

AGENUS INC  
Form 10-K  
March 07, 2014  
Table of Contents

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, 2013

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

(State or other jurisdiction of incorporation or organization)

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

(Title of each class)

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 and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulations S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form

10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting

company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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 30, 2013 was: \$87.1 million. There were 62,173,299 shares of the registrant’s Common Stock outstanding as of February 24, 2014.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement for the registrant’s 2014 Annual Meeting of Stockholders, which definitive proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the registrant’s fiscal year end of December 31, 2013, are incorporated by reference into Part III of this Annual Report on Form 10-K.

---

Table of Contents

## TABLE OF CONTENTS

	Page
PART I	
ITEM 1. <u>BUSINESS</u>	<u>3</u>
<u>Our Business</u>	<u>3</u>
<u>Our Products and Technologies Under Development</u>	<u>4</u>
<u>Intellectual Property Portfolio</u>	<u>9</u>
<u>Regulatory Compliance</u>	<u>10</u>
<u>Competition</u>	<u>11</u>
<u>Employees</u>	<u>12</u>
<u>Corporate History</u>	<u>12</u>
<u>Availability of Periodic SEC Reports</u>	<u>13</u>
ITEM 1A. <u>RISK FACTORS</u>	<u>13</u>
ITEM 1B. <u>UNRESOLVED STAFF COMMENTS</u>	<u>33</u>
ITEM 2. <u>PROPERTIES</u>	<u>34</u>
ITEM 3. <u>LEGAL PROCEEDINGS</u>	<u>34</u>
ITEM 4. <u>MINE SAFETY DISCLOSURES</u>	<u>34</u>
<u>EXECUTIVE OFFICERS OF THE REGISTRANT</u>	<u>34</u>
PART II	
ITEM 5. <u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	<u>36</u>
ITEM 6. <u>SELECTED FINANCIAL DATA</u>	<u>37</u>
ITEM 7. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>39</u>
ITEM 7A. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>47</u>
ITEM 8. <u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	<u>48</u>
ITEM 9. <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	<u>75</u>
ITEM 9A. <u>CONTROLS AND PROCEDURES</u>	<u>75</u>
ITEM 9B. <u>OTHER INFORMATION</u>	<u>77</u>
PART III	
ITEM 10. <u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	<u>77</u>
ITEM 11. <u>EXECUTIVE COMPENSATION</u>	<u>77</u>
ITEM 12. <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	<u>77</u>
ITEM 13. <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	<u>77</u>
ITEM 14. <u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	<u>77</u>
PART IV	
ITEM 15. <u>EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	<u>78</u>

Table of Contents

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 certain “forward-looking” statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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,” “potential,” “opportunity,” “future” and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on the Company's current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to 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, our ability to successfully integrate our recent acquisition of our wholly-owned subsidiary, 4-Antibody AG, the timing of the introduction of products, the effect of new accounting pronouncements, uncertainty regarding our future operating results and our profitability, anticipated sources of funds 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 made. We undertake no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events or otherwise.

We believe that 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 any forward-looking statement contained in this Annual Report on Form 10-K. We encourage you to read those descriptions carefully. We caution investors not to place significant reliance on forward-looking statements contained in this document; such statements need to be evaluated in light of all the information contained in this document. Furthermore, the statements speak only as of the date of this document, and we undertake no obligation to update or revise these statements. Oncophage®, Stimulon® and Retrocyte Display® are registered trademarks of Agenus Inc. and its subsidiaries. All rights reserved.

Table of Contents

PART I

Item 1. Business

Our Business

Agenus Inc. (including its subsidiaries, also referred to as “Agenus,” the “Company,” “we,” “us,” and “our”) is a biopharmaceutical company developing a portfolio of immuno-oncology candidates, including checkpoint modulators, heat shock protein vaccines and adjuvants. We are focused on immunotherapeutic products based on our core platform technologies with multiple product candidates advancing through the clinic, including several product candidates that have advanced into late-stage clinical trials through corporate partners. We assess the development, commercialization and/or partnering strategies with respect to each of our internal product candidates periodically based on several factors, including clinical trial results, competitive positioning, and funding requirements and resources.

Our core technology portfolio consists of our Checkpoint Antibody Program, our Heat Shock Protein (“HSP”) Platform (based on our HSP technologies), and our Saponin Platform (based on our saponin adjuvant technologies). Our Checkpoint Antibody Program became part of our portfolio with the recent acquisition of 4-Antibody AG, a private European-based biopharmaceutical company (“4-AB”). This acquisition (the “Acquisition”) provided us with a technology platform for the rapid discovery and optimization of fully-human antibodies against a wide array of molecular targets. This platform has been applied to six immune checkpoint targets seeking therapeutic antibody check point modulators (“CPMs”) to regulate immune response to cancers and other diseases. Our proprietary antibody discovery engine, Retrocyte Display<sup>®</sup>, is designed to generate high quality therapeutic antibody drug candidates quickly using a high-throughput approach incorporating human antibody libraries expressed in mammalian B-lineage cells. We currently have pre-clinical checkpoint antibody programs targeting GITR, OX40, CTLA-4, PD-1, TIM-3 and LAG-3 from 4-AB’s technologies. We have selected two GITR agonists and one CTLA-4 antagonist to advance into pre-clinical development. We are targeting to identify development candidates for the other four checkpoint programs during 2014, and to be in a position to file investigational new drug applications on four candidates within the next two years.

Within our HSP Platform we are developing our Prophage Series cancer vaccines. Our Prophage Series cancer vaccines are autologous therapies derived from cells extracted from the patient’s tumor. As a result, Prophage Series vaccines contain a precise antigenic ‘fingerprint’ of a patient’s particular cancer and are designed to reprogram the body’s immune system to target only cells bearing this fingerprint, reducing the risk that powerful anti-cancer agents will target healthy tissue and cause debilitating side effects often associated with chemotherapy and radiation therapy. We believe that in contrast to many other autologous vaccines that are based on cellular preparations, the Prophage Series is based on a stable protein preparation produced via a relatively simple manufacturing process. Our Prophage Series G vaccines are currently being studied in two different settings of glioblastoma multiforme, or GBM: newly diagnosed and recurrent disease.

Also within our HSP Platform, is HerpV, a recombinant, synthetic vaccine containing multiple antigens derived from the herpes simplex 2 virus. HerpV is currently in a Phase 2 clinical trial, and we believe it is one of the most clinically-advanced therapeutic vaccines for the treatment of genital herpes in clinical development. Combining our heat shock protein technology and our QS-21 Stimulon adjuvant, HerpV represents a potential new approach to the treatment of genital herpes. Rather than attempting to suppress the virus, which is what antivirals do, HerpV has the potential to enable the individual’s own immune system to stop the virus from causing and transmitting disease without chronic treatment. In November 2013, we released top line results from a Phase 2, randomized, double blind, multicenter clinical trial of HerpV in HSV-2 positive genital herpes patients, which showed that the trial met its primary endpoint. We anticipate reporting additional study results assessing the efficacy of a booster injection of HerpV during the first half of 2014.

Within our Saponin Platform is QS-21 Stimulon<sup>®</sup> adjuvant, or QS-21 Stimulon. QS-21 Stimulon is a saponin extracted from the bark of the Quillaja saponaria tree, also known as the Soapbark, an evergreen tree native to warm temperate central Chile. An adjuvant, such as QS-21 Stimulon, is a substance added to a vaccine or other immunotherapy that is intended to enhance immune response. QS-21 Stimulon has become a key component in the

development of investigational preventive vaccine formulations across a wide variety of infectious diseases, including several investigational therapeutic vaccines intended to treat cancer and degenerative disorders. QS-21 Stimulon has been widely studied and approximately 50,000 patients have received vaccines containing the adjuvant. The key licensees of QS-21 Stimulon are GlaxoSmithKline ("GSK") and JANSSEN Alzheimer Immunotherapy ("JANSSEN AI"). QS-21 Stimulon is currently being studied in 21 vaccine indications, which include GSK's Phase 3 vaccine programs for RTS,S for malaria, MAGE-A3 cancer immunotherapeutic for non-small cell lung cancer and melanoma and HZ/su for shingles. In addition, JANSSEN AI's QS-21 Stimulon adjuvant-containing vaccine candidate is in Phase 2 trials for the treatment of Alzheimer's disease. If any of our partners' products containing QS-21 Stimulon successfully completes clinical development and receives approval for commercial sale, we are generally entitled to receive royalties for 10 years after commercial launch, with some exceptions.

## Table of Contents

Our business activities have included 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 common stock is currently listed on The Nasdaq Capital Market (“Nasdaq”) under the symbol “AGEN”.

## Our Products and Technologies Under Development

Research and development expenses for the years ended December 31, 2013, 2012, and 2011, were \$13.0 million, \$10.6 million, and \$11.0 million, respectively. Set forth below are the details of our research and development programs.

### The Checkpoint Antibody Program

Effective February 2014, we acquired 4-AB, a private European-based biopharmaceutical company, providing us with a technology platform for the rapid discovery and optimization of fully-human antibodies against a wide array of molecular targets. We are applying this antibody platform to discover and optimize checkpoint modulators (“CPMs”) that regulate immune response to cancers and other diseases. Our proprietary discovery engine within the platform, Retrocyte Display<sup>®</sup>, is designed to generate high quality therapeutic antibody drug candidates quickly using a high-throughput approach incorporating human antibody libraries expressed in mammalian B-lineage cells. We currently have pre-clinical checkpoint antibody programs targeting GITR, OX40, CTLA-4, PD-1, TIM-3 and LAG-3 from 4-AB’s technologies, and have selected two GITR agonists and one CTLA-4 antagonist to advance into pre-clinical development. We are targeting to identify development candidates for the other four checkpoint programs during 2014, and to be in a position to file investigational new drug applications on four candidates within the next two years.

Checkpoints within the body are endogenous processes that regulate immune response. These molecules serve as checks employed by the body to prevent runaway immune responses which can be debilitating, or even deadly. Unfortunately, these necessary mechanisms of control can hinder the anti-cancer immune response. They can be sabotaged by cancer cells as a defense against immune attack. Thus, while checkpoints usually function to appropriately regulate immune responses, cancers can “co-opt” check point processes to evade destruction by the immune system. CPMs are potential medicines (usually antibodies) that bind to checkpoint proteins and either enhance or block specific checkpoint processes. CPMs, one of the most exciting new approaches to cancer therapy, are designed to make cancers more susceptible to destruction by the body’s immune responses. CPMs include compounds like Bristol Meyer Squibb’s Yervoy and Merck’s PD-1 antagonist.

It took 4-AB over seven years to build the Retrocyte Display<sup>®</sup> Antibody Platform, which we believe is one of the best ways to generate fully human monoclonals. 4-AB has institutional and corporate collaborations, including with the Ludwig Cancer Research, and Recepta Biopharma SA, and we are in active discussions for additional future collaborations. In collaboration with our partners, we will explore ways to advance the emerging portfolio of CPMs as single agents and in optimized combinations, including potential combinations with Prophage and other agents.

### The Heat Shock Protein Platform

Heat shock proteins (HSP) are a group of proteins present in all cells. Their expression is increased when cells are exposed to elevated temperatures or other stresses. The immunological function of HSPs was first discovered when it was shown that HSPs purified from cancer cells produced immunity to cancer whereas HSPs purified from normal tissue did not. This discovery led to the understanding that HSPs actually chaperone (bind to and carry) the “peptide fingerprint,” which includes the antigenic peptides of the cells from which they are purified. It was further identified that immunization with HSPs work by interacting with antigen presenting cells that then express the HSP-associated antigenic peptides to cause a CD4+ and CD8+ T-cell immune response that in turn targets the cancer cells.

Collectively, these many years of research taught us the importance of targeting cancer with high specificity. In order to provide effective immunization, HSPs must be isolated from cancer cells. Since HSPs are expressed in all tumor cells, the approach of immunizing with HSPs is broadly applicable to a variety of cancer types. Agenus pioneered the use of the heat shock protein, gp96, purified from the patients' own tumor tissue, as a way to make a patient-specific vaccine.

Because cancer is a highly variable disease from one patient to another, due to rapid mutation of cancer cells, we believe that a patient-specific vaccination approach is required to generate a more robust and targeted immune response against the disease. For certain diseases, such as genital herpes, we do not believe that a personalized vaccination approach is required,



## Table of Contents

since the pathogen does not vary as greatly from patient to patient as do cancer cells. For example, in our HerpV product candidate for the treatment of genital herpes, we complex, or bind, several defined antigenic herpes peptides to an HSP (Hsc70) that we genetically engineer, creating an HSPPC. This HSPPC, when injected into the skin, is designed to elicit a cellular immune response to the synthetic peptides carried by the HSP.

### The Prophage Series Vaccines

Our Prophage Series cancer vaccines are autologous therapies derived from cells extracted from the patient's tumor. As a result, Prophage Series vaccines contain a precise antigenic 'fingerprint' of a patient's particular cancer and are designed to reprogram the body's immune system to target only cells bearing this fingerprint, reducing the risk that powerful anti-cancer agents will target healthy tissue and cause debilitating side effects often associated with chemotherapy and radiation therapy. We believe that in contrast to many other autologous vaccines that are based on cellular preparations, the Prophage Series is based on a stable protein preparation produced via a relatively simple manufacturing process. Our Prophage Series G vaccines are currently being studied in two different settings of glioblastoma multiforme, or GBM: newly diagnosed and recurrent disease.

Each Prophage Series vaccine is manufactured using a patient's own tumor which is removed through surgery. After the patient undergoes surgery to remove cancerous tumor tissue, the tumor is shipped frozen in a specially designed kit provided by the company to our Lexington, Massachusetts facility. Each Prophage Series vaccine is produced in about 10 hours, after which it undergoes extensive quality testing which takes about 2 weeks. The turnaround time from the date of surgery is about 3 to 4 weeks which generally fits well with the patient's recovery time from surgery. Once we release the vaccine, it is shipped frozen overnight to the hospital pharmacy or clinician. Prophage Series vaccines are given as a simple intradermal injection. In this effort, Agenus has established, within a single facility, well-defined, cost efficient manufacturing under Good Manufacturing Practices (GMPs) that have supported the processing of over 1,000 tumor samples from across the globe.

Since the first patient was enrolled in a clinical trial studying a Prophage Series vaccine in 1997, nearly 900 cancer patients have been treated with our vaccine in multiple cancers and across numerous clinical trials. The results of these trials have been published and/or presented at major conferences. These results indicate consistent clinical and/or immunological activity across many types of cancer.

Because our Prophage Series vaccines are derived from the patient's own tumor, they are unlike the majority of approved therapies and as such, they are experiencing a long development process and incurring high development costs, either of which could delay or prevent our commercialization efforts. For additional information regarding regulatory risks and uncertainties, please read the risks identified in Part 1-Item 1A. "Risk Factors" of this Annual Report on Form 10-K.

The Prophage Series G-100 and G-200 vaccines are currently being studied in two different settings of glioblastoma multiforme; patients who have been newly diagnosed as well as those with recurrent disease. Glioblastoma is the most common primary malignant brain tumor and accounts for the majority of diagnoses of malignant cancers of the brain. In addition, our Prophage Series vaccines are currently being studied in stage III and IV metastatic melanoma.

### Glioblastoma Multiforme

GBM is a cancer affecting the central nervous system arising from glial cells which become cancerous. GBM, the most common primary malignant brain tumor, is currently a rapidly fatal disease. The American Cancer Society estimates that 23,380 new cases of the brain and other nervous system cancers will be diagnosed during 2014 in the U.S., and that 14,320 people will die from these tumors during 2014 in the U.S.

We have investigator-sponsored Phase 2 trials fully enrolled in the United States testing the Prophage Series vaccine candidates G-100 (HSPPC-96) and G-200 in newly diagnosed and recurrent GBM, respectively. In June 2011, results from the Phase 2 trial in recurrent GBM were presented at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) showing, among other things, that measures of immune response post vaccination with G-200 demonstrated a significant tumor-specific CD8+ T-cell response as well as innate immune responses as marked by a significant increase in the levels of circulating NK cells. Subsequently, in December 2013, these Phase 2 results were published demonstrating that more than 90% of the patients treated with Prophage Series G-200 were alive at six months after surgery and 30% were alive at twelve months. Additionally, the median overall survival was approximately eleven months. This compares favorably to historical control data with expected median survival for

recurrent GBM patients of three to nine months. The primary objective of this multi-center, single arm Phase 2 trial was to assess the survival rate at six months. The data was published in a manuscript in Neuro-Oncology, the official journal of the Society of Neuro-Oncology.

In September 2013, we announced the results of a recent analysis from a multiple-center, Phase 2 clinical trial in 46 patients with newly diagnosed GBM treated with Prophage Series G-100 (HSPPC-96) in combination with the current standard of care (radiation and temozolomide) which showed that, to date, patients treated with HSPPC-96 had a median progression

## Table of Contents

free survival (PFS) of 17.8 months, with 63% of the patients progression free at 12 months and 20% of patients progression free at 24 months. These results indicate improvement when compared to patients treated with the standard of care, for which median PFS is 6.9 months. Median overall survival (OS), the primary endpoint of the trial, is 23.3 months to date and remains durable in patients treated with HSPPC-96. In this study, the 12 month survival rate is 85%, with 50% of patients still alive and being followed, with many surviving beyond the 24 month study period. For the standard of care alone, the median OS rate is 14.6 months to date.

In addition to the Phase 2 trial in patients with newly diagnosed GBM, the Alliance for Clinical Trials in Oncology, a cooperative group of the NCI, is supporting a randomized Phase 2 clinical trial of the HSPPC-96 vaccine in combination with bevacizumab (Avastin®) in approximately 222 patients with surgically resectable, recurrent GBM. Patients have already been randomized into this trial and active recruitment is underway at multiple centers in the United States. We believe that this trial is the largest vaccine trial ever funded by the NCI in brain tumors and the largest vaccine study ever conducted in combination with Avastin. The study is designed to compare efficacy of the HSPPC-96 vaccine administered with bevacizumab either concomitantly or at progression, versus treatment with bevacizumab alone. The primary endpoint is overall survival. This study design is supported in part by previous research indicating a potential synergistic effect between the mechanisms of action behind both HSPPC-96 and bevacizumab.

