERNED BY THE LAWS OF THE STATE OF NEW YORK.

21. Submission to Jurisdiction. ANY LEGAL ACTION OR PROCEEDING ARISING UNDER THIS WARRANT OR IN ANY WAY CONNECTED WITH OR RELATED OR INCIDENTAL TO THE DEALINGS OF THE COMPANY OR THE HOLDER OR ANY OF THEM WITH RESPECT TO THIS WARRANT, IN EACH CASE WHETHER NOW EXISTING OR HEREAFTER ARISING, SHALL BE BROUGHT IN THE COURTS OF THE STATE OF NEW YORK SITTING IN NEW YORK COUNTY (BOROUGH OF MANHATTAN) OR OF THE UNITED STATES FOR THE SOUTHERN DISTRICT OF SUCH STATE. EACH OF THE COMPANY AND THE HOLDER CONSENTS, FOR ITSELF AND IN RESPECT OF ITS PROPERTY, TO THE EXCLUSIVE JURISDICTION OF THOSE COURTS AND AGREES THAT IT WILL NOT COMMENCE OR SUPPORT ANY SUCH ACTION OR PROCEEDING IN ANOTHER JURISDICTION. THE COMPANY AND THE HOLDER IRREVOCABLY WAIVE ANY OBJECTION, INCLUDING ANY OBJECTION TO THE LAYING OF VENUE OR BASED ON THE GROUNDS OF *FORUM NON CONVENIENS*, WHICH IT MAY NOW OR HEREAFTER HAVE TO THE BRINGING OF ANY ACTION OR PROCEEDING IN SUCH JURISDICTION IN RESPECT THIS WARRANT OR OTHER DOCUMENT RELATED THERETO. EACH OF THE COMPANY AND THE HOLDER IRREVOCABLY CONSENTS TO SERVICE OF PROCESS IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS WARRANT IN THE MANNER PROVIDED FOR NOTICES (OTHER THAN FACSIMILE) IN SECTION 11. NOTHING IN THIS WARRANT WILL AFFECT THE RIGHT OF THE COMPANY OR THE HOLDER TO SERVE PROCESS IN ANY OTHER MANNER PERMITTED BY APPLICABLE LAW.

22. Waiver of Jury Trial. EACH OF THE COMPANY AND THE HOLDER HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS WARRANT. EACH OF THE COMPANY AND THE HOLDER (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF THE OTHER HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HAVE BEEN INDUCED TO ENTER INTO THIS WARRANT, BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 22.

23. Counterparts. This Warrant may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Warrant delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Warrant.

24. No Strict Construction. This Warrant shall be construed without regard to any presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Company has duly executed this Warrant on the Original Issue Date.

AGENUS INC.

By:

Name: Christine Klaskin
Title: Vice President, Finance

[Holder]

By:

Name:
Title:

Address for Notices to the Holder:

Email:

Exhibit A

FORM OF EXERCISE NOTICE

(To be executed by the Holder to exercise the right to purchase shares of Common Stock under the foregoing Warrant)

To: Agenus Inc.

The undersigned is the Holder of Warrant No. [ ] (the "Warrant") issued by Agenus Inc., a Delaware corporation (the "Company"). Capitalized terms used herein and not otherwise defined have the respective meanings set forth in the Warrant.

1. The Warrant is currently exercisable to purchase a total of _____ Warrant Shares.

2. The undersigned Holder hereby exercises its right to purchase _____ Warrant Shares pursuant to the Warrant.

3. The Holder shall pay the sum of $_____ to the Company in accordance with the terms of the Warrant.

4. Pursuant to this exercise, the Company shall deliver to the Holder _____ Warrant Shares in accordance with the terms of the Warrant.

5. Following this exercise, the Warrant shall be exercisable to purchase a total of _____ Warrant Shares.

Dated:

Name of Holder:

(Print)

By:

Title:

(Signature must conform in all respects to name of Holder as specified on face of the Warrant)

Exhibit B

FORM OF ASSIGNMENT

(to be completed and signed only upon transfer of Warrant)

FOR VALUE RECEIVED, the undersigned hereby sells, assigns and transfers unto _____ the right represented by the within Warrant to purchase _____ shares of Common Stock of Agenus Inc. to which the within warrant relates and appoints _____ attorney to transfer said right on the books of Agenus Inc. with full power of substitution in the premises.

Dated:

(Signature must conform in all respects to name of Holder as specified on face of the Warrant)

Address of Transferee:

In the presence of:

Exhibit 4.12

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following summary description of the Common Stock (as defined below) of Agenus Inc. (the "Company") is based on the provisions of the Company's Amended and Restated Certificate of Incorporation (as amended, the "Charter"), the Company's Fifth Amended and Restated By-laws (the "By-laws"), and the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL"). This information may not be complete in all respects and is qualified entirely by reference to the provisions of the Charter, the By-laws, and the DGCL. The Charter and By-laws are filed as exhibits to the Annual Report on Form 10-K to which this Description of Securities is an exhibit.

General

The Charter authorizes us to issue 400,000,000 shares of common stock, par value $0.01 per share (the "Common Stock"), and 5,000,000 shares of preferred stock, par value $0.01 per share. The Common Stock is registered under Section 12 of the Securities Exchange Act of 1934, as amended, and listed on the Nasdaq Capital Market under the symbol "AGEN."

Common Stock

Each holder of the Common Stock shall be entitled to one vote for each share of Common Stock held of record by such holder on all matters on which stockholders generally are entitled to vote and does not have cumulative voting rights. Directors are elected by a plurality of the votes cast by the stockholders entitled to vote on the election.

Dividends of cash or property may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Company's board of directors (the "Board") and subject to any preferential dividend rights of any then outstanding preferred stock. The holders of the Common Stock shall have no preemptive rights to subscribe for any shares of any class of stock of the Company whether now or hereafter authorized. The Common Stock shall not be convertible into, or exchangeable for, shares of any other class or classes or of any other series of the same class of the Company's capital stock. Upon the dissolution, liquidation or winding up of the affairs of the Company, whether voluntary or involuntary, after payment or provision for payment of the debts and liabilities of the Company and of the preferential and other amounts, if any, to which the holders of preferred stock shall be entitled, holders of Common Stock shall be entitled to receive all assets of the Company available for distribution to its stockholders, ratably in proportion to the number of shares held by each such stockholder.

Anti-Takeover Effects of the Charter, By-laws and the DGCL

Authorized but Unissued Shares.

The Company's authorized but unissued shares of Common Stock and preferred stock are available for future issuance without stockholder approval, except as may be required by

applicable stock exchange requirements. The Board has the authority under the Charter to issue preferred stock with rights superior to the rights of the holders of Common Stock. As a result, the issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control of the Company without further action by the stockholders and may adversely affect the voting and other rights of the holders of Common Stock.

Classified Board

The Charter provides that the Board be divided into three classes, with staggered three-year terms. As a result, only one class of directors is elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. The Charter also provides that the number of directors will be fixed exclusively pursuant to a resolution adopted by the Board.

Removal of Directors

The Charter provides that the Company's directors may be removed only for cause by the affirmative vote of at least a majority of the outstanding shares of capital stock entitled to vote at a special meeting called at least in part for that purpose.

Action by Written Consent; Special Meeting of Stockholders

The Charter requires that any action required or permitted to be taken by the Company's stockholders must be effected at a duly called annual or special meeting of the stockholders and cannot be taken by written consent in lieu of a meeting. A special meeting of the stockholders may be called only by the President of the Company or the Board. These provisions may have the effect of delaying, deferring or preventing a change in control and may also delay or prevent changes in management of the Company.

Advance Notice Procedures

The By-laws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of the Company's stockholders, including proposed nominations of persons for election to the Board. Stockholders at an annual meeting are only able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given the Company's Chairman of the Board, President or Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the By-laws do not give the Board the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the By-laws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the Company.

Super Majority Approval Requirements

The Charter provides that the affirmative vote of holders of at least 80% of the total votes eligible to be cast in the election of directors is required to amend, alter, change or repeal specified provisions. This requirement of a supermajority vote to approve amendments to the Charter could enable a minority of the Company's stockholders to exercise veto power over any such amendments.

Section 203 of the DGCL

The Company is subject to Section 203 of the DGCL, which regulates acquisitions of some Delaware corporations. In general, Section 203 prohibits, with some exceptions, a publicly held Delaware corporation such as us from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time that the stockholder became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or by-laws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

EXHIBIT 21.1

SUBSIDIARIES OF AGENUS INC.