### Melanoma

In January 2014, we announced the initiation of an investigator-sponsored, randomized Phase 2 clinical trial of the Prophage vaccine in combination with ipilimumab in patients with stage III and IV metastatic melanoma. This study, which is an investigator-sponsored trial at the University of Texas Health Science Center in Houston, is designed to evaluate the safety, feasibility and immunogenicity of the combination of the Prophage vaccine and ipilimumab with or without low-dose cyclophosphamide in approximately 25 patients. This study represents the first time that one of our Prophage Series cancer vaccines has been evaluated in the clinic in combination with a checkpoint inhibitor antibody.

### Renal Cell Carcinoma

In April 2008, the Russian Ministry of Public Health issued a registration certificate for the use of Oncophage for the treatment of kidney cancer patients at intermediate risk for disease recurrence. Because, among other things, we have limited resources and minimal sales and marketing experience, commercialization of Oncophage has been slow, and only modest sales of Oncophage in Russia have occurred. The Russian registration was our first product approval from a regulatory authority, and the first approval of a patient-specific therapeutic cancer vaccine in a major market. In December 2011, we out-licensed this program to NewVac LLC (a subsidiary of ChemRar Ventures LLC, "NewVac"), a company focused on the development of innovative technology for cancer immunotherapy.

In December 2011, we granted NewVac an exclusive license to manufacture, market and sell Oncophage as well as pursue a development program in the Russian Federation and certain other CIS countries ("NewVac Agreement"). The NewVac Agreement may be terminated by either party upon a material breach if the breach is not cured within the time specified in the agreement. The NewVac Agreement may also be terminated by us if certain milestones are not achieved and by NewVac without cause. The NewVac Agreement has an initial term of three years and may be extended under certain terms for a period ending the later of December 2021, or the expiration of the last valid claim of the licensed patent rights, as defined in the NewVac Agreement. Upon termination of the NewVac Agreement, all activity under the agreement immediately ceases. During the term of the NewVac Agreement we are entitled to receive modest milestone payments in addition to payments for supply of Oncophage and/or royalties in the low double-digits on net sales of Oncophage.

### Manufacturing

Commercial and clinical supplies of Oncophage and other vaccine candidates deriving from the Prophage Series are manufactured in our Lexington, Massachusetts facility. We estimate that this facility could support the production of up to 4,000 batches per year. On average, it takes eight to 10 hours of direct processing time to manufacture a patient batch of vaccine.

After manufacturing, Prophage Series vaccines are tested and released by our quality systems staff. The quality control organization performs a series of release assays designed to ensure that the 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 Good Manufacturing Practices, also known as cGMP, as mandated by the FDA and foreign regulatory agencies.

Our manufacturing staff is rigorously trained and routinely evaluated for conformance to manufacturing procedures and quality standards. This oversight is intended to ensure compliance with FDA and foreign regulations and to provide consistent

6

---

## Table of Contents

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.

### HerpV

HerpV, formerly known as AG-707 plus QS-21 Stimulon, is an investigational therapeutic vaccine candidate directed at the virus that causes genital herpes (herpes simplex virus-2, or HSV-2) and is the first potential recombinant (off-the-shelf) application of our HSP technology. HerpV includes our proprietary QS-21 Stimulon adjuvant. HerpV is a polyvalent "off-the-shelf" vaccine consisting of recombinant human heat shock protein-70 associated with a total of thirty-two distinct antigens representative of genital herpes virus (HSV-2) genome. This means that it may be applicable to a broader patient population and may have potential in managing outbreaks and disease transmission. We consider HerpV to be part of a platform technology, since with the integration of heat shock proteins with antigenic peptides, we could potentially create therapeutic vaccines for various infectious diseases.

Genital herpes is one of the most common ulcerating diseases of the genital mucosa. The World Health Organization currently estimates that in the U.S., approximately 40 to 60 million people are HSV-2-infected, with an incidence of 1-2 million infections and 600,000 to 800,000 clinical cases per year. Prevalence in the 30-40 year-old population is about 30%. This disease often results in recurrent painful sores in the genital area. Current therapies involve taking a daily medication that only partly suppresses the virus.

The published results of a Phase 1 study show that HerpV administered with our QS-21 Stimulon adjuvant was associated with a significant induction of both CD4+ and CD8+ cellular immune responses. We believe that this is the first instance of a herpes vaccine candidate eliciting both CD4 and CD8 cellular immunity in human subjects. In November 2013, we released top line results from a Phase 2, randomized, double blind, multicenter clinical trial of HerpV in HSV-2 positive genital herpes patients. The Phase 2 trial met its primary endpoint. The primary analysis, which looked at viral shedding after the initial three injections, shows that patients who received HerpV had a statistically significant reduction in viral shedding. This study was designed to determine the biological efficacy of HerpV on genital viral shedding after three injections of the vaccine. As of the date of this report, all subjects in the study have received a booster injection of HerpV that was given six months after the first vaccination followed by determination of genital viral shedding for an additional 45-day period. We anticipate reporting additional study results after booster injection during the first half of 2014.

### The Saponin Platform & QS-21 Stimulon

QS-21 Stimulon, from our Saponin Platform, is an adjuvant, or a substance added to a vaccine or other immunotherapy that is intended to enhance immune response. It is a saponin extracted from the bark of the Quillaja saponaria tree, also known as the Soapbark, an evergreen tree native to warm temperate central Chile. QS-21 Stimulon has become a key component in the development of investigational preventive vaccine formulations across a wide variety of infectious diseases, including several investigational therapeutic vaccines intended to treat cancer and degenerative disorders. There are approximately 21 vaccines containing QS-21 Stimulon in clinical development by us and our licensees, including a total of four in Phase 3 testing by GSK for malaria, melanoma, non-small cell lung cancer and shingles, and one in Phase 2 trials with JANSSEN AI for the treatment of Alzheimer's disease. Assuming regulatory approval, the first products containing QS-21 Stimulon are anticipated to be launched in 2015. If any of our partners' products containing QS-21 Stimulon successfully completes clinical development and receives approval for commercial sale, we are generally entitled to receive royalties for 10 years after commercial launch, with some exceptions. The pipeline of product candidates containing QS-21 Stimulon is very diverse, encompassing prophylactic as well as therapeutic vaccines for infectious diseases, multiple cancer types, and Alzheimer's disease. We do not incur clinical development costs for the product candidates of our licensees. In addition to the programs of our licensees, our internally-developed vaccine candidate HerpV, which is in a Phase 2 study for the treatment of genital herpes in Herpes Simplex Virus 2 (HSV-2) positive subjects, contains QS-21 Stimulon. See "Heat Shock Protein Technology - HerpV" above.

QS-21 Stimulon has the ability to stimulate antibody, or humoral, immune response, and has also been shown to activate cellular immunity. A natural product, QS-21 Stimulon is a triterpene glycoside, or saponin, purified from the bark of a South American tree called Quillaja saponaria. It is sufficiently characterized with a known molecular

structure, thus distinguishing it from other adjuvant candidates, which are typically emulsions, polymers, or biologicals. QS-21 Stimulon has been tested in approximately 185 clinical trials involving, in the aggregate, over 50,000 subjects in a variety of cancer indications, infectious diseases, and other disorders. 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 antibody responses than aluminum hydroxide or aluminum phosphate, the adjuvants most commonly used in approved vaccines in the United States today.

7

---

Table of Contents

## Partnered QS-21 Stimulon Programs

A number of pharmaceutical and biotechnology companies have licensed QS-21 Stimulon from us for use in vaccines to treat a wide variety of human diseases. Companies with QS-21 Stimulon programs include GSK and JANSSEN AI. In return for rights to use QS-21 Stimulon, these companies have generally agreed to pay us license fees, manufacturing payments, milestone payments, and royalties on product sales for at least 10 years after commercial launch, with some exceptions. In addition to our corporate licensing arrangements, we have developed a number of academic collaborations to test new vaccine concepts and products containing QS-21 Stimulon.

GSK. 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. 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 the Company or certain of our assets. The first right to negotiate will expire after five years. 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. We refer to the GSK License Agreement, the Amended GSK Supply Agreement and the GSK First Right to Negotiate Agreement, from time to time as the "GSK Agreements". As of December 31, 2013, we have received \$21.3 million of a potential \$24.3 million in upfront and milestone payments related to the GSK Agreements. We are generally entitled to receive low single-digit royalties on net sales for a period of 7-10 years after the first commercial sale of a resulting GSK product with some exceptions. 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 milestone payment obligations survive termination or expiration of the GSK Agreements for any reason, and 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 believe QS-21 Stimulon is a key component included in several of GSK's proprietary adjuvant systems and a number of GSK's vaccine candidates currently in development are formulated using adjuvant systems containing QS-21 Stimulon. GSK has ongoing Phase 3 studies evaluating its investigational MAGE-A3 Antigen-Specific Cancer Immunotherapeutic containing QS-21 Stimulon in melanoma and non-small cell lung cancer. We anticipate data from the Phase 3 trial in non-small cell lung cancer will be reported during the first half of 2014. GSK's DERMA study, a Phase 3 randomized, blinded, placebo-controlled MAGE-A3 trial did not meet its first co-primary endpoint in melanoma patients. In an independent analysis, the study did not significantly extend the disease-free survival period when compared to placebo in the overall MAGE-A3 positive trial population. In line with the Independent Data Monitoring Committee's unanimous recommendation, GSK will continue the study until the second co-primary endpoint is assessed. This co-primary endpoint is based on predefined criterion that was agreed upon by regulatory authorities. This analysis, which is based on gene signature, is designed to prospectively identify patients who may have the capability to be more immunologically responsive and therefore can potentially benefit from treatment. If further analysis shows that the predefined gene signature subset data are successful, there is the potential that a regulatory filing could be considered. GSK anticipates that these data will be available in 2015. In October 2011, The New England Journal of Medicine published results of a Phase 3 trial of GSK Biologicals' RTS,S malaria vaccine candidate containing QS-21 Stimulon. Results of the study, the largest malaria vaccine efficacy and safety trial ever conducted, demonstrate that RTS,S provided young African children with significant protection against clinical and severe malaria-reducing risk by 56 percent and 47 percent, respectively, for the 12-month period following

vaccination. In November 2012, The New England Journal of Medicine published results of a second Phase 3 trial for RTS,S. In this study, infants (aged 6-12 weeks at first vaccination) receiving the RTS,S vaccine candidate experienced one-third fewer episodes of both clinical and severe malaria and experienced similar reactions to the injection when compared to those who received the control meningococcal C conjugate vaccine. Both co-primary endpoints in the large ongoing efficacy trial were met. In November 2013, additional Phase 3 data was reported that shows that RTS,S helps protect young children and infants from clinical malaria up to 18 months post vaccination. GSK plans to submit a regulatory application in Africa in 2014.

Elan/JANSSEN Alzheimer's Immunotherapy. Elan Pharmaceuticals, Inc. and/or its affiliates ("Elan") had a commercial license for the use of QS-21 Stimulon in the research and commercialization of Elan's Alzheimer's disease vaccine candidate that contains QS-21 Stimulon ("JANSSEN Product"). Effective September 14, 2009, we entered into an Amended and Restated License Agreement with Elan, which was assigned by Elan to JANSSEN AI on September 17, 2009 (the "JANSSEN AI



Table of Contents

License Agreement”). Under the terms of the JANSSEN AI License Agreement, JANSSEN AI has the right to develop, make, have made, use, sell, offer for sale, import, and have sold, the JANSSEN Product. In addition, pursuant to the terms of the JANSSEN AI License Agreement, JANSSEN AI has the right to manufacture all of its requirements of QS-21 Stimulon for use in the JANSSEN Product. We have no further supply obligations to JANSSEN AI. If all benchmarks are met under the JANSSEN AI License Agreement, we could receive up to \$11.5 million in future milestone payments; \$1.5 million has been received as of December 31, 2013. Furthermore, under the terms of the JANSSEN AI License Agreement, we are entitled to receive mid-single-digit royalties on net sales of the JANSSEN Product for a period of at least 10 years after the first commercial sale of such product, if any. Expiration or termination of the JANSSEN AI License Agreement is without prejudice to any rights that accrued to the benefit of the parties prior to the date of such expiration or termination. Upon expiration of the JANSSEN AI License Agreement, JANSSEN AI will have a royalty-free license. JANSSEN may terminate the JANSSEN AI License Agreement by giving us written notice. If a material breach is not cured within the time specified in the JANSSEN AI License Agreement, either party may terminate. Upon early termination of the JANSSEN AI License Agreement, JANSSEN AI's license rights terminate and future payment obligations do not accrue. The termination or expiration of the JANSSEN AI License Agreement will not relieve either party from any obligation which accrued prior to the termination or expiration. However, in the event that JANSSEN elects an early termination of the JANSSEN AI License Agreement, all rights to know-how, manufacturing technology and patents covered under the JANSSEN AI License Agreement will revert back to us.

**Manufacturing**

Except in the case of GSK and JANSSEN AI, we have retained worldwide manufacturing rights for QS-21 Stimulon. We have the right to subcontract manufacturing for QS-21 Stimulon and we have a supply agreement with a contract manufacturer for the production of QS-21 Stimulon through September 2014. In addition, under the terms of our agreement with GSK, GSK is committed to supply certain quantities of commercial grade QS-21 Stimulon to us and our licensees for a fixed period of time.

**Intellectual Property Portfolio**

We seek to protect our technologies through a combination of patents, trade secrets and know-how and currently have exclusive rights, through outright ownership or through exclusive licenses, to approximately 60 issued United States patents and approximately 99 issued foreign patents. We also have exclusive rights to approximately 13 pending United States patent applications and approximately 43 pending foreign patent applications. While we have patent coverage in Russia for Oncophage, we may not have rights in other territories where we may pursue regulatory approval for Prophage Series vaccine candidates.

Our issued patents include those that cover our core technologies including HSPs for the treatment of cancers and infectious disease, and saponin adjuvants.

The issued patents that cover the Prophage Series vaccines expire at various dates between 2015 and 2024. The issued patents relating to HerpV expire at various dates between 2014 and 2029. Our patents to purified QS-21 Stimulon have expired. Additional protection for QS-21 Stimulon in combination with other agents is provided by our other issued patents which expire between 2017 and 2022. We continue to explore means of extending the life cycle of our patent portfolio.

Through our acquisition of 4-AB, we own patents and patent applications directed to various methods and compositions, including methods for identifying therapeutic antibodies and product candidates arising out of 4-AB's technology platforms. In particular, we own patents and patent applications relating to Retrocyte Display®, a high throughput antibody expression platform for the identification of fully human monoclonal antibodies. This patent family is projected to expire between 2029 and 2030. We also own patents and/or patent applications relating to methods for generating precursor lymphocytes and use thereof for production of binding proteins (projected to expire between 2021 and 2024); retroviral vector particles and uses thereof (projected to expire in 2030); and antibodies that target and neutralize human Cytomegalovirus (projected to expire in 2030). As we advance our research and development efforts with our institutional and corporate collaborators, we intend to seek patent protection for newly-identified therapeutic antibodies and product candidates.

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

Mount Sinai School of Medicine

In November 1994, we entered into a patent license agreement with the Mount Sinai School of Medicine (the “Mount Sinai Agreement”). Through the Mount Sinai Agreement, we obtained an exclusive, worldwide license to patent rights relating to the heat shock protein technology that resulted from the research and development performed by Dr. Pramod Srivastava, our founding scientist and a former member of our Board of Directors. We agreed to pay Mount Sinai a royalty on the net sales of products covered by the licensed patent rights and also provided Mount Sinai with a 0.45% equity interest in the Company (approximately 10,300 shares) valued at approximately \$90,000 at the time of issuance. The term of the Mount Sinai

## Table of Contents

Agreement ends when the last of the licensed patents expires (2016) or becomes no longer valid. If we fail to pay royalties that are due under the agreement, Mount Sinai may issue written notice to us. If we continue to fail to pay royalties after 60 days from receipt of the written notice, Mount Sinai can terminate the agreement. The Mount Sinai Agreement requires us to use due diligence to make the products covered by the licensed patent rights commercially available, including a requirement for us to use best efforts to reach a number of developmental milestones, which have been achieved. If we fail to comply with the due diligence provisions of the agreement, Mount Sinai could take actions to convert our exclusive license to a non-exclusive license after six months written notice. The Mount Sinai Agreement does not contain any milestone payment provisions.

### Fordham University

During 1995, Dr. Srivastava moved his research to Fordham University (“Fordham”). We entered into a sponsored research and technology license agreement with Fordham in March 1995 (the “Fordham Agreement”) relating to the continued development of the heat shock protein technology and agreed to make payments to Fordham to sponsor Dr. Srivastava’s research. Through the Fordham Agreement, we obtained an exclusive, perpetual, worldwide license to all of the intellectual property, including all the patent rights, which resulted from the research and development performed by Dr. Srivastava at Fordham. We also agreed to pay Fordham a royalty on the net sales of products covered by the Fordham Agreement through the last expiration date on the patents under the agreement (2018) or when the patents become no longer valid. The agreement does not contain any milestone payment provisions or any diligence provisions. Dr. Srivastava moved his research to the University of Connecticut Health Center (“UConn”) during 1997 and, accordingly, the parts of the agreement related to payments for sponsored research at Fordham terminated in mid-1997. During the term of this agreement, we paid Fordham approximately \$2.4 million.

### University of Connecticut

In May 2001, we entered into a license agreement with UConn which was amended in March 2003 and June 2009. Through the license agreement, we obtained an exclusive worldwide license to patent rights resulting from inventions discovered under a research agreement that was effective from February 1998 until December 2006. The term of the license agreement ends when the last of the licensed patents expires (2024) or becomes no longer valid. UConn may terminate the agreement: (1) if, after 30 days written notice for breach, we continue to fail to make any payments due under the license agreement, or (2) we cease to carry on our business related to the patent rights or if we initiate or conduct actions in order to declare bankruptcy. We may terminate the agreement upon 90 days written notice. We are required to make royalty payments on any obligations created prior to the effective date of termination of the license agreement. Upon expiration or termination of the license agreement due to breach, we have the right to continue to manufacture and sell products covered under the license agreement which are considered to be works in progress for a period of 6 months. The license agreement contains aggregate milestone payments of approximately \$1.2 million for each product we develop covered by the licensed patent rights. These milestone payments are contingent upon regulatory filings, regulatory approvals, and commercial sales of products. We have also agreed to pay UConn a royalty on the net sales of products covered by the license agreement as well as annual license maintenance fees beginning in May 2006. Royalties otherwise due on the net sales of products covered by the license agreement may be credited against the annual license maintenance fee obligations. Under the March 2003 amendment, we agreed to pay UConn an upfront payment and to make future payments for each patent or patent application with respect to which we exercised our option under the research agreement. As of December 31, 2013, we have paid approximately \$535,000 to UConn under the license agreement. The license agreement gives us complete discretion over the commercialization of products covered by the licensed patent rights but also requires us to use commercially reasonable diligent efforts to introduce commercial products within and outside the United States. If we fail to meet these diligence requirements, UConn may be able to terminate the license agreement.

### Regulatory Compliance

Governmental authorities in the United States and other countries extensively regulate the preclinical 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 preclinical, 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, or GCP, or Good Laboratory Practices, or GLP, for specific non-clinical toxicology studies. The FDA may also require confirmatory trials, post-

## Table of Contents

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 preclinical 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 or, in the case of biologics, like the Prophage Series vaccines, a biologics license application ("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 and infectious diseases. In addition, many competitors focus on immunotherapy as a treatment for cancer and infectious diseases. In particular, some of these companies are developing cancer vaccines produced from a patient's own cells or tissue. Others are focusing on developing heat shock protein products. Prior to regulatory approval, we 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. In addition, we compete for funding, access to licenses, personnel, and third-party collaborations. 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- Our competitors in the biotechnology and pharmaceutical

## Table of Contents

industries 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.

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 and could compete with QS-21 Stimulon for inclusion in vaccines in development. These adjuvants include, but are not limited to, oligonucleotides, under development by Pfizer, Idera, Colby, and Dynavax, MF59 under development by Novartis, IC31, under development by Intercell, and MPL, under development by GSK. In the past, the Company has provided QS-21 Stimulon to other entities under materials transfer arrangements. In at least one instance, it is possible that this material was used unlawfully 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 for our ability to execute future partnering and licensing deals with 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 we develop.

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. Any diminution of this goodwill may have an adverse effect on our ability to commercialize this technology, either alone or with a third party.

We are aware of certain programs and products under development by other companies that may compete with our programs and products. Several of these companies have products that utilize similar technologies and/or patient-specific medicine techniques. Genentech markets Avastin, and Eisai and Arbor Pharmaceuticals market Gliadel, for treatment of recurrent glioma. In addition, TVAX Biomedical and Stemline Therapeutics are developing immunotherapy candidates (TVI-Brain-1 and SL-701, respectively) for recurrent glioma. Schering Corporation, a subsidiary of Merck, markets Temodar for treatment of patients with newly diagnosed glioma. Other companies are developing vaccine candidates for the treatment of patients with newly diagnosed glioma, such as Innocell Corp (Immuncell-LC), ImmunoCellular Therapeutics (ICT-107), Northwest Biotherapeutics (DC-Vax), Immatics (IMA-950), Activartis Biotech (GBM-Vax) and Celldex (CDX-110). Celldex is also currently developing a vaccine candidate for recurrent glioma. Other companies may begin development programs as well. Oncophage may compete with therapies currently in development for non-metastatic RCC, such as sorafenib, sunitinib, temsirolimus, bevacizumab and pazopanib. As vaccines from our Prophage Series are potentially developed in other indications, they could face additional competition in those indications. In addition, and prior to regulatory approval, our Prophage Series vaccines and all of 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.

Valtrex (GSK) and Famvir (Novartis) are small molecule drugs marketed for treatment of genital herpes. Other companies are engaged in research and/or clinical development for vaccines for treatment of genital herpes including Genocea and Vical. AiCuris GmbH is engaged in clinical research of a small molecule drug for treatment of genital herpes and has completed a Phase 2 trial.

We are aware of several large companies that have antibody-based products on the market or in clinical development that are directed to the same biological target as some of our programs, including Bristol-Myers Squibb, which markets ipilimumab, an anti-CTLA-4 antibody, and has an anti-PD1 antibody in development, Medimmune, which has anti-CTLA-4, OX-40 and PD1 antibodies in development, Merck and Curetech, which each has an anti-PD1 antibody in development, and Pfizer, which has an anti-CTLA-4 antibody in development.

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 and infectious disease therapies

continue to accelerate.

#### Employees

As of February 21, 2014, we had approximately 114 employees, of whom 27 were Ph.D.s and 3 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

12

---



Table of Contents

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](http://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 ("Securities 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 information in the sections entitled "Financial" and "News," as sources of information about us.

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 occurs, 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 Business

If we incur operating losses for longer than we expect, or we are not able to raise additional capital, we may be unable to continue our operations, or we may become insolvent.

Our net losses for the years ended December 31, 2013, 2012, and 2011, were \$30.1 million, \$11.3 million, and \$23.3 million, respectively. We expect to incur additional losses over the next several years as we continue research and clinical development of our technologies and pursue partnering opportunities, regulatory strategies, commercialization, and related activities, and such losses may increase as a result of our recent acquisition of 4-AB (the "Acquisition"). Furthermore, our ability to generate cash from operations is dependent on the success of our licensees and collaborative partners, as well as the likelihood and timing of new strategic licensing and partnering relationships and/or successful development and commercialization of vaccines containing QS-21 Stimulon, our Prophage Series vaccines and our other product candidates. From our inception through December 31, 2013, we have incurred net losses totaling \$649.1 million.

On December 31, 2013, we had \$27.4 million in cash and cash equivalents. We believe that, based on our current plans and activities, our working capital resources at December 31, 2013 along with the net proceeds from our equity offering in February 2014 of approximately \$56.0 million, and potential proceeds from license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements through the first half of 2015. We expect to attempt to raise additional funds in advance of depleting our funds although additional funding may not be available on favorable terms, or at all. For the year ended December 31, 2013, our average monthly cash used in operating activities was approximately \$1.6 million. We do not anticipate significant capital expenditures during 2014. We have financed our operations primarily through the sale of equity and debt securities. In order to finance future operations, we will be required to raise additional funds in the capital markets, through arrangements with collaborative partners, or from other sources. Additional financing may not be available on favorable terms, or at all. If we are unable to raise additional funds when we need them or if we incur operating losses for longer than we expect, we may not be able to continue some or all of our operations, or we may become insolvent. We also may be forced to license or sell technologies to others under agreements that allocate to third parties substantial portions of the potential value of these technologies.

There are a number of factors that will influence our future capital requirements, including, without limitation, the following:

13

---

Table of Contents

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our future product candidates, and conducting preclinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our and our licensees' product candidates;
- the cost of manufacturing;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property rights;
- the costs associated with any successful commercial operations; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

General economic conditions in the United States economy and abroad may have a material adverse effect on our liquidity and financial condition, particularly if our ability to raise additional funds is impaired. The ability of potential patients and/or health care payers to pay for our products could also be adversely impacted, thereby limiting our potential revenue. In addition, any negative impacts from any deterioration in the credit markets on our collaborative partners could limit potential revenue from our product candidates.

We have significant debt, and we may not be able to make interest or principal payments when due. In April 2013 we exchanged our 8% senior secured convertible notes due August 2014 (the "2006 Notes"), including accrued and unpaid interest, for \$10.0 million in cash, 2,500,000 shares of our common stock, a revenue interest in certain QS-21 Stimulon partnered programs and a royalty interest in HerpV. The \$10.0 million cash payment was financed by entering into a Loan and Security Agreement with Silicon Valley Bank for a \$5.0 million loan that bears interest at 6.75% annually (the "SVB Loan"), and a Note Purchase Agreement with various investors to issue senior subordinated notes in the aggregate principal amount of \$5.0 million with annual interest at 10% (the "Subordinated Notes"). The SVB Loan is payable in equal monthly installments of approximately \$278,000 due monthly beginning November 2013 and ending in April 2015. The Subordinated Notes are due in April 2015.

Our ability to satisfy our obligations under this indebtedness will depend upon our future performance, which is subject to many factors, including the factors identified in this "Risk Factors" section and other factors beyond our control. If we are not able to generate sufficient cash flow from operations in the future to service our indebtedness, we may be required, among other things, to:

- seek additional financing in the debt or equity markets;
- refinance or restructure all or a portion of our indebtedness;
- sell, out-license, or otherwise dispose of assets; and/or
- reduce or delay planned expenditures on research and development and/or commercialization activities.

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

Other than for the year ended December 31, 2012, we have had negative cash flows from operations. The net cash provided by operations of \$1.0 million for the year ended December 31, 2012, primarily resulted from one-time payments received under amended license agreements and therefore our net cash provided by operations for the year ended December 31, 2012 is not indicative of future results. For the years ended December 31, 2013, and 2011, net cash used in operating activities was \$19.5 million, and \$16.2 million, respectively.

Our outstanding debt instruments contain significant restrictive and affirmative covenants.

14

---

## Table of Contents

The SVB Loan is secured by a lien against substantially all of our assets as well as the assets of our subsidiary Antigenics Inc., and contains, among other things, a number of restrictions and covenants that limit our ability to:

- incur certain additional indebtedness;
- make certain investments;
- pay dividends other than dividends required pursuant to pre-existing commitments;
- make payments on subordinated indebtedness other than regularly scheduled payments of interest;
- create certain liens;
- consolidate, merge, sell or otherwise dispose of our assets; and/or
- change our line of business.

The SVB Loan also specifies a number of events of default (some of which are subject to applicable cure periods), including, among other things:

- covenant defaults;
- other non-payment defaults;
- bankruptcy;
- certain penalties and judgments from a governmental authority;
- cross-defaults in respect of indebtedness over \$50,000; and
- insolvency defaults.

Additionally, any material adverse change with respect to us or Antigenics Inc., constitutes an event of default. Upon the occurrence of an event of default under the SVB Loan, subject to cure periods in certain circumstances, the Lender may declare all amounts outstanding to be immediately due and payable and may foreclose upon our assets that secure the SVB Loan. During the continuance of an event of default which does not accelerate the maturity of the SVB Loan, interest will accrue at a default rate equal to the otherwise applicable rate plus 5%. We may prepay the SVB Loan at any time, in full, subject to certain notice requirement and a prepayment premium equal to 4% of the outstanding principal amount of the SVB Loan.

The Subordinated Notes also include default provisions which allow for the acceleration of the principal payment of the 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 Subordinated Notes, default on other indebtedness with an aggregate principal balance of \$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 \$5 million if such amount will not be covered by third-party insurance.

If we default on the SVB Loan or the Subordinated Notes and the repayment of such indebtedness is accelerated, our liquidity will be materially and adversely affected.

We may not receive anticipated QS-21 Stimulon revenues from our licensees.

With the exception of our HerpV program, we currently rely upon and expect to continue to rely upon third party licensees, particularly GlaxoSmithKline (“GSK”) and JANSSEN Alzheimer Immunotherapy (“JANSSEN AI”), to develop, test, market and manufacture vaccines that utilize our QS-21 Stimulon adjuvant. We expect that we will rely on similar relationships if we develop new adjuvants in our Saponin Platform.

In return for rights to use QS-21 Stimulon, our licensees have generally agreed to pay us license fees, milestone payments and royalties on product sales for a minimum of 10 years after commercial launch, with some exceptions. As each licensee controls its own product development process, we cannot predict our licensees' requirements for QS-21 Stimulon in the future or to what extent, if any, they will develop vaccines that use QS-21 Stimulon as an adjuvant. Our licensees may initiate or terminate programs containing QS-21 Stimulon at any time. Clinical trials being conducted by our licensees, including those being conducted by GSK and JANSSEN AI, may not be successful. The results of these trials and other factors may cause our licensees to terminate programs containing QS-21 Stimulon. In the event that our licensees develop vaccines using QS-21 Stimulon, there is no guarantee that these products will obtain regulatory approval or, if so approved, will generate significant royalties, if any, or that we will be able to collect royalties in the future. In addition, where we had previously supplied GSK and JANSSEN AI with all their requirements of QS-21 Stimulon, we have amended our agreements so that they are permitted to manufacture their own QS-21 Stimulon. We are unable to predict what amount of QS-21 Stimulon, if any, will be purchased from us by

other licensees or collaborators in the future. Any inability to receive anticipated QS-21 Stimulon revenues would have a material adverse effect on our business, financial condition and results of operations.

## Table of Contents

In connection with the exchange of our 2006 Notes, we entered into a Revenue Interests Assignment Agreement with the holders of the 2006 Notes. This agreement granted these holders a contractual right to the proceeds of 20% of our revenue interests from QS-21 Stimulon partnered programs and a 0.5% royalty on net sales of HerpV. Due to uncertainties surrounding the future revenue stream generated from our licensees, we are unable to predict the precise dollar value reduction in revenue that will result from this agreement to pay the 2006 Note holders their share of the proceeds from QS-21 Stimulon and HerpV programs. Any reduction in revenues generated from QS-21 Stimulon could have a material adverse effect on our business, financial condition and results of operations.

Our HerpV therapeutic vaccine candidate is in early stage development and we may not be able to successfully develop this candidate.

Based on the results of our Phase 1 clinical trial of HerpV, which includes QS-21 Stimulon, we advanced this product candidate into a Phase 2 trial that measured the effect of vaccination on viral shedding in individuals infected with HSV-2 (genital herpes). In November 2013, we announced that the Phase 2 trial met its primary endpoint, a statistically significant reduction in viral shedding. Additional study results, including booster and immune response data, are expected during the first half of 2014. While our clinical trials to date have yielded positive findings, they were limited in size and scope. There is no guarantee that future clinical trials will be successful, that a reduction in viral shedding will translate into clinical benefit, or that the safety profile will be considered acceptable. In addition, we may not have the resources required to advance the vaccine further and even if we do have such resources, the success of future clinical trials will be dependent on, upon other things, maintaining sufficient supply of the required investigational materials, enrolling sufficient patients and the adherence of these patients to the study protocol. Our HerpV development program in general may not be successful or yield a partnering opportunity for us. Furthermore, it is possible that research and discoveries by others will render our product candidate obsolete or noncompetitive.

We may not be able to market and sell vaccines from our Prophage Series.

The probability and timing of submissions and/or approval of Prophage Series vaccines is uncertain.

A Phase 2 trial testing the Prophage Series G-100 vaccine candidate in newly diagnosed glioma has been fully enrolled and patient follow up is ongoing. While early data from this study have been encouraging, these data may not be supported in later follow-up of patients or in subsequent clinical trials. Separately, the Alliance for Clinical Trials in Oncology, a cooperative group of the NCI, opened patient enrollment in a randomized Phase 2 trial of the Prophage Series G-200 vaccine in combination with Avastin® (bevacizumab) in patients with surgically resectable recurrent glioma. This trial may not meet enrollment expectations and/or it might not be successful, and even if it is successful, the trial is not intended to provide the necessary evidence of efficacy and/or safety to support biologics license application ("BLA") filings.

Due to our lack of resources, our ability to perform additional studies may be limited. In addition, studies may take years to complete and may fail to support regulatory filings for many reasons. Our Prophage Series vaccines are a novel class of patient-specific (derived from the patient's own tumor) oncology therapies, and the U.S. Food and Drug Administration ("FDA") and foreign regulatory agencies, including the European Medicines Agency, which is responsible for product approvals in Europe, and Health Canada, which is responsible for product approvals in Canada, have limited experience in reviewing these types of therapies. Therefore, product candidates derived from the Prophage Series vaccines may experience high development costs and a long regulatory review process, either of which could delay or prevent commercialization efforts.

If we or our licensee are unable to purify heat shock proteins we may have difficulty successfully initiating or completing clinical trials or supporting commercial sales. Even if we or our licensees do successfully complete ongoing or future clinical trials or are successful manufacturing any approved products, we may have difficulty generating a sizable market or commercial sales.

Our ability to successfully develop and commercialize the Prophage Series vaccines for a particular cancer depends in part on our, and following successful technology transfer to NewVac LLC ("NewVac"), our licensee for Oncophage in the Russian Federation and certain other CIS countries, its ability to purify heat shock proteins from that type of cancer. If we or NewVac experience difficulties in purifying heat shock proteins for a sufficiently large number of patients in our clinical trials, we may face delays in enrolling sufficient patients and subsequently utilize more internal resources to satisfy enrollment requirements. Manufacturing failures may also lower the probability of a successful

analysis of the data from clinical trials and, ultimately, the ability to obtain regulatory approvals and generate commercial sales. Manufacturing difficulties may also adversely affect NewVac's ability to commercialize Oncophage in its licensed territory. We have successfully manufactured product across many different cancer types, however, the success rate per indication has varied. We have evolved our manufacturing processes to better accommodate a wider range of tumor types. Our current manufacturing technologies have been successful in manufacturing product from approximately 92% of the RCC tumors received and approximately 85% of the tumors received from patients enrolled in Phase 2 clinical trials in glioma. In addition, we may encounter problems with other types of cancer or patients as we expand our research. If we cannot overcome these problems, the number of patients or cancer



Table of Contents

types that our heat shock protein product candidates could treat would be limited. In addition, if we commercialize our heat shock protein product candidates, we may not be able to replicate past manufacturing success rates and we may face claims from patients for whom we are unable to produce a vaccine.

Manufacturing problems or increased demand may cause delays, unanticipated costs, or loss of revenue streams. If the future clinical or commercial demand for our products or product candidates is substantially greater than we anticipate, our capacity may not be able to meet product demand. In addition, higher manufacturing loads may result in higher manufacturing failure rates as the operation becomes more complex. We currently manufacture our Prophage Series vaccines in our Lexington, MA facility. While we believe we will be able to cover demand in the near term, there is no guarantee that we will be able to meet all future or unanticipated increases in demand, and a failure to do so could adversely affect our business. Such demand may also limit our ability to manufacture product in support of clinical trials, and this could cause a delay or failure in our Prophage Series vaccine development programs. Manufacturing of Prophage Series vaccines is complex, and various factors could cause delays or an inability to supply vaccine. Deviations in the processes controlling manufacture could result in production failures. Furthermore, we have limited manufacturing resources and there is no assurance that we will be able to obtain the necessary resources, timely or at all, to meet any increased demand.

Regulatory bodies may require us to make our manufacturing facility a single product facility. In such an instance, we would no longer have the ability to manufacture products other than Prophage Series vaccines in our current facility. Except in the case of GSK and JANSSEN AI, we have retained worldwide manufacturing rights for QS-21 Stimulon. We have the right to subcontract manufacturing for QS-21 Stimulon for our other existing and future QS-21 Stimulon manufacturing and supply needs, and we have a supply agreement with a contract manufacturer for the production of QS-21 Stimulon through September 2014. If we are not able to renew this agreement we may not be able to supply QS-21 Stimulon to meet future supply obligations on favorable terms or at all. For example, although GSK is a source of QS-21 Stimulon supply for us, their obligation to supply is for a limited duration, and various factors could impact our decision to exercise this right. In addition, we or our currently contracted suppliers may not have the ability to manufacture commercial grade QS-21 Stimulon.