Antigenics LLC., a Delaware limited liability company and a wholly-owned subsidiary of Agenus Inc.

Aronex Pharmaceuticals, Inc., a Delaware corporation and a wholly-owned subsidiary of Agenus Inc.

Antigenics Therapeutics Limited, a company organized under the laws of Ireland and a wholly-owned subsidiary of Agenus Inc.

Agenus Royalty Fund, LLC, a Delaware limited liability company and a wholly-owned subsidiary of Agenus Inc.

Agenus Switzerland Inc., a joint stock company organized under the laws of Switzerland formerly known as 4-Antibody AG, and a wholly-owned subsidiary of Agenus Inc.

Agenus West, LLC, a Delaware limited liability company and a wholly-owned subsidiary of Agenus Inc.

Agenus UK Limited, a private limited company organized under the laws of England and Wales and a wholly-owned subsidiary of Agenus Inc.

AgenTus Therapeutics, Inc., a Delaware corporation and a majority-owned subsidiary of Agenus Inc.

AgenTus Therapeutics Limited, a private limited company organized under the laws of England and Wales and a wholly-owned subsidiary of AgenTus Therapeutics, Inc.

AgenTus Therapeutics SA, a company organized under the laws of Belgium and a wholly-owned subsidiary of AgenTus Therapeutics, Inc.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Agenus Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333 40440, 333-40442, 333-50434, 333-69580, 333-106072, 333-115984, 333-143807, 333-143808, 333-151745, 333-160084, 333-160087, 333-160088, 333-176609, 333-183066, 333-183067, 333-189926, 333-195851, 333-209074, 333-212889, 333-228271, 333-233097, and 333-233100) on Form S-8 and (Nos. 333-161277, 333-163221, 333-189534, 333-195852, 333-203807, 333-206513, 333-208135, 333-208890, 333-209749, 333-209941, 333-215640, 333-221008, 333-221465, 333-222670, 333-228273, and 333-234333) on Form S-3 of Agenus Inc. of our reports dated March 16, 2020, with respect to the consolidated balance sheets of Agenus Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes and the effectiveness of internal control over financial reporting as of December 31, 2019, which reports appear in the December 31, 2019 annual report on Form 10 K of the Company.

Our report on the consolidated financial statements refers to a change in the Company's method of accounting for leases as of January 1, 2019, due to the adoption of Accounting Standards Update 2016-02, Leases (Topic 842), as amended.

Our report on the consolidated financial statements refers to a change in the Company's method of accounting for revenue as of January 1, 2018, due to the adoption of Accounting Standards Update 2014-09, Revenue from Contracts with Customers (Topic 606), as amended.

Our report on the consolidated financial statements contains an explanatory paragraph that states that the Company's recurring losses from operations and net capital deficiency raise substantial doubt about the entity's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ KPMG LLP

Boston, Massachusetts
March 16, 2020

Exhibit 31.1

Certification Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended

I, Garo H. Armen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Agenus Inc.;

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

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

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles;

   c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent function):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 16, 2020

/s/ GARO H. ARMEN, PH.D.

Garo H. Armen, Ph.D.
Chief Executive Officer and Principal Executive Officer

Exhibit 31.2

Certification Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended

I, Christine M. Klaskin, certify that:

1. I have reviewed this Annual Report on Form 10-K of Agenus Inc.;

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

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

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles;

   c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent function):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 16, 2020

/s/ CHRISTINE M. KLASKIN

Christine M. Klaskin
VP, Finance and Principal Financial Officer

Exhibit 32.1

Certification
Pursuant to 18 U.S.C. Section 1350,
As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 10-K of Agenus Inc. (the "Company") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned to his/her knowledge hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(i) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(ii) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ GARO H. ARMEN, PH.D.
Garo H. Armen, Ph.D.
Chief Executive Officer and Principal Executive Officer

/s/ CHRISTINE M. KLASKIN
Christine M. Klaskin
VP, Finance and Principal Financial Officer

Date: March 16, 2020

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished to the Securities and Exchange Commission as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 2019 and should not be considered filed as part of the Annual Report on Form 10-K.