We currently rely upon and expect to continue to rely upon third parties, potentially including our collaborators or licensees, to produce materials required to support our product candidates, preclinical studies, clinical trials, and commercial efforts. A number of factors could cause production interruptions at our manufacturing facility or at our contract manufacturers or suppliers, including equipment malfunctions, labor or employment retention problems, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers. Alternatively, there is the possibility we may have excess manufacturing capacity if product candidates do not progress as planned. There are a limited number of contract manufacturers or suppliers that are capable of manufacturing our product candidates or the materials used in their manufacture. If we are unable to do so ourselves or to arrange for third-party manufacturing or supply of these product candidates or materials, or to do so on commercially reasonable terms, we may not be able to complete development of these product candidates or commercialize them ourselves or through our collaborative partners or licensees. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, and the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Biopharmaceutical manufacturing is also subject to extensive government regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of product candidates. In addition, facilities are subject to ongoing inspections, and minor changes in manufacturing processes may require additional regulatory approvals, either of which could cause us to incur significant additional costs and lose revenue.

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

We have in the past, and may continue to seek, marketing and regulatory approvals of our product candidates in non-U.S. jurisdictions. For example, our Oncophage vaccine is approved for sale in Russia for the treatment of kidney cancer patients at intermediate risk for disease recurrence, and we have partnered with NewVac to commercialize this product in the Russian Federation. In addition, due to the Acquisition, we now have research and development operations in Switzerland and Germany. Various risks associated with foreign operations may impact our success. Possible risks include fluctuations in the value of foreign and domestic currencies, disruptions in the import, export, and transportation of patient tumors and our product, the

## Table of Contents

product and service needs of foreign customers, difficulties in building and managing foreign relationships, the performance of our licensees or collaborators, geopolitical instability, and unexpected regulatory, economic, or political changes in foreign markets. See "Risk Factors- Even if we receive marketing approval for our product candidates, such product approvals could be subject to restrictions or withdrawals. Regulatory requirements are subject to change." and "Risk Factors - We may fail to realize the benefits we expect to realize as a result of the Acquisition."

If we, or our licensees, fail to obtain adequate levels of reimbursement for our product candidates there may be no commercially viable market for these products, or the commercial potential of these products may be significantly limited.

Public and private insurance programs may determine that they will not cover our product candidates or the product candidates of our licensees. Government-sponsored health care systems typically pay a substantial share of health care costs, and they may regulate reimbursement levels of products to control costs. If we or our licensees are unsuccessful in obtaining substantial reimbursement for our product candidates from national or regional funds, we will have to rely on private-pay, which may delay or prevent our launch efforts, because the ability and willingness of patients to pay for our products is unclear.

We, or our licensees, may not be able to obtain health insurance coverage of our product candidates, and if coverage is obtained, it may be substantially delayed, or there may be significant restrictions on the circumstances in which the products would be reimbursed. We are unable to predict what impact any future regulation or third-party payer initiatives relating to reimbursement will have on our sales.

Our competitors in the biotechnology and pharmaceutical industries 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 collaborative 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, directed at cancer, infectious diseases and degenerative disorders. Many of our competitors, including large pharmaceutical companies, have greater financial and human resources and more experience than we do. Our competitors may:

- commercialize their product candidates sooner than we commercialize our own;
- develop safer or more effective therapeutic drugs or preventive vaccines and other therapeutic products;
- implement more effective approaches to sales and marketing and capture some of our potential market share;
- 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; or
- adversely affect our ability to recruit patients for our clinical trials.

There is no guarantee that our products or product candidates will be able to compete with potential future products being developed by our competitors.

Competitive products in our HerpV program include Valtrex (GSK) and Famvir (Novartis), which are small molecule drugs marketed for treatment of genital herpes. Other companies are engaged in research and/or clinical development for vaccines for treatment of genital herpes including Genocea and Vical. AiCuris GmbH is engaged in clinical research of a small molecule drug for treatment of genital herpes and has completed a Phase 2 trial.

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 and could compete with QS-21 Stimulon for inclusion in vaccines in development. These adjuvants include, but are not limited to, oligonucleotides, under development by Pfizer, Idera, Colby, and Dynavax, MF59 under development by Novartis, IC31, under development by Intercell, and 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 unlawfully 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 with our ability to do future partnering and licensing deals with 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. Any diminution of this goodwill may have an adverse effect on our ability to commercialize this technology, either alone or with a third party.

Table of Contents

In competition with our Prophage Series product candidates, Genentech markets Avastin and Eisai and Arbor Pharmaceuticals market Gliadel, both for treatment of recurrent glioma. In addition, TVAX Biomedical and Stemline Therapeutics are developing immunotherapy candidates (TVI-Brain-1 and SL-701, respectively) for recurrent glioma. Schering Corporation, a subsidiary of Merck, markets Temodar for treatment of patients with newly diagnosed glioma. Other companies are developing vaccine candidates for the treatment of patients with newly diagnosed glioma, such as Innocell Corp (Immuncell-LC), ImmunoCellular Therapeutics (ICT-107), Northwest Biotherapeutics (DC-Vax), Immatics (IMA-950), Activartis Biotech (GBM-Vax) and Celldex (CDX-110). Celldex is also currently developing a vaccine candidate for recurrent glioma. Other companies may begin such development as well.

As vaccines from our Prophage Series are potentially developed in other indications, they could face additional competition in those indications. In addition, and prior to regulatory approval, our Prophage Series vaccines and all of 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 have six preclinical checkpoint antibody programs that have been commenced by 4-AB. We are aware of several large companies that have antibody-based products on the market or in clinical development that are directed to the same biological target as some of these programs, including Bristol-Myers Squibb, which markets ipilimumab, an anti-CTLA-4 antibody, and has an anti-PD1 antibody in development, Medimmune, which has anti-CTLA-4, OX-40 and PD1 antibodies in development, Merck and Curetech, which each has an anti-PDI antibody in development, and Pfizer, which has an anti-CTLA-4 antibody in development.

Our future growth depends on our ability to successfully identify, develop, acquire or in-license products and product candidates; otherwise, we may have limited growth opportunities.

An important part of our business strategy is to continue to develop a pipeline of product candidates by developing, acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our existing business. However, these business activities may entail numerous operational and financial risks, including:

Table of Contents

• difficulty or inability to secure financing to fund development activities for such development, acquisition or in-licensed products or technologies;

• incurrence of substantial debt or dilutive issuances of securities to pay for development, acquisition or in-licensing of new products;

• disruption of our business and diversion of our management's time and attention;

• higher than expected development, acquisition or in-license and integration costs;

• exposure to unknown liabilities;

• difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;

• inability to retain key employees of any acquired businesses;

• difficulty in managing multiple product development programs; and

• inability to successfully develop new products or clinical failure.

We have limited resources to identify and execute the development, acquisition or in-licensing of products, businesses and technologies and integrate them into our current infrastructure. We may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations, and/or acquire, in-license, and/or advance new product candidates. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential development, acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

Failure to enter into and/or maintain significant licensing, distribution and/or collaboration agreements on favorable terms to us may hinder our efforts to develop and commercialize our product candidates and could increase our development timelines as well as our need to rely on other financing mechanisms, such as sales of debt or equity securities, to fund our operations.

We have been engaged in efforts to enter into licensing, distribution and/or collaborative agreements with one or more pharmaceutical or biotechnology companies to assist us with development and/or commercialization of our product candidates. If we are successful in entering into such agreements, we may not be able to negotiate agreements with economic terms similar to those negotiated by other companies. We may not, for example, obtain significant upfront payments, substantial royalty rates or milestones. If we fail to enter into any such agreements, our efforts to develop and/or commercialize our products or product candidates may be undermined. In addition, if we do not raise funds through any such agreements, we will need to rely on other financing mechanisms, such as sales of debt or equity securities, to fund our operations. Such financing mechanisms, if available, may not be sufficient or timely enough to advance our programs forward in a meaningful way in the short-term.

While we have been pursuing these business development efforts for several years, we have not entered into a substantial agreement relating to the potential development or commercialization of any of our Prophage Series vaccines other than the agreement with NewVac giving them an exclusive license to manufacture, market and sell Oncophage as well as pursue a development program in the Russian Federation and certain other CIS countries. To date, the NewVac arrangement has not provided substantial benefit to us, and there is no guarantee that it will. In addition, other companies may not be interested in pursuing patient-specific vaccines like our Prophage Series vaccines, and many other companies have been and may continue to be unwilling to commit to an agreement prior to receipt of additional clinical data, if at all.

In addition, we would consider license and/or co-development opportunities to advance HerpV and antibody candidates derived from the Retrocyte Display technology platform of 4-AB. However, collaborative partners or licensees may defer discussions until these assets are further developed, or they may not engage in such discussions on terms acceptable to us or at all.

## Table of Contents

Because we rely on collaborators and licensees for the development and commercialization of most of our product candidate programs, these programs may not prove successful, and/or we may not receive significant payments from such parties.

Part of our strategy is to develop and commercialize a majority 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 and on the success of the other parties in performing research, preclinical and clinical testing, completing regulatory applications, and commercializing product candidates. For example, the development of candidates from the Prophage G Series is currently dependent in a large part on the efforts of our institutional collaborators, such as the Brain Tumor Research Center at the University of California, San Francisco, which has conducted or is in the process of conducting Phase 2 clinical trials of Prophage Series vaccines G-100 and G-200 for the treatment of glioma and the Alliance for Clinical Trials in Oncology, a National Cancer Institute cooperative group, which is sponsoring a Phase 2 clinical trial of G-200 in patients with surgically resectable recurrent glioma. When our licensees or third party collaborators sponsor clinical trials using our product candidates, we cannot control the timing or quality of such trials or related activities. In addition, substantially all product candidates containing QS-21 Stimulon, other than HerpV, depend on the success of our collaborative partners or licensees, and our relationships with these third parties. Such product candidates depend on our collaborators and licensees successfully enrolling patients and completing clinical trials, being committed to dedicating the resources to advance these product candidates, obtaining regulatory approvals, and successfully commercializing product candidates. We have granted NewVac an exclusive license to manufacture, market and sell Oncophage in the Russian Federation and certain other CIS countries. NewVac has faced challenges establishing manufacturing capabilities and securing government reimbursement, which has impacted its ability to commercialize the product in the licensed territory. NewVac may terminate this agreement at any time without cause. We do not expect to receive financial or other benefits, if any, from our relationship with NewVac or the sale of Oncophage in the Russian Federation or CIS countries.

In addition, our research, development, and commercialization efforts with respect to antibody candidates from the Retrocyte Display technology platform include the participation of institutional and corporate collaborators. For example, 4-AB has collaborative arrangements with Ludwig Cancer Research and Brazil-based Recepta Biopharma SA, among others. If we are not able to preserve these arrangements, as well as advance additional collaborations, on terms favorable to us, this may diminish the value of the Acquisition to us and could have a negative impact on our operations.

Development activities for our collaborative programs may fail to produce marketable products due to unsuccessful results or abandonment of these programs, failure to enter into future collaborations or license agreements, or the inability to manufacture product supply requirements for our collaborators and licensees. Several of our agreements also require us to transfer important rights and regulatory compliance responsibilities to our collaborators and licensees. As a result of these collaborative agreements, we will not control the nature, timing, or cost of bringing these product candidates to market. Our collaborators and licensees could choose not to devote resources to these arrangements or, under certain circumstances, may terminate these arrangements early. They may cease pursuing product candidates or elect to collaborate with different companies. In addition, these collaborators and licensees, outside of their arrangements with us, may develop technologies or products that are competitive with those that we are developing. From time to time, we may also become involved in disputes with our collaborators or licensees. Such disputes could result in the incurrence of significant expense, or the termination of collaborations. We may be unable to fulfill all of our obligations to our collaborators, which may result in the termination of collaborations. As a result of these factors, our strategic collaborations may not yield revenue. Furthermore, we may be unable to enter into new collaborations or enter into new collaborations on favorable terms. Failure to generate significant revenue from collaborations would increase our need to fund our operations through sales of debt or equity securities and would negatively affect our business prospects.

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

Garo H. Armen, Ph.D., the Chairman of our Board of Directors and our Chief Executive Officer, co-founded the Company in 1994, and has been, and continues to be, integral to building our company and developing our technology. If Dr. Armen is unable or unwilling to continue his relationship with Agenus, our business may be adversely impacted.

Effective December 1, 2005, we entered into an employment agreement with Dr. Armen. Subject to the earlier termination as provided in the agreement, the agreement had an original term of one year and is automatically extended thereafter for successive terms of one year each, unless either party provides notice to the other at least ninety days prior to the expiration of the original or any extension term. Dr. Armen plays an important role in our day-to-day activities. We do not carry key employee insurance policies for Dr. Armen or any other employee.



## Table of Contents

We also rely on a small staff of highly trained and experienced senior management and scientific, administrative and operations personnel and consultants to conduct our business. Reductions in our staffing levels have eliminated redundancies in key capabilities and skill sets among our full time staff and required us to rely more heavily on outside consultants and third parties. In addition, if in the future we need to perform sales, marketing and distribution functions for commercial and/or international operations, we will need to recruit experienced personnel and/or engage external consultants incurring significant expenditures.

Reduction in expenses and resulting changes to our compensation and benefit programs have reduced the competitiveness of these programs and thereby increased employee retention risk. The competition for qualified personnel in the biotechnology field is intense, and if we are not able to continue to attract and retain qualified personnel and/or maintain positive relationships with our outside consultants, we may not be able to achieve our strategic and operational objectives.

### Risks Related to the Acquisition

We have incurred and will continue to incur significant transaction costs in connection with the Acquisition.

We have incurred and will continue to incur substantial legal, accounting, financial advisory and/or other costs and our management has devoted considerable time and effort in connection with the Acquisition. These and other fees and expenses may be significant and could have an adverse impact on our operating results.

Because 4-AB was acquired by us very recently, there may be aspects of its business or financial results that may not be well understood by us until we fully integrate 4-AB's operations into our business. Among other matters, although we do not believe that we will incur or assume any liabilities or obligations out of the ordinary course of business in connection with 4-AB's business (other than approximately \$1 million of obligations relating to transaction-related payments and certain 4-AB indebtedness totaling approximately \$500,000), we may ultimately determine that unknown or unanticipated material liabilities exist.

We may fail to realize the benefits we expect to realize as a result of the Acquisition.

The long-term success of the Acquisition will depend, in part, on our ability to realize the anticipated synergies, business opportunities and growth prospects from combining the businesses of Agenus and 4-AB. We may never realize these anticipated synergies, business opportunities and growth prospects. Integrating operations will be complex and will require significant efforts and expenditures on the part of both Agenus and 4-AB. Employees might leave or be terminated. Our management might have its attention diverted while trying to integrate operations and corporate and administrative infrastructures. We might experience increased competition that limits our ability to expand our business, and we might not be able to capitalize on expected business opportunities, including maintaining current collaboration relationships and advancing the development of the 4-AB technologies. We may experience difficulties reconciling 4-AB's system of financial reporting, which has been based upon International Financial Reporting Standards, or IFRS, for small and medium-sized entities, with U.S. Generally Accepted Accounting Principles, or U.S. GAAP. Moreover, assumptions underlying estimates of expected cost savings as a result of the Acquisition may be inaccurate, and general industry and business conditions might deteriorate. If any of these factors limit our ability to integrate the operations of Agenus and 4-AB successfully or on a timely basis, or to develop the business opportunities that we expect to realize from the Acquisition, the expectations of future results of operations, including certain cost savings and synergies expected to result from the Acquisition, might not be met.

The issuance of shares of our common stock in the Acquisition will dilute the interest held by our stockholders prior to the Acquisition.

We issued 3,334,079 shares of our common stock to the shareholders of 4-AB at closing having a fair market value of \$10.1 million. In addition, we may be obligated in the future to pay certain contingent milestone payments, payable at our election in cash or shares of our common stock that may exceed \$40 million. The issuance of any such additional shares of our common stock in connection with such contingent milestone payments would cause a

reduction in the relative percentage interest of our current stockholders in the ownership of our common stock and could have the effect of depressing the market price of our common stock.

#### Risks Related to Regulation of the Biopharmaceutical Industry

The drug development and approval process is uncertain, time-consuming, and expensive.

Clinical development, including preclinical testing and the process of obtaining and maintaining regulatory approvals for new therapeutic products, is lengthy, expensive, and uncertain. As of December 31, 2013, we have spent approximately 19

Table of Contents

years and \$303.5 million on our research and development program in heat shock proteins for cancer. It also can vary substantially based on the type, complexity, and novelty of the product. We must provide regulatory authorities with manufacturing, product characterization, and preclinical and clinical data demonstrating that our product candidates are safe and effective before they can be approved for commercial sale. It may take us many years to complete our testing, and failure can occur at any stage of testing. Interim results of preclinical studies or clinical trials do not necessarily predict their final results, and acceptable results in early studies might not be seen in later studies. Any preclinical or clinical test may fail to produce results satisfactory to regulatory authorities for many reasons, including but not limited to insufficient product characterization, poor study structure conduct or statistical analysis planning, failure to enroll a sufficient number of patients or failure to prospectively identify the most appropriate patient eligibility criteria, and collectability of data. Preclinical and clinical data can be interpreted in different ways, which could delay, limit, or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, adverse medical events during a clinical trial, or safety issues resulting from products of the same class of drug could require a preclinical study or clinical trial to be repeated or cause a program to be terminated, even if other studies or trials relating to the program are successful. We or the FDA, other regulatory agencies, or an institutional review board may suspend or terminate human clinical trials at any time on various grounds.

The timing and success of a clinical trial is dependent on obtaining and maintaining sufficient cash resources, successful production of clinical trial material, enrolling sufficient patients in a timely manner, avoiding serious or significant adverse patient reactions, and demonstrating efficacy of the product candidate in order to support a favorable risk versus benefit profile, among other considerations. The timing and success of our clinical trials, in particular, are also dependent on clinical sites and regulatory authorities accepting each trial's protocol, statistical analysis plan, product characterization tests, and clinical data. In addition, regulatory authorities may request additional information or data that is not readily available. Delays in our ability to respond to such requests would delay, and failure to adequately address concerns would prevent, our commercialization efforts. We have encountered in the past, and may encounter in the future, delays in initiating trial sites and enrolling patients into our clinical trials. Future enrollment delays will postpone the dates by which we expect to complete the impacted trials and the potential receipt of regulatory approval. There is no guarantee we will successfully initiate and/or complete our clinical trials.

Delays or difficulties in obtaining regulatory approvals or clearances for our product candidates may:

- adversely affect the marketing of any products we or our licensees or collaborators develop;
- impose significant additional costs on us or our licensees or collaborators;
- diminish any competitive advantages that we or our licensees or collaborators may attain;
- limit our ability to receive royalties and generate revenue and profits; and
- adversely affect our business prospects and ability to obtain financing.

Delays or failures in our receiving regulatory approval for our product candidates in a timely manner may result in us having to incur additional development expense and subject us to having to secure additional financing. As a result, we may not be able to commercialize them in the time frame anticipated, and our business will suffer.

Even if we receive marketing approval for our product candidates, such product approvals could be subject to restrictions or withdrawals. Regulatory requirements are subject to change.

Regulatory authorities generally approve products for particular indications. If an approval is for a limited indication, this limitation reduces the size of the potential market for that product. Product approvals, once granted, are subject to continual review and periodic inspections by regulatory authorities. Our operations and practices are subject to regulation and scrutiny by the United States government, as well as governments of any other countries in which we do business or conduct activities. Later discovery of previously unknown problems or safety issues, and/or failure to comply with domestic or foreign laws, knowingly or unknowingly, can result in various adverse consequences, including, among other things, possible delay in approval or refusal to approve a product, warning letters, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the government to renew marketing applications, complete withdrawal of a marketing application, and/or criminal prosecution, withdrawal of an approved product from the market, and/or exclusion from government health care programs. Such regulatory enforcement could have a direct and negative impact on the product for which approval is granted, but also could have a negative impact on the approval of any pending applications for marketing approval of

new drugs or supplements to approved applications.

Because we are a company operating in a highly regulated industry, regulatory authorities could take enforcement action against us in connection with our, or our licensees or collaborators, business and marketing activities for various reasons. For example, the Foreign Corrupt Practices Act prohibits U.S. companies and their representatives from offering, promising, authorizing, or making payments to foreign officials for the purpose of obtaining or retaining business abroad.

23

---

## Table of Contents

From time to time, new legislation is passed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA and other foreign health authorities. Additionally, regulations and guidance are often revised or reinterpreted by health agencies in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted, or whether regulations, guidance, or interpretations will change, and what the impact of such changes, if any, may be. For example, the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the “ACA”), enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. With regard to pharmaceutical products, among other things, ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare D program. We expect both government and private health plans to continue to require healthcare providers, including healthcare providers that may one day purchase our products, to contain costs and demonstrate the value of the therapies they provide.

New data from our research and development activities, and/or resource considerations could modify our strategy and result in the need to adjust our projections of timelines and costs of programs.

Because we are focused on novel technologies, our research and development activities, including our nonclinical studies and clinical trials, involve the ongoing discovery of new facts and the generation of new data, based on which we determine next steps for a relevant program. These developments can occur with varying frequency and constitute the basis on which our business is conducted. We need to make determinations on an ongoing basis as to which of these facts or data will influence timelines and costs of programs. We may not always be able to make such judgments accurately, which may increase the costs we incur attempting to commercialize our product candidates. We monitor the likelihood of success of our initiatives and we may need to discontinue funding of such activities if they do not prove to be commercially feasible, due to our limited resources.

We may need to successfully address a number of technological challenges in order to complete development of our product candidates. Moreover, these product candidates may not be effective in treating any disease or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining regulatory approvals or prevent or limit commercial use.

### Risks Related to Intellectual Property Rights

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

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.

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. In addition, because our patent on QS-21 Stimulon composition of matter has already expired, our patent rights are limited to protecting certain combinations of QS-21 Stimulon with other adjuvants or formulations of QS-21 Stimulon with other agents, such as excipients that improve performance of the compound. However, there is no

guarantee that a third party would necessarily choose to use QS-21 Stimulon in combination with such adjuvants or formulate it with the other agents covered by our patents. We are aware of other companies that claim to produce material comparable to QS-21 Stimulon. At least one other party has also developed derivatives of QS-21 that have shown biological activity.

Our strategy depends on our ability to identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we 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. Despite our efforts to

## Table of Contents

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.

The patent landscape in the field of therapeutic antibody development, manufacture and commercialization is crowded. For example, we are aware of third party patents directed to methods for identifying and producing therapeutic antibodies, We are also aware of third party patents directed to antibodies to numerous targets for which we also seek to identify, develop, and commercialize antibodies, including without limitation CTLA-4, PD-1, GITR, OX40, TIM-3, and LAG-3. For example, some patents claim antibodies based on competitive binding with existing antibodies, some claim antibodies based on specifying sequence or other structural information, and some claim various methods of discovery, production, or use of such antibodies. These or other third party patents could impinge on or foreclose our freedom to operate in relation to our technology platforms, including Retrocyte Display, as well as to development and commercialization of antibodies identified by us as therapeutic candidates. As we discover and develop our candidate antibodies, 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.

We have exclusive rights to approximately 60 issued United States patents and approximately 99 issued foreign patents. We also have exclusive rights to approximately 13 pending United States patent applications and approximately 43 pending foreign patent applications. However, our patents may not protect us against our competitors. Our patent positions, and those of other 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, or 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.

The issued patents that cover the Prophage Series vaccines expire at various dates between 2015 and 2024. The issued patents related to HerpV expire at various dates between 2014 and 2029. Our patent to purified QS-21 Stimulon expired in 2008. Additional protection for QS-21 Stimulon in combination with other agents is provided by our other issued patents which expire between 2017 and 2022. We continue to explore means of extending the life cycle of our patent portfolio.

Through our acquisition of 4-AB, we also own 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 4-AB's technology platforms. In particular, we own patents and patent applications relating to Retrocyte Display®, a high throughput antibody expression platform for the identification of fully human monoclonal antibodies. This patent family is projected to expire between 2029 and 2030. In addition, as we advance our research and development efforts with our institutional and corporate collaborators, we intend to seek patent protection for

newly-identified therapeutic antibodies and product candidates. We can provide no assurance that any of our patents, including these newly acquired patents, will have commercial value, or that any of our existing or future patent applications, including these newly acquired patent applications, will result in the issuance of valid and enforceable patents.

The patent position of 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 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



Table of Contents

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.

Our patent on QS-21 Stimulon composition of matter has expired and we rely primarily on unpatented technology and know-how to protect our rights to QS-21 Stimulon.

Our patent on QS-21 Stimulon composition of matter has expired, and our patent rights are limited to protecting certain combinations of QS-21 Stimulon with other adjuvants or formulations of QS-21 Stimulon with other agents. Although our licenses also rely on unpatented technology, know-how, and confidential information, these intellectual property rights may not be enforceable in certain jurisdictions and, we may not be able to collect anticipated revenue from our licensees. Any such inability would have a material adverse effect on our business, financial condition and results of operations.

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

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 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 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 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

Table of Contents

preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. 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.

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, as a result of the Acquisition, we now have six preclinical checkpoint antibody programs, and the patent landscape around the discovery, development, manufacture and commercial use of therapeutic antibodies is crowded.

Patents that we may ultimately be found to infringe could be issued to third parties. 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, we or our licensors 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

Table of Contents

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.

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.

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.

## Table of Contents

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 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.

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 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.

### Risks Related to Litigation

We may face litigation that could result in substantial damages and may divert management's time and attention from our business.

We may currently be a party, or may become a party, to legal proceedings, claims and investigations that arise in the ordinary course of business such as, but not limited to, patent, employment, commercial and environmental matters. 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.

We maintain property and general commercial insurance coverage as well as errors and omissions and directors and officers insurance policies. This insurance coverage may not be sufficient to cover us for future claims.

We are also exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional 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 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. 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.

Employee misconduct could also involve the improper use 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,

29

---



## Table of Contents

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 attention of our management team.

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 commercial sales of Oncophage in Russia, and may face even greater risks if we sell our other product candidates 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:

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

We manufacture the Prophage Series 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 anticipate that the logistics of shipping will become more complex if the number of patients we treat increases and that shipments of tumor and/or vaccines may be lost, delayed, or damaged. Additionally, complexities unique to the logistics of commercial products may delay shipments and limit our ability to move commercial product in an efficient manner without incident. We do not have any other insurance that covers loss of or damage to the Prophage Series 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.

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.



Table of Contents

Risks Related to our Common Stock

Our stock may be delisted from The Nasdaq Capital Market, which could affect its market price and liquidity. Our common stock is currently listed on The Nasdaq Capital Market (“Nasdaq”) under the symbol “AGEN.” In the event that we fail to maintain compliance with the applicable listing requirements, our common stock could become subject to delisting from Nasdaq. Although we are currently in compliance with all of the listing standards for listing on Nasdaq, we cannot provide any assurance that we will continue to be in compliance in the future. We have been non-compliant with the minimum bid price requirement set forth in Nasdaq Marketplace Rule 5550(a)(2) three times since our move to The Nasdaq Capital Market in April 2009.

Provisions in our organizational documents could prevent or frustrate attempts by stockholders to replace 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.

The first right to negotiate provision contained in our agreement with one of our licensees could hinder or delay a change of control of our company or the sale of certain of our assets

We have entered into a First Right to Negotiate and Amendment Agreement with GSK that affords GSK, one of our licensees, a first right to negotiate with us in the event we determine to initiate a process to effect a change of control of our company with, or to sell certain of our assets to, an unaffiliated third party or in the event that a third party commences an unsolicited tender offer seeking a change of control of our company. In such event, we must provide GSK a period of time to determine whether it wishes to negotiate the terms of such a transaction with us. If GSK affirmatively so elects, we are required to negotiate with GSK in good faith towards effecting a transaction of that nature for a specified period. During the negotiation period, we are obligated not to enter into a definitive agreement with a third party that would preclude us from negotiating and/or executing a definitive agreement with GSK. If GSK determines not to negotiate with us or we are unable to come to an agreement with GSK during this period, we may enter into the specified change of control or sale transaction within the following 12 months, provided that such a transaction is not on terms in the aggregate that are materially less favorable to us and our stockholders (as determined by our Board of Directors, in its reasonable discretion) than terms last offered to us by GSK in a binding written proposal during the negotiation period. The first right to negotiate terminates on March 2, 2017. Although GSK's first right to negotiate does not compel us to enter into a transaction with GSK nor prevent us from negotiating with or entering into a transaction with a third party, the first right to negotiate could inhibit a third party from engaging in discussions with us concerning such a transaction or delay our ability to effect such a transaction with a third party. Our stock has historically had low trading volume, and its public trading price has been volatile.

Between our initial public offering on February 4, 2000 and December 31, 2013, and for the year ended December 31, 2013, the closing price of our common stock has fluctuated between \$1.80 and \$315.78 per share and \$2.40 and \$4.93 per share, respectively. The average daily trading volume for the year ended December 31, 2013 was approximately 367,000 shares. 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:

Table of Contents

• continuing operating losses, which we expect over the next several years as we continue our development activities;

• announcements of decisions made by public officials;

• results of our preclinical studies and clinical trials;

• announcements of new collaboration agreements with strategic partners or developments by our existing collaborative partners;

• 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 the Acquisition;

• 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;

• 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 biotechnology and biopharmaceutical industries;

• 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 biotechnology and pharmaceutical companies generally 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.

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 December 31, 2013, we had approximately 36,348,000 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 8,200,000 shares of common stock under our equity incentive plans. We have also filed registration statements to permit the sale of approximately 167,000 shares of common stock under our employee stock purchase plan, to permit the sale of 225,000 shares of common stock under our Directors' Deferred Compensation Plan, to permit the sale of approximately 8,274,000 shares of common stock pursuant to various private placement agreements and to permit the sale of approximately 10,000,000 shares of our common stock pursuant to our At Market Issuance Sales Agreement. As of December 31, 2013, an aggregate of 12.9 million of these shares remain available for sale. In addition, we have agreed to file a registration statement on Form S-3 to permit the sale of the shares of our common stock that were issued in connection with the Acquisition not later than 90 days after the Acquisition. The market price of our common stock may decrease based on the expectation of such sales.

As of December 31, 2013, warrants to purchase approximately 3,280,000 shares of our common stock with a weighted average exercise price per share of \$11.28 were outstanding.

As of December 31, 2013, options to purchase 4,163,100 shares of our common stock with a weighted average exercise price per share of \$5.72 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, 2013 we have 147,274 nonvested shares outstanding.



## Table of Contents

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.

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, 2013, 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.

We anticipate additional commitments of management time to ensure that our internal control over financial reporting of the operations of 4-AB complies with Section 404 of the Sarbanes-Oxley Act of 2002. Prior to the Acquisition, 4-AB was a privately held company organized under the laws of Switzerland and, as such, it has not been subject to financial reporting requirements applicable to public companies and was not required to prepare and publish audited financial statements in accordance with U.S. GAAP. Accordingly, our efforts to ensure that our internal control over the financial reporting of the operations of 4-AB will cause us to incur significant additional costs.

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.

If our stockholders do not approve an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of our common stock, our ability to provide adequate incentives to our employees and competitively pursue future opportunities could be materially adversely effected.

In February 2014 we raised approximately \$56.0 million in a public offering by issuing approximately 22.2 million shares of our common stock. In order to maximize the benefit of this financing for us and in response to high investor demand, we had to deplete all remaining authorized shares available for issuance under our Amended and Restated Certificate of Incorporation. Furthermore, we opted to unreserve shares otherwise available for issuance under our 2009 Equity Incentive Plan. As a result, we are currently unable to offer equity incentives under the 2009 Equity Incentive Plan to new or existing employees, including those employees who joined us through the Acquisition. The unavailability of authorized shares of common stock places us in a competitive disadvantage since our ability to attract

and retain key personnel, and to utilize non-cash compensation for other legitimate corporate business purposes, is compromised.

Our board of directors has approved an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 70,000,000 to 140,000,000. We intend to submit the amendment to our stockholders for approval at our 2014 Annual Meeting of Stockholders. If stockholder approval is not received for this amendment, we believe it will compromise our ability to provide incentives to our employees and to competitively pursue future business and financial endeavors with common stock consideration, and this could have an adverse effect on our business.



Table of Contents

## Item 1B. Unresolved Staff Comments

None

## Item 2. Properties

We maintain our manufacturing, research and development, and corporate offices in Lexington, Massachusetts. During April 2011, we executed a Fifth Amendment of Lease reducing our occupied space in this facility from approximately 162,000 square feet to approximately 82,000 square feet. This lease agreement terminates in August 2023 with an option to renew for one additional ten-year period. We have sublet a portion of this facility under a lease that expires in June 2015.

During December 2012 we entered into a commercial lease for approximately 5,600 square feet of office space in New York, New York for use as corporate offices that terminates in May 2020.

Through our acquisition of 4-AB, we also have facilities in Jena, Germany under a lease that expires June 2016 and in Basel, Switzerland under a lease that expires June 2014.

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 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

## Executive Officers of the Registrant

Set forth below is certain information regarding our current executive officers, including their age, as of March 1, 2014:

Name	Age	Title
Garo H. Armen, Ph.D.	61	Chairman of the Board and Chief Executive Officer
Christine M. Klaskin	47	Vice President, Finance, Principal Accounting Officer, and Principal Financial Officer
Ozer Baysal	58	Chief Business Officer
Robert Stein	63	Chief Scientific Officer
Karen H. Valentine	42	Vice President and General Counsel
Kerry A. Wentworth	41	Vice President, Clinical, Regulatory & Quality

Garo H. Armen, PhD—Dr. Armen has been Chairman and CEO since the Company's founding in 1994. From mid-2002 through 2004, he was Chairman of the Board of Directors for the biopharmaceutical company Elan Corporation, plc., which he helped restructure. Dr. Armen is also the founder and Chairman of the Children of Armenia Fund, a philanthropic organization established in 2000 that is dedicated to the positive development of the children and youth of rural Armenia. He holds a Ph.D. degree in physical organic chemistry from the City University of New York.

Christine M. Klaskin—Christine M. Klaskin has been Vice President, Finance, Principal Accounting Officer since October 2006 and Principal Financial Officer since May 2012. Since joining Agenus Inc. in 1996 as finance manager, Ms. Klaskin has held various positions within the finance department and has been involved in all equity and debt offerings of the Company including its IPO. Ms. Klaskin is currently a member of the board of directors of American DG Energy Inc. Prior



Table of Contents

to joining Agenus, Ms. Klaskin was employed by Arthur Andersen as an audit manager. Ms. Klaskin received her Bachelor of Accountancy from The George Washington University.

Ozer Baysal - Ozer Baysal has been Chief Business Officer since January 2013. His principal role is to lead Agenus' efforts in establishing commercial capability and accelerating Agenus' transition to becoming a fully integrated biopharmaceutical company. Prior to joining Agenus Mr. Baysal spent more than 30 years with Pfizer in a broad number of functional and geographic areas, most recently serving as President of Europe, Emerging Markets Region. While at Pfizer, he held key leadership positions in Marketing, Sales, and Manufacturing, and was actively involved with numerous licensing and M&A activities. Mr. Baysal holds a bachelor's degree from Bosphorus University in Industrial Engineering and has completed the Programs for Leadership and Management Development at Harvard Business School.

Robert Stein - Bob Stein has been Chief Scientific Officer since February 2014. Dr. Stein leads our Research, Preclinical Development and Translational Medicine functions and helps shape our clinical development strategy for the Prophage Series vaccines and HerpV. In addition, he is leading the integration of 4-Antibody into our business. Dr. Stein brings over 30 years of experience and accomplishments in the pharmaceutical and biotech industry to the Agenus leadership team. Over the course of his career Dr. Stein has played a pivotal role in bringing eight drugs to the market including Sustiva®, Fablyn®, Viviant®, PanRetin®, TargRetin®, Promacta®, & Eliquis®. Prior to joining Agenus he held a number of senior management positions including Chief Scientific Officer & Senior Vice President of Research for Ligand Pharmaceuticals, Executive Vice President of Research & Preclinical Development for Dupont Merck, President and Chief Scientific Officer for Incyte Pharmaceuticals, President of Roche Palo Alto and CEO of KineMed. Dr. Stein spent the early part of his career at Merck, Sharp and Dohme Research Laboratories. He holds an MD and a PhD in Physiology & Pharmacology from Duke University. Dr. Stein filed a personal voluntary bankruptcy petition under Chapter 7 in August of 2012 and the bankruptcy was discharged in May 2013.

Karen H. Valentine—Karen Higgins Valentine has been Vice President and General Counsel since January 2008 and also has served as Secretary since 2007 and Chief Compliance Officer of the Company since 2008. Prior to joining Agenus Inc. in 2004, Ms. Valentine was an associate in the biotechnology practice of Palmer & Dodge LLP (now Edwards Wildman). Ms. Valentine is currently a member of the board of directors of the Northeast Chapter of the Association of Corporate Counsel. Ms. Valentine graduated cum laude with a bachelor's degree in neuroscience from Colgate University, and received her law degree, magna cum laude, from Boston University School of Law.

Kerry A. Wentworth—Kerry Wentworth has been Vice President, Clinical, Regulatory & Quality since June 2006. Before joining Agenus Inc. in 2005, Ms. Wentworth served as senior director of regulatory affairs at Genelabs Technologies, where she was responsible for the business' regulatory and quality functions. There she focused on the late-stage clinical development and subsequent US and European commercial application filings for the company's lead product Prestara. Prior to Genelabs, Ms. Wentworth held various positions in regulatory affairs at Shaman Pharmaceuticals and at Genzyme Corporation. Ms. Wentworth received a BS in pre-veterinary medicine from the University of New Hampshire.

Table of Contents

## 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."

The following table sets forth, for the periods indicated, the high and low sale prices per share of our common stock.

	High	Low
2012		
First Quarter	\$6.85	\$2.00
Second Quarter	7.41	4.76
Third Quarter	5.47	4.30
Fourth Quarter	4.95	3.37
2013		
First Quarter	4.95	3.71
Second Quarter	5.40	3.55
Third Quarter	4.13	2.45
Fourth Quarter	3.49	2.40

As of February 21, 2014, there were approximately 1,710 holders of record and approximately 19,900 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 deems relevant.

## Stock Performance

The following graph shows the cumulative total stockholder return on our common stock over the period from December 31, 2008 to December 31, 2013, 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, 2008. 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 Securities 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").

Table of ContentsCOMPARISON OF CUMULATIVE TOTAL RETURN OF AGENUS INC.,  
NASDAQ STOCK MARKET (U.S. COMPANIES) INDEX  
AND NASDAQ BIOTECHNOLOGY INDEX

	12/31/2008	12/31/2009	12/31/2010	12/31/2011	12/31/2012	12/31/2013
Agenus Inc.	100.00	133.00	210.14	69.35	142.17	90.99
NASDAQ Stock Market (U.S. Companies) Index	100.00	144.00	168.48	165.11	191.53	264.31
NASDAQ Biotechnology Index	100.00	116.00	133.40	149.41	197.22	327.39
Recent Sales of Unregistered Securities						

On February 12, 2014, we issued 3,334,079 shares of our common stock to the shareholders of 4-AB in private transactions in connection with the Share Exchange Agreement, dated January 10, 2014, by and among Agenus Inc., 4-Antibody AG, certain shareholders of 4-Antibody AG and Vischer AG. The issuance of these shares of our common stock was not registered under the Securities Act in reliance upon the exemptions from registration provided by Regulation S promulgated under the Securities Act, based on representations from the applicable shareholders of 4-AB that they are not "U.S. persons" within the meaning of Rule 902 of Regulation S, and Section 4(2) of the Securities Act, as the transactions did not involve any public offering.

Information concerning our equity compensation plans is set forth in our Definitive Proxy Statement with respect to our 2014 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission no later than 120 days after the end of the fiscal year under the heading "Equity Plans," which is incorporated herein by reference.

Table of Contents

## Item 6. Selected Financial Data

We have derived the consolidated balance sheet data set forth below as of December 31, 2013 and 2012, and the consolidated statement of operations data for each of the years in the three-year period ended December 31, 2013, from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

You should read the selected 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, and stockholders’ deficit in the periods presented below include the effects of the receipt of net proceeds from our debt offerings, equity offerings, the exercise of stock options and warrants, and employee stock purchases that totaled approximately \$36.6 million, \$10.5 million, \$8.1 million, \$11.6 million, and \$18.7 million in the years ended December 31, 2013, 2012, 2011, 2010, and 2009, respectively.

	For the Year Ended December 31,				
	2013	2012	2011	2010	2009
	(In thousands, except per share data)				
<b>Consolidated Statement of Operations Data:</b>					
Revenue	\$3,045	\$15,961	\$2,756	\$3,360	\$3,334
Operating expenses:					
Cost of goods sold	(536	) (672	) —	(123	) —
Research and development	(13,005	) (10,564	) (11,023	) (12,878	) (16,903
General and administrative	(14,484	) (11,465	) (10,820	) (12,112	) (14,110
Loss from operations	(24,980	) (6,740	) (19,087	) (21,753	) (27,679
Non-operating income	(2,673	) 110	2	4,680	2,568
Interest expense, net	(2,420	) (4,695	) (4,191	) (4,834	) (5,207
Net loss (1)	(30,073	) (11,325	) (23,276	) (21,907	) (30,318
Dividends on convertible preferred stock	(3,159	) (792	) (790	) (790	) (790
Net loss attributable to common stockholders	(33,232	) \$(12,117	) \$(24,066	) \$(22,697	) \$(31,108
Net loss attributable to common stockholders per common share, basic and diluted	\$(1.12	) \$(0.51	) \$(1.21	) \$(1.41	) \$(2.36
Weighted average number of shares outstanding, basic and diluted	29,766	23,629	19,899	16,108	13,170
	December 31,				
	2013	2012	2011	2010	2009
	(In thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents, and short-term investments	\$27,352	\$21,468	\$10,748	\$19,782	\$30,065
Total current assets	28,175	22,615	12,004	20,854	31,533
Total assets	34,835	29,093	19,808	30,907	45,874
Total current liabilities	10,296	4,813	4,754	5,416	5,355
Long-term debt, less current portion	5,348	35,714	32,726	34,050	49,494
Stockholders’ deficit	(4,481	) (17,600	) (20,831	) (14,707	) (16,975

Given our history of incurring operating losses, no income tax benefit has been recognized in our consolidated (1) statements of operations 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.

Table of ContentsItem 7. Management's Discussion and Analysis of Financial Condition and Results of Operations  
Overview

We are a biopharmaceutical company developing a portfolio of immuno-oncology candidates, including checkpoint modulators, heat shock protein vaccines and adjuvants. We are focused on immunotherapeutic products based on our core platform technologies with multiple product candidates advancing through the clinic, including several product candidates that have advanced into late-stage clinical trials through corporate partners. We assess the development, commercialization and/or partnering strategies with respect to each of our internal product candidates periodically based on several factors, including clinical trial results, competitive positioning, and funding requirements and resources.

Our core technology portfolio consists of our Checkpoint Antibody Program, our Heat Shock Protein ("HSP") Platform (based on our HSP technologies), and our Saponin Platform (based on our saponin adjuvant technologies). Our Checkpoint Antibody Program became part of our portfolio with the recent acquisition of 4-Antibody AG, a private European-based biopharmaceutical company ("4-AB"). This acquisition (the "Acquisition") provided us with a technology platform for the rapid discovery and optimization of fully-human antibodies against a wide array of molecular targets. This platform has been applied to six immune checkpoint targets seeking therapeutic antibody check point modulators ("CPMs") to regulate immune response to cancers and other diseases. Our proprietary antibody discovery engine, Retrocyte Display<sup>®</sup>, is designed to generate high quality therapeutic antibody drug candidates quickly using a high-throughput approach incorporating human antibody libraries expressed in mammalian B-lineage cells. We currently have pre-clinical checkpoint antibody programs targeting GITR, OX40, CTLA-4, PD-1, TIM-3 and LAG-3 from 4-AB's technologies. We have selected two GITR agonists and one CTLA-4 antagonist to advance into pre-clinical development. We are targeting to identify development candidates for the other four checkpoint programs during 2014, and to be in a position to file investigational new drug applications on four candidates within the next two years.

Within our HSP Platform we are developing our Prophage Series cancer vaccines. Our Prophage Series cancer vaccine are autologous therapies derived from cells extracted from the patient's tumor. As a result, Prophage Series vaccines contain a precise antigenic 'fingerprint' of a patient's particular cancer and are designed to reprogram the body's immune system to target only cells bearing this fingerprint, reducing the risk that powerful anti-cancer agents will target healthy tissue and cause debilitating side effects often associated with chemotherapy and radiation therapy. We believe that in contrast to many other autologous vaccines that are based on cellular preparations, the Prophage Series is based on a stable protein preparation produced via a relatively simple manufacturing process. Our Prophage Series G vaccines are currently being studied in two different settings of glioblastoma multiforme, or GBM: newly diagnosed and recurrent disease.

Also within our HSP Platform, is HerpV, a recombinant, synthetic vaccine containing multiple antigens derived from the herpes simplex 2 virus. HerpV is currently in a Phase 2 clinical trial, and we believe it is one of the most clinically-advanced therapeutic vaccines for the treatment of genital herpes in clinical development. Combining our heat shock protein technology and our QS-21 Stimulon adjuvant, HerpV represents a potential new approach to the treatment of genital herpes. Rather than attempting to suppress the virus, which is what antivirals do, HerpV has the potential to enable the individual's own immune system to stop the virus from causing and transmitting disease without chronic treatment. In November 2013, we released top line results from a Phase 2, randomized, double blind, multicenter clinical trial of HerpV in HSV-2 positive genital herpes patients, which showed that the trial met its primary endpoint. We anticipate reporting additional study results assessing the efficacy of a booster injection of HerpV during the first half of 2014.

Within our Saponin Platform is QS-21 Stimulon<sup>®</sup> adjuvant, or QS-21 Stimulon. QS-21 Stimulon is a saponin extracted from the bark of the Quillaja saponaria tree, also known as the Soapbark, an evergreen tree native to warm temperate central Chile. QS-21 Stimulon has become a key component in the development of investigational preventive vaccine formulations across a wide variety of infectious diseases, including several investigational therapeutic vaccines intended to treat cancer and degenerative disorders. QS-21 Stimulon has been widely studied and



approximately 50,000 patients have received vaccines containing the adjuvant. The key licensees of QS-21 Stimulon are GlaxoSmithKline ("GSK") and JANSSEN Alzheimer Immunotherapy ("JANSSEN AI"). QS-21 Stimulon is currently being studied in 21 vaccine indications, which include GSK's Phase 3 vaccine programs for RTS,S for malaria, MAGE-A3 cancer immunotherapeutic for non-small cell lung cancer and melanoma and HZ/su for shingles. In addition, JANSSEN AI's QS-21 Stimulon adjuvant-containing vaccine candidate is in Phase 2 trials for the treatment of Alzheimer's disease. If any of our partners' products containing QS-21 Stimulon successfully completes clinical development and receives approval for commercial sale, we are generally entitled to receive royalties for 10 years after commercial launch, with some exceptions.

Table of Contents

In addition to our internal development efforts, we continue to pursue partnering opportunities. We are seeking partners for select products in our portfolio, which include HerpV, QS-21 Stimulon and the Prophage G-Series vaccines, G-100 and G-200 as well as our antibody therapeutic candidates. We are also exploring in-licensing, acquisitions and sponsored research opportunities. Our business activities have included product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development, business development, and support of our collaborations. Research and development expenses for the years ended December 31, 2013, 2012, and 2011, were \$13.0 million, \$10.6 million, and \$11.0 million, respectively. We have incurred significant losses since our inception. As of December 31, 2013, we had an accumulated deficit of \$649.1 million.

We have financed our operations primarily through the sale of equity and debt securities. We believe that, based on our current plans and activities, our working capital resources at December 31, 2013, plus the net proceeds from our February 2014 equity offering and potential proceeds from license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements through the first half of 2015. We expect to attempt to raise additional funds in advance of depleting our current funds. We may attempt to raise funds by: (1) out-licensing technologies or products to one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities. Satisfying long-term liquidity needs may require the successful commercialization and/or one or more partnering arrangements for (1) HerpV and the Prophage Series vaccines, (2) vaccines containing QS-21 Stimulon under development by our licensees, and/or (3) potential other product candidates, each of which will require additional capital. If we incur operating losses for longer than we expect and/or we are unable to raise additional capital, we may become insolvent and be unable to continue our operations.

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

#### Historical Results of Operations

##### Year Ended December 31, 2013 Compared to the Year Ended December 31, 2012

**Revenue:** We generated revenue of \$3.0 million and \$16.0 million during the years ended December 31, 2013 and 2012, respectively. Revenue includes license fees and service revenue, and in 2012, royalties earned. For the year ended December 31, 2012, we recognized revenue of \$6.5 million through an expanded license agreement with GSK, which provided GSK with additional license rights in an undisclosed indication, and \$6.25 million through a license of non-core technologies with an existing licensee that resulted in a buy-out of the current royalty stream related to the license. During each of the years ended December 31, 2013 and 2012, we recorded revenue of \$1.6 million and \$1.5 million, respectively, from the amortization of deferred revenue. Our revenue for the year ended December 31, 2012 primarily resulted from one-time payments received under amended license agreements and therefore is not indicative of future results.

**Research and Development:** Research and development expenses include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, costs of consultants, and administrative costs. Research and development expense increased 23.1% to \$13.0 million for the year ended December 31, 2013 from \$10.6 million for the year ended December 31, 2012. Increased expenses primarily relate to the increased activity in our HerpV program as well as increased compensation expense related to bonuses for research and development personnel partially offset by decreased amortization expense.

**General and Administrative:** General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 26.3% to \$14.5 million for the year ended December 31, 2013 from \$11.5 million for the year ended December 31, 2012. Increased expenses related to increased compensation expense in connection with bonuses for general and administrative personnel and increased professional fees related to our corporate activities, partially offset by decreased amortization expense.

**Non-operating (loss) income:** Non-operating loss for the year ended December 31, 2013 consists primarily of a loss on the extinguishment of our 2006 Notes partially offset by the decrease in the fair value of our contingent royalty obligation and the gain on the sale of an equity investment.

Interest Expense: Interest expense decreased to \$2.4 million for the year ended December 31, 2013 from \$4.7 million for the year ended December 31, 2012 due to the extinguishment of our 2006 Notes during 2013.

Year Ended December 31, 2012 Compared to the Year Ended December 31, 2011

Revenue: We generated revenue of \$16.0 million and \$2.8 million during the years ended December 31, 2012 and 2011, respectively. Revenue includes license fees and royalties earned, and in 2012, service revenue. For the year ended

Table of Contents

December 31, 2012, we recognized revenue of \$6.5 million through an expanded license agreement with GSK, which provided GSK with additional license rights in an undisclosed indication, and \$6.25 million through a license of non-core technologies with an existing licensee that resulted in a buy-out of the current royalty stream related to the license. During the years ended December 31, 2012 and 2011, we recorded revenue of \$1.5 million and \$1.6 million, respectively, from the amortization of deferred revenue. Our revenue for the year ended December 31, 2012 primarily resulted from one-time payments received under amended license agreements and therefore is not indicative of future results.

**Research and Development:** Research and development expense decreased 4.2% to \$10.6 million for the year ended December 31, 2012 from \$11.0 million for the year ended December 31, 2011. Decreased expenses related to our general cost-containment efforts and the status of our products under development were partially offset by increased expenses related to our HerpV program and non-cash share-based compensation expense.

**General and Administrative:** General and administrative expenses increased 6.0% to \$11.5 million for the year ended December 31, 2012 from \$10.8 million for the year ended December 31, 2011. Our non-cash share-based compensation expense increased \$1.3 million for the year ended December 31, 2012 over the year ended December 31, 2011. This increase was partially offset by decreased expenses related to our general cost-containment efforts.

**Interest Expense:** Interest expense increased to \$4.7 million for the year ended December 31, 2012 from \$4.2 million for the year ended December 31, 2011. This increase is related to an increase in the amount of debt discount amortized related to our 2006 Notes in addition to the increase in the principal amount of debt outstanding. Interest on our 2006 Notes was payable in cash or, at our option, in additional notes or a combination thereof. During the years ended December 31, 2012 and 2011, interest expense included \$1.5 million and \$2.8 million, respectively, paid in the form of additional 2006 Notes.

**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**

Prior to 2002, we did not track costs on a per project basis, and therefore have estimated the allocation of our total research and development costs to our largest research and development programs for that time period. During 2013, these research and development programs consisted largely of HerpV and our Prophage Series vaccines, as indicated in the following table (in thousands).

Research and Development Program	Product	Year Ended December 31,			Prior to 2011	Total
		2013	2012	2011		
Heat shock proteins for cancer	Prophage Series Vaccines	\$5,882	\$5,613	\$10,182	\$281,851	\$303,528
Heat shock proteins for infectious diseases	HerpV	6,358	4,862	734	18,354	30,308
Vaccine adjuvant *	QS-21 Stimulon	753	85	94	12,404	13,336
Other research and development programs		12	4	13	33,527	33,556
Total research and development expenses		\$13,005	\$10,564	\$11,023	\$346,136	\$380,728

\* Prior to 2000, costs were incurred by Aquila Biopharmaceuticals, Inc., a company we acquired in November 2000. 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 HerpV is now in a Phase 2 trial and the further development of our Prophage Series vaccines is subject to evaluation and uncertainty, we are unable to reliably estimate the cost of completing our research and development programs, the timing of bringing such programs to various markets, and, therefore, when, if ever, material cash inflows are likely to commence. Programs involving QS-21 Stimulon, other than our

## Table of Contents

HerpV program, depend on our collaborative partners or licensees 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

#### Prophage Series Vaccines

We started enrolling patients in our first clinical trial studying a Prophage Series vaccine at Memorial Sloan-Kettering Cancer Center in New York, New York in November 1997. To date, nearly 900 cancer patients have been treated with our vaccine in clinical trials. The results of these trials have been published and/or presented at major conferences.

These results indicate consistent clinical and/or immunological activity across many types of cancer.

Because Prophage Series vaccines are novel therapeutic vaccines that are patient-specific, meaning derived from the patient's own tumor, they are experiencing a long development process and high development costs, either of which could delay or prevent our commercialization efforts. 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. Phase 2 trials are fully enrolled in the United States testing the Prophage Series vaccine candidates G-100 and G-200 in newly diagnosed and recurrent glioma, respectively. In addition, through the support of the Alliance for Clinical Trials in Oncology, a cooperative group of the National Cancer Institute (NCI), the NCI opened patient enrollment in 2013 for a 222-patient, multi-center, randomized Phase 2 trial of Prophage Series vaccine G-200 in combination with Avastin® (bevacizumab) in patients with surgically resectable recurrent glioma. The G-100 and G-200 studies are solely based in the United States. For additional information regarding our Prophage Series vaccines, please read Part I-Item 1. "Business" of this Annual Report on Form 10-K.

#### HerpV

In October 2005, we initiated a multicenter Phase 1 clinical trial of HerpV (designated in the study as AG-707 plus QS-21 Stimulon) in HSV-2 (genital herpes). We completed enrollment in a Phase 2 study in February 2013 and in November 2013, released top line results from this study which met its primary endpoint. At this time, all subjects in the study have received a booster injection of HerpV that was given six months after the first vaccination followed by determination of genital viral shedding for an additional 45-day period. We anticipate reporting additional study results after booster injection during the first half of 2014. For additional information regarding HerpV, please read Part I-Item 1. "Business" of this Annual Report on Form 10-K.

#### QS-21 Stimulon

QS-21 Stimulon® adjuvant, from our Saponin Platform, is an adjuvant, or a substance added to a vaccine or other immunotherapy, that is intended to enhance immune response. The key licensees of QS-21 Stimulon are GSK and JANSSEN AI. There are approximately 21 vaccines containing QS-21 Stimulon in clinical development, including a total of four in Phase 3 testing by GSK for malaria, melanoma, non-small cell lung cancer and shingles, and one in Phase 2 trials with JANSSEN AI for the treatment of Alzheimer's disease. Assuming regulatory approval, the first products containing QS-21 Stimulon are anticipated to be launched in 2015, and we are generally entitled to royalties for at least 10 years after commercial launch, with some exceptions. However, there is no guarantee that we will be able to collect royalties in the future. The pipeline of product candidates containing QS-21 Stimulon is very diverse, encompassing prophylactic as well as therapeutic vaccines for infectious diseases, multiple cancer types, and Alzheimer's disease. We do not incur clinical development costs for these products of our licensees. 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 \$649.1 million as of December 31, 2013. We expect to incur significant losses over the next several years as we continue clinical trials, manage our regulatory processes, prepare for potential commercialization of products, and continue development of our technologies. We have financed our operations primarily through the sale of equity and debt, and interest income earned on cash, cash equivalents, and short-term investment balances. From our inception through December 31, 2013, we have raised aggregate net proceeds of \$561.5 million through the sale of common and preferred stock, the

exercise of stock options and warrants, proceeds from our employee stock purchase plan, and the issuance of convertible and other notes. During February 2014, we raised additional net proceeds of approximately \$56.0 million through an underwritten offering of our common stock. In addition, during the quarter ended March 31, 2012, we received \$9.0 million from GSK for a first right to negotiate the

Table of Contents

purchase of Agenus or certain of its assets and an expanded license agreement and \$6.25 million through a license of non-core technologies with an existing licensee. We granted GSK the first right to negotiate for the purchase of the Company or certain of our assets which will expire in March 2017.

We also maintain an effective registration statement to sell an aggregate of up to ten million shares of our common stock from time to time pursuant to an At the Market Issuance Sales Agreement with MLV & Co. LLC, as sales agent. As of December 31, 2013, we have 5.2 million shares available for sale under this agreement. However, as a result of our issuance of shares of our common stock in connection with our February 2014 public offering and the Acquisition, we do not currently have sufficient authorized shares of common stock in order to continue to make sales under this agreement. Our board of directors has approved an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 70,000,000 to 140,000,000. We intend to submit the amendment to our stockholders for approval at our 2014 Annual Meeting of Stockholders. While we believe that the amendment is in the best interest of the Company and its stockholders, we do not think that it is necessary to maintain our current liquidity position.

As of December 31, 2013, we had debt outstanding of \$9.6 million in principal. On April 15, 2013, we entered into a Securities Exchange Agreement with the holders of our 2006 Notes whereby we exchanged all of the 2006 Notes, including accrued and unpaid interest, for \$10.0 million in cash, 2,500,000 shares of our common stock, and a contractual right to the proceeds of 20% of our revenue interests from certain QS-21 Stimulon partnered programs and a 0.5% royalty on net sales of HerpV. To finance the cash portion of this exchange we entered into two new debt arrangements. On April 15, 2013, we entered into a Loan and Security Agreement with Silicon Valley Bank for senior secured debt in the aggregate principal amount of \$5.0 million (the "SVB Loan"). The SVB Loan bears interest at a rate of 6.75% per annum, payable in cash on the first day of each month with principal payments beginning November 2013 and ending with the final principal payment in April 2015. We also entered into a Note Purchase Agreement with various investors for senior subordinated notes (the "Subordinated Notes") in the aggregate principal amount of \$5.0 million due in April 2015. The Subordinated Notes bear interest at a rate of 10% per annum, payable in cash on the first day of each month in arrears. We also issued to the holders of the Subordinated Notes four year warrants to purchase 500,000 unregistered shares of our common stock at an exercise price of \$4.41 per share.

Our cash and cash equivalents at December 31, 2013 were \$27.4 million, an increase of \$5.9 million from December 31, 2012. We believe that, based on our current plans and activities, our cash balance of \$27.4 million as of December 31, 2013, plus net proceeds of approximately \$56.0 million received from the underwritten offering in February 2014, and potential proceeds from license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements through the first half of 2015. We continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be feasible, restrict capital expenditures and/or reduce the scale of our operations.

We expect to attempt to raise additional funds in advance of depleting our current funds. In order to fund our operations beyond 2015, we will need to contain costs and raise additional funds. We may attempt to raise funds by: (1) out-licensing technologies or products to 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 ability to successfully enter into any such arrangements is uncertain, and if funds are not available, or not available on terms acceptable to us, we may be required to revise our planned clinical trials, other development activities, capital expenditures, and/or the scale of our operations. While we expect to attempt to raise additional funds in advance of depleting our current funds, we may not be able to raise funds or raise amounts sufficient to meet the long-term needs of the business. Satisfying long-term liquidity needs may require the successful commercialization and/or one or more partnering arrangements for (1) HerpV and the Prophage Series vaccines, (2) vaccines containing QS-21 Stimulon under development by our licensees, and/or (3) potential other product candidates, each of which will require additional capital.

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 institutions and clinical research organizations to conduct and monitor our clinical studies. Under these



agreements, subject to the enrollment of patients and performance by the applicable institution of certain services, we have estimated our total payments to be \$52.6 million over the term of the studies. Through December 31, 2013, we have expensed \$50.5 million as research and development expenses and \$49.4 million has been paid related to these clinical studies. The timing of expense recognition and future payments related to these agreements is subject to the enrollment of patients and performance by the applicable institution of certain services.

We have also entered into sponsored research agreements related to our product candidates that required payments of \$6.6 million, all of which have been paid as of December 31, 2013. We plan to enter into additional sponsored research agreements, and we anticipate significant additional expenditures will be required to advance our clinical trials, apply for regulatory approvals, continue development of our technologies, and bring our product candidates to market. Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing collaborative arrangements

Table of Contents

with academic and collaborative partners and licensees and by entering into new collaborations. As a result of our collaborative agreements, we will not completely control the efforts to attempt to bring those product candidates to market. For example, we have various agreements with collaborative partners and/or licensees that allow the use of our QS-21 Stimulon adjuvant in numerous vaccines. These agreements grant exclusive worldwide rights in some fields of use and co-exclusive or non-exclusive rights in others. These agreements generally call for royalties to be paid to us on future sales of licensed vaccines that include QS-21 Stimulon, which may or may not be achieved. Significant investment in manufacturing capacity could be required if we were to retain our manufacturing and supply rights.

Net cash used in operating activities for the year ended December 31, 2013 was \$19.5 million while cash provided by operating activities for the year ended December 31, 2012 was \$1.0 million. This cash provided by operating activities for the year ended December 31, 2012 primarily resulted from one-time payments received under amended license agreements and therefore is not indicative of future results. During the year ended December 31, 2012, we recognized revenue of \$12.8 million related to expanded license agreements. We continue to support and develop our QS-21 Stimulon partnering collaborations, and anticipate earning royalties from products containing QS-21 Stimulon in 2015. Our future ability to generate cash from operations will depend on achieving regulatory approval of our product candidates, and market acceptance of our product candidates, achieving benchmarks as defined in existing collaborative 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, 2013 (in thousands).

	Total	Payments Due by Period			
		Less than 1 Year	1 – 3 Years	3 – 5 Years	More than 5 Years
Long-term debt (1)	\$10,545	\$4,276	\$6,269	\$—	\$—
Operating leases (2)	14,447	1,407	2,936	3,144	6,960
Total	\$24,992	\$5,683	\$9,205	\$3,144	\$6,960

(1) Includes fixed interest payments.

(2) Effective May 2013, we sublet part of our Lexington facility to ImmuneXcite, Inc. whose lease expires in June 2016. Our Lexington facility and New York office leases expire August 2023 and May 2020, respectively.

#### Off-Balance Sheet Arrangements

At December 31, 2013, 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.

Share-Based Compensation

In accordance with the fair value recognition provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 718, Compensation—Stock Compensation, we recognize share-based

Table of Contents

compensation expense net of an estimated forfeiture rate and only recognize compensation expense for those share-based awards expected to vest. Compensation expense is recognized on a straight-line basis over the requisite service period of the award.

Stock options granted to certain non-employees have been accounted for based on the fair value method of accounting in accordance with ASC 505-50, Equity- Equity-Based Payments to Non-Employees. As a result, the noncash charge to operations for non-employee options with vesting or other performance criteria is affected each reporting period, until the non-employee options vest, by changes in the fair value of our common stock. Under the provisions of ASC 505-50, the change in fair value of vested options issued to non-employees is reflected in the statement of operations each reporting period, until the options are exercised or expire.

Determining the appropriate fair value model and calculating the fair value of share-based awards requires the use of highly subjective assumptions, including the expected life of the share-based awards and stock price volatility. The assumptions used in calculating the fair value of share-based awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future. In addition, if our actual forfeiture rate is materially different from our estimate, the share-based compensation expense could be significantly different from what we have recorded in the current period. See Note 8 of the notes to our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K for a further discussion on share-based compensation.

**Revenue Recognition**

Revenue for services under research and development contracts are recognized as the services are performed, or as clinical trial materials are provided. Non-refundable milestone payments that represent the completion of a separate earnings process are recognized as revenue when earned. License fees and royalties are recognized as they are earned. Revenue recognized from collaborative agreements is based upon the provisions of ASC 605-25, Revenue Recognition—Multiple Element Arrangements, as amended by Accounting Standards Update 2009-13.

**Fair Value Measurements**

In accordance with ASC 820, Fair Value Measurements and Disclosures, we measure fair value based on a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. The fair value hierarchy is broken down into three levels based on the source of inputs.

We have elected to measure our contingent royalty consideration at fair value in accordance with ASC 825, Financial Instruments. The fair value of our contingent royalty consideration is based on significant inputs not observable in the market, which require it to be reported as a Level 3 liability within the fair value hierarchy. The valuation uses assumptions we believe would be made by a market participant. In particular, the valuation analysis used the Income Approach based on the sum of the economic income that an asset is anticipated to produce in the future. In this case that asset is the potential royalty income to be paid to us as a result of certain license agreements for QS-21 Stimulon and the potential net sales generated from HerpV. The fair value of the contingent royalty consideration is estimated by applying a risk adjusted discount rate to the probability adjusted royalty revenue stream based on expected approval dates. These fair value estimates are most sensitive to changes in the probability of regulatory approvals. The Discounted Cash Flow method of the Income Approach was chosen as the method best suited to valuing the contingent royalty consideration.

**Recent Accounting Pronouncements**

In February 2013, the FASB issued Accounting Standards Update No. 2013-02, "Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income", ("ASU 2013-02"). ASU 2013-02 requires entities to disclose items reclassified out of Accumulated Other Comprehensive Income ("AOCI") and into net income in their entirety, the effect of the reclassification on each affected net income line item, and, for AOCI reclassification items that are not reclassified in their entirety into net income, a cross reference to other required U.S. GAAP disclosures. This consolidated standard is effective for annual periods beginning after December 31, 2012 and interim periods within those years. The application of this standard did not have a material impact on our consolidated financial statements.

In July 2013, the FASB issued Accounting Standards Update No. 2013-11, "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists", ("ASU 2013-11"). ASU 2013-11 amends ASC 740, "Income Taxes", by providing guidance on the financial statement presentation of an unrecognized benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. ASU 2013-11 does not affect the recognition or measurement of uncertain tax positions under ASC 740. ASU 2013-11 will be

45

---

Table of Contents

effective for interim and annual periods beginning after December 15, 2013, with early adoption permitted. We do not expect the adoption of ASU 2013-11 to have any impact on our consolidated financial statements.

46

---

Table of Contents

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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. During the year ended December 31, 2013, there has been no material change with respect to our interest rate and foreign currency exposures or our approach toward those exposures. However, our acquisition of 4-AB will result in increased foreign currency exposure.

We had cash and cash equivalents at December 31, 2013 of \$27.4 million, which are exposed to the impact of interest and foreign currency exchange rate changes, and our interest income fluctuates as interest rates change. 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, 2013, 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 derivative or other financial instruments that would require disclosure under this item.

Table of Contents

Item 8. Financial Statements and Supplementary Data  
INDEX TO FINANCIAL STATEMENTS

<u>Report of Independent Registered Public Accounting Firm</u>	<u>49</u>
<u>Consolidated Balance Sheets</u>	<u>50</u>
<u>Consolidated Statements of Operations</u>	<u>52</u>
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	<u>53</u>
<u>Consolidated Statements of Cash Flows</u>	<u>56</u>
<u>Notes to Consolidated Financial Statements</u>	<u>57</u>

48

---



Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Agenus Inc.:

We have audited the accompanying consolidated balance sheets of Agenus Inc. and subsidiaries as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2013. 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 conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Agenus Inc. and subsidiaries as of December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2013, 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), Agenus Inc. and subsidiaries' internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control—Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 7, 2014 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Boston, Massachusetts

March 7, 2014

Table of Contents

AGENUS INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

	December 31, 2013	December 31, 2012
<b>ASSETS</b>		
Cash and cash equivalents	\$27,351,969	\$21,468,269
Inventories	—	16,022
Accounts receivable	1,200	552,334
Prepaid expenses	658,412	545,907
Other current assets	162,997	32,156
Total current assets	28,174,578	22,614,688
Plant and equipment, net of accumulated amortization and depreciation of \$27,637,443 and \$27,404,751 at December 31, 2013 and 2012, respectively	2,784,845	2,606,428
Goodwill	2,572,203	2,572,203
Other long-term assets	1,303,855	1,299,304
Total assets	\$34,835,481	\$29,092,623
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current portion, long-term debt	\$3,518,550	\$204,088
Current portion, deferred revenue	1,660,679	1,527,883
Accounts payable	834,740	634,752
Accrued liabilities	4,215,221	2,168,338
Other current liabilities	66,683	277,927
Total current liabilities	10,295,873	4,812,988
Convertible notes	—	35,679,232
Other long-term debt	5,347,690	34,427
Deferred revenue	3,193,809	4,800,776
Contingent royalty consideration	18,799,141	—
Other long-term liabilities	1,679,671	1,365,357
Commitments and contingencies (Notes 11 and 14)		
<b>STOCKHOLDERS' DEFICIT</b>		
Preferred stock, par value \$0.01 per share; 5,000,000 authorized at December 31, 2013 and 2012:		
Series A-1 convertible preferred stock; 31,620 shares and 0 shares designated, issued, and outstanding at December 31, 2013 and 2012, respectively; liquidation value of \$32,269,603 at December 31, 2013		—
Series A convertible preferred stock; 0 and 31,620 shares designated, issued, and outstanding at December 31, 2013 and 2012, respectively; liquidation value of \$32,016,485 at December 31, 2012	—	316
Series B2 convertible preferred stock; 3,105 shares designated, issued, and outstanding at December 31, 2013 and 2012	31	31
Common stock, par value \$0.01 per share; 70,000,000 shares authorized December 31, 2013 and 2012; 36,391,191 and 24,645,112 shares issued at December 31, 2013 and 2012, respectively	363,912	246,451
Additional paid-in capital	644,571,866	595,917,080
Treasury stock, at cost; 43,490 shares of common stock at December 31, 2013 and 2012	(324,792)	(324,792)
Accumulated deficit	(649,092,036)	(619,019,367)
Noncontrolling interest	—	5,580,124

Edgar Filing: AGENUS INC - Form 10-K

Total stockholders' deficit	(4,480,703	) (17,600,157	)
Total liabilities and stockholders' deficit	\$34,835,481	\$29,092,623	

50

---

Table of Contents

See accompanying notes to consolidated financial statements.

51

---

Table of Contents

AGENUS INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS  
For the Years Ended December 31, 2013, 2012, and 2011

	2013	2012	2011
Revenue:			
Service revenue	1,417,864	1,489,821	—
Research and development revenue	1,627,343	14,470,895	2,755,772
Total revenues	3,045,207	15,960,716	2,755,772
Operating expenses:			
Cost of revenues	(536,118 )	(671,972 )	—
Research and development	(13,005,366 )	(10,564,195 )	(11,022,391 )
General and administrative	(14,483,835 )	(11,465,092 )	(10,820,187 )
Operating loss	(24,980,112 )	(6,740,543 )	(19,086,806 )
Other income (expense):			
Non-operating (loss) income	(2,672,759 )	110,473	1,941
Interest expense	(2,427,729 )	(4,718,037 )	(4,210,097 )
Interest income	7,931	23,336	18,787
Net loss	(30,072,669 )	(11,324,771 )	(23,276,175 )
Dividends on convertible preferred stock	(3,159,782 )	(791,735 )	(790,500 )
Net loss attributable to common stockholders	\$(33,232,451 )	\$(12,116,506 )	\$(24,066,675 )
Per common share data, basic and diluted:			
Net loss attributable to common stockholders	\$(1.12 )	\$(0.51 )	\$(1.21 )
Weighted average number of common shares outstanding, basic and diluted	29,765,547	23,628,903	19,898,632

See accompanying notes to consolidated financial statements.

Table of Contents

AGENUS INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)  
 For the Years Ended December 31, 2013, 2012, and 2011

	Series A Convertible Preferred Stock	Series A Convertible Preferred Stock	Series B Convertible Preferred Stock	Series B Convertible Preferred Stock	Common Stock	Common Stock	Additional Paid-In Capital	Treasury Stock Number of Shares	Treasury Stock Amount	Accumulated Deficit
	Number of Shares	Par Value	Number of Shares	Par Value	Number of Shares	Par Value				
Balance at December 31, 2010	31,620	\$316	3,105	\$31	18,647,626	\$186,476	\$569,849,178	43,490	\$(324,792)	\$(584,418,421)
Net loss	—	—	—	—	—	—	—	—	—	(23,276,175)
2006 Note Amendment—conversion option valuation	—	—	—	—	—	—	755,000	—	—	—
Shares sold at the market	—	—	—	—	2,552,492	25,525	7,477,850	—	—	—
Shares issued in private placements	—	—	—	—	88,333	883	476,117	—	—	—
Share-based compensation	—	—	—	—	—	—	3,335,066	—	—	—
Reclassification of liability classified option grants	—	—	—	—	—	—	(78,079)	)	—	—
Vesting of nonvested shares	—	—	—	—	165,586	1,656	(1,656)	)	—	—
Shares issued to CEO in lieu of cash compensation	—	—	—	—	36,577	366	155,834	—	—	—
Shares issued to consultants for services	—	—	—	—	16,192	162	94,538	—	—	—
Exercise of stock options	—	—	—	—	319	3	1,435	—	—	—
Employee share purchases	—	—	—	—	20,524	205	80,893	—	—	—
Shares issued to director for services	—	—	—	—	7,388	74	36,926	—	—	—
Dividends on series A convertible preferred stock (\$25 per share)	—	—	—	—	—	—	(790,500)	)	—	—
Balance at December 31, 2011	31,620	316	3,105	31	21,535,037	215,350	581,392,602	43,490	(324,792)	(607,694,596)

See accompanying notes to consolidated financial statements.

Table of Contents

AGENUS INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)  
 (Continued)

For the Years Ended December 31, 2013, 2012, and 2011

	Series A Convertible Preferred Stock		Series A-B2 Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Deficit	Noncon- Interest
	Number of Shares	Par Value	Number of Shares	Par Value	Number of Shares	Par Value		Number of Shares	Amount		
Net loss	—	—	—	—	—	—	—	—	—	(11,324,771 )	—
Shares sold at the market	—	—	—	—	2,469,870	24,699	10,439,504	—	—	—	—
Share-based compensation	—	—	—	—	—	—	4,074,814	—	—	—	—
Reclassification of liability classified option grants	—	—	—	—	—	—	(31,945 )	—	—	—	—
Vesting of nonvested shares	—	—	—	—	523,210	5,232	(5,232 )	—	—	—	—
Shares issued to CEO in lieu of cash compensation	—	—	—	—	39,231	392	158,008	—	—	—	—
Shares issued to consultants for services	—	—	—	—	5,000	50	22,400	—	—	—	—
Exercise of stock options	—	—	—	—	6,825	68	26,313	—	—	—	—
Employee share purchases	—	—	—	—	28,859	289	51,904	—	—	—	—
Shares issued to director for services	—	—	—	—	3,601	36	9,214	—	—	—	—
Issuance of director deferred shares	—	—	—	—	33,479	335	174,748	—	—	—	—
Dividends on series A convertible preferred stock (\$12.50 per share)	—	—	—	—	—	—	(395,250 )	—	—	—	—
Balance at December 31, 2012	31,620	\$316	—	\$31	24,645,112	\$246,451	\$595,917,080	43,490	\$(324,792)	\$(619,019,367)	\$5,580

See accompanying notes to consolidated financial statements.



Table of Contents

AGENUS INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)  
(Continued)

For the Years Ended December 31, 2013, 2012, and 2011

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B2 Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Deficit
	Number of Shares	Par Value	Number of Shares	Par Value	Number of Shares	Par Value	Number of Shares	Par Value		Number of Shares	Amount	
Net loss	—	—	—	—	—	—	—	—	—	—	—	(30,072,669)
Shares sold at the market	—	—	—	—	—	—	4,831,132	48,312	16,942,004	—	—	—
Common stock issued to preferred shareholder	(31,620)	(316)	1,620	316	—	—	666,666	6,667	(6,667)	—	—	—
Extinguishment of debt	—	—	—	—	—	—	2,500,000	25,000	17,971,813	—	—	—
Shares sold in registered direct offering	—	—	—	—	—	—	3,333,333	33,333	9,439,161	—	—	—
Share-based compensation	—	—	—	—	—	—	—	—	4,054,561	—	—	—
Reclassification of liability classified option grants	—	—	—	—	—	—	—	—	(4,347)	—	—	—
Vesting of nonvested shares	—	—	—	—	—	—	339,800	3,398	(3,398)	—	—	—
Shares issued to CEO in lieu of cash compensation	—	—	—	—	—	—	43,887	439	157,961	—	—	—
Exercise of stock options	—	—	—	—	—	—	4,503	45	15,085	—	—	—
Employee share purchases	—	—	—	—	—	—	26,758	267	88,613	—	—	—
Balance at December 31, 2013	—	\$—	31,620	\$316	3,105	\$31	36,391,191	\$363,912	\$644,571,866	43,490	\$(324,792)	\$(649,092,000)

See accompanying notes to consolidated financial statements.

Table of Contents

AGENUS INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
For the Years Ended December 31, 2013, 2012, and 2011

	2013	2012	2011
Cash flows from operating activities:			
Net loss	\$(30,072,669 )	\$(11,324,771 )	\$(23,276,175 )
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	586,343	1,622,736	2,252,412
Share-based compensation	4,127,786	4,303,961	2,646,767
Non-cash interest expense	1,820,787	3,141,475	4,167,849
Loss on extinguishment of debt	3,322,657	—	—
Gain on sale of investment	(355,500 )	—	—
Change in fair value of derivative liability	(291,517 )	—	—
Loss on disposal of assets	59,110	11,026	37,447
Changes in operating assets and liabilities:			
Accounts receivable	551,134	(552,334 )	35,000
Inventories	16,022	4,050	6,360
Prepaid expenses	(112,505 )	(9,637 )	168,474
Accounts payable	189,638	(181,848 )	105,667
Deferred revenue	(1,474,171 )	2,707,613	(1,531,495 )
Accrued liabilities and other current liabilities	1,916,467	542,349	(269,713 )
Other operating assets and liabilities	183,473	747,982	(591,504 )
Net cash (used in) provided by operating activities	(19,532,945 )	1,012,602	(16,248,911 )
Cash flows from investing activities:			
Proceeds from maturities of available-for-sale securities	—	—	5,000,000
Purchases of available-for-sale securities	—	—	(4,998,799 )
Proceeds from sale of equipment	—	—	23,884
Proceeds from sale of investment	450,000	—	—
Purchases of plant and equipment	(813,520 )	(103,442 )	(54,547 )
Net cash used in investing activities	(363,520 )	(103,442 )	(29,462 )
Cash flows from financing activities:			
Net proceeds from sales of equity	26,462,810	10,464,203	7,980,375
Proceeds from employee stock purchases	104,010	78,574	82,536
Financing of property and equipment	(53,297 )	(38,744 )	(28,063 )
Payments of series A convertible preferred stock dividends	—	(592,875 )	(790,500 )
Payments of long-term debt	(555,556 )	(100,000 )	—
Debt issuance costs	(177,802 )	—	—
Proceeds from issuance of long-term debt	10,000,000	—	—
Payments of convertible notes	(10,000,000 )	—	—
Net cash provided by financing activities	25,780,165	9,811,158	7,244,348
Net increase (decrease) in cash and cash equivalents	5,883,700	10,720,318	(9,034,025 )
Cash and cash equivalents, beginning of year	21,468,269	10,747,951	19,781,976
Cash and cash equivalents, end of year	\$27,351,969	\$21,468,269	\$10,747,951
Supplemental cash flow information:			
Cash paid for interest	\$579,650	\$1,573,554	\$12,458
Non-cash investing and financing activities:			
Issuance of senior secured convertible notes as payment in-kind for interest	\$—	\$1,499,981	\$2,829,105

Edgar Filing: AGENUS INC - Form 10-K

Convertible note adjustment to equity for conversion option	—	—	5,580,124
Reclassification of derivative liability into equity	—	—	755,000
Long-term debt—equipment financing	—	—	171,640
Issuance of common stock, \$0.01 par value, as payment of long-term debt including accrued and unpaid interest	11,275,000	—	—
Deemed dividend on Series A convertible preferred stock	2,906,664	—	—
Contingent royalty consideration	19,090,658	—	—
Elimination of non-controlling interest	5,580,124	—	—
See accompanying notes to consolidated financial statements.			

56

---

Table of Contents

AGENUS INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Description of Business

Agenu s Inc. (including its subsidiaries, also referred to as "Agenu s," the "Company," "we," "us," and "our") is a biopharmaceutical company developing a portfolio of immuno-oncology candidates, including heat shock protein vaccines and adjuvants. We are focused on immunotherapeutic products based on our core platform technologies with multiple product candidates advancing through the clinic, including several product candidates that have advanced into late-stage clinical trials through corporate partners. We assess the development, commercialization and/or partnering strategies with respect to each of our internal product candidates periodically based on several factors, including clinical trial results, competitive positioning, and funding requirements and resources.

Our core technology portfolio consists of our Heat Shock Protein ("HSP") Platform (based on our HSP technologies), and our Saponin Platform (based on our saponin adjuvant technologies). Within our HSP Platform we are developing our Prophage Series cancer vaccines and our Recombinant Series. In our Prophage Series we have tested product candidates in Phase 3 clinical trials for the treatment of renal cell carcinoma ("RCC"), the most common type of kidney cancer, and for metastatic melanoma, as well as in Phase 1 and Phase 2 clinical trials in a range of indications.

Prophage Series vaccine R-100 is registered for use in Russia for the treatment of RCC in patients at intermediate risk of recurrence as Oncophage® vaccine. Phase 2 trials are fully enrolled in the United States testing the Prophage Series vaccine candidates G-100 and G-200 in newly diagnosed and recurrent glioma, respectively. In addition, the Cancer Therapy Evaluation Program of the National Cancer Institute (NCI) opened patient enrollment in 2013 for a 222-patient, multi-center, randomized Phase 2 trial of Prophage Series vaccine G-200 in combination with Avastin® (bevacizumab) in patients with surgically resectable recurrent glioma. HerpV, a therapeutic vaccine candidate from the Recombinant Series which contains QS-21 Stimulon, has been tested in a Phase 1 clinical trial for the treatment of genital herpes and is now in a Phase 2 trial. Within our Saponin Platform is QS-21 Stimulon® adjuvant, or QS-21 Stimulon, which is used by our licensees in numerous vaccines under development in trials, some as advanced as Phase 3, for a variety of diseases, including cancer, shingles, malaria, Alzheimer's disease, human immunodeficiency virus, and tuberculosis.

Our business activities have included 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.

We have incurred significant losses since our inception. As of December 31, 2013, we had an accumulated deficit of \$649.1 million. Since our inception, we have financed our operations primarily through the sale of equity and convertible notes, and interest income earned on cash, cash equivalents, and short-term investment balances. We believe that, based on our current plans and activities, our cash balance of \$27.4 million as of December 31, 2013, plus the net proceeds from our equity offering in February 2014 of approximately \$56.0 million (see Note 17), along with the estimated additional proceeds from our license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements through the first half of 2015. We continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be feasible, restrict capital expenditures and/or reduce the scale of our operations.

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 HerpV is in a Phase 2 trial and the development of our Prophage Series vaccines is subject to further evaluation and uncertainty, we are unable to reliably estimate the cost of completing research and development programs, the timing of bringing such programs to various markets, and, therefore, are unable to determine when, if ever, material cash inflows from operating activities are likely to commence. We will continue to adjust other spending as needed in order to preserve liquidity.

As of December 31, 2013, we had debt outstanding of \$9.6 million in principal (payments of approximately \$278,000 are due monthly ending April 2015 with an additional \$5.0 million due in April 2015). In April 2013, we exchanged our \$39.0 million 8% senior secured convertible notes due August 2014 (the "2006 Notes") including accrued and unpaid interest, for \$10 million in cash, 2,500,000 shares of our common stock, and a revenue interest in certain QS-21 Stimulon partnered programs

Table of Contents

and HerpV. The cash portion of this exchange was financed through the issuance of new debt (see Note 12 for further detail). This exchange resulted in the elimination of \$5.6 million of non-controlling interest and a loss on extinguishment of \$3.3 million.

(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 wholly-owned subsidiaries. All significant intercompany transactions and accounts have been eliminated in consolidation. Certain prior period amounts have been retrospectively adjusted in order to conform to the current period's presentation.

(b) Segment Information

We are managed and operated as one business. The entire business is managed by a single executive operating committee that reports to the chief executive officer. We do not operate separate lines of business with respect to any of our product candidates. Accordingly, we do not prepare discrete financial information with respect to separate product areas or by location and do not have separately reportable segments as defined by Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 280, Segment Reporting.

(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) Investments

We classify investments in marketable securities at the time of purchase.

(f) 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 and cash equivalents 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.

(g) Inventories

Inventories are stated at the lower of cost or market. Cost has been determined using standard costs that approximate the first-in, first-out method. Inventory as of December 31, 2012 consisted solely of finished goods.

(h) Plant and Equipment

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 \$586,000, \$1.6 million, and \$2.2 million, for the years ended December 31, 2013, 2012, and 2011, respectively.

(i) Fair Value of Financial Instruments

The estimated fair values of all of our financial instruments, excluding debt, 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, is \$9.6 million and \$39.0 million at December 31, 2013 and 2012, respectively.

(j) Revenue Recognition



Table of Contents

Revenue for services under research and development contracts are recognized as the services are performed, or as clinical trial materials are provided. Non-refundable milestone payments that represent the completion of a separate earnings process are recognized as revenue when earned. License fees and royalties are recognized as they are earned. Revenue recognized from collaborative agreements is based upon the provisions of ASC 605-25, Revenue Recognition – Multiple-Element Arrangements, as amended by Accounting Standards Update 2009-13. Product revenue is recognized as product is shipped. For the years ended December 31, 2013, 2012, and 2011, 44%, 49%, and 48%, respectively, of our revenue was earned from one research partner. In addition, 40%, and 43% of our revenue for the years ended December 31, 2012 and 2011, respectively, was earned from one of our licensees and 47% and 9% of our revenue for the years ended December 31, 2013 and 2012, respectively, was earned from one service customer. The revenues from the licensee did not continue past 2012 and the revenue from the service customer will not continue past 2013.

**(k) Foreign Currency Transactions**

Gains and losses from our euro based currency accounts and foreign currency 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. We do not currently use derivative financial instruments to manage the risks associated with foreign currency fluctuations. We recorded foreign currency losses of \$9,000, \$11,000, and \$9,000, for the years ended December 31, 2013, 2012, and 2011, respectively. Such losses are included as a component of operating expenses.

**(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 and ASC 505-50, Equity-Based Payments to Non-Employees. Share-based compensation expense is recognized based on the estimated grant date fair value, and is recognized net of an estimated forfeiture rate such that we recognize compensation cost for those shares expected to vest. Compensation cost is recognized on a straight-line basis over the requisite service period of the award. See Note 8 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 recorded when they more likely than not are 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, nonvested 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, 2013, 2012, and 2011, as they would be anti-dilutive:

Table of Contents

	At December 31,		
	2013	2012	2011
Warrants	3,280,396	3,309,378	3,309,378
Stock options	4,163,100	2,748,883	1,814,161
Nonvested shares	147,274	249,968	135,791
Convertible preferred stock	333,333	333,333	333,333

(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 our fair value to our net book value to determine if there is an indicator of impairment. Our fair value is based on our quoted market price of our common stock to derive the market capitalization as of the date of the impairment test. ASC 350, "Intangibles, Goodwill and Other" states that if the carrying value of the 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.

(q) Accounting for Asset Retirement Obligations

We record the fair value of an asset retirement obligation as a liability in the period in which we incur a legal obligation associated with the retirement of tangible long-lived assets that result from the acquisition, construction, development, and/or normal use of the assets. A legal obligation is a liability that a party is required to settle as a result of an existing or enacted law, statute, ordinance, or contract. We are also required to record a corresponding asset that is depreciated over the life of the asset. Subsequent to the initial measurement of the asset retirement obligation, the obligation will be adjusted at the end of each period to reflect the passage of time (accretion) and changes in the estimated future cash flows underlying the obligation. Changes in the liability due to accretion are charged to the consolidated statement of operations, whereas changes due to the timing or amount of cash flows are an adjustment to the carrying amount of the related asset. Our asset retirement obligations primarily relate to the expiration of our facility lease and anticipated costs to be incurred based on our lease terms.

(r) Long-lived Assets

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. 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) Recent Accounting Pronouncements

In February 2013, the FASB issued Accounting Standards Update No. 2013-02, "Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income", ("ASU 2013-02"). ASU 2013-02 requires entities to disclose items reclassified out of Accumulated Other Comprehensive Income ("AOCI") and into net income in their entirety, the effect of the reclassification on each affected net income line item, and, for AOCI reclassification items that are not reclassified in their entirety into net income, a cross reference to other required U.S. GAAP disclosures. This consolidated standard is effective for annual periods beginning after December 31, 2012 and interim periods within those years. The application of this standard did not have a material impact on our consolidated financial statements. In July 2013, the FASB issued Accounting Standards Update No. 2013-11, "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists", ("ASU 2013-11"). ASU 2013-11 amends ASC 740, "Income Taxes", by providing guidance on the financial statement presentation of an unrecognized benefit when a net operating loss carryforward, a similar tax loss, or a tax credit

carryforward exists. ASU 2013-11 does not affect the recognition or measurement of uncertain tax positions under ASC 740. ASU 2013-11 will be effective for interim and annual periods beginning after December 15, 2013, with early adoption permitted. We do not expect the adoption of ASU 2013-11 to have any impact on our consolidated financial statements.

(3) Investments

60

---

Table of Contents

## Cash Equivalents and Short-term Investments

Cash equivalents and short-term investments consisted solely of institutional money market funds with cost approximating the estimated fair value as of December 31, 2013 and 2012.

Proceeds from maturities of available-for-sale securities amounted to \$5.0 million for the year ended December 31, 2011. Gross realized gains and gross realized losses included in net loss as a result of those maturities were immaterial. No available-for-sale securities were sold before their maturity in 2011. As a result of the short-term nature of our investments, there were no unrealized holding gains or losses as of December 31, 2013 and 2012.

## (4) Plant and Equipment

Plant and equipment as of December 31, 2013 and 2012 consists of the following (in thousands).

	2013	2012	Estimated Depreciable Lives
Furniture, fixtures, and other	\$ 1,698	\$ 1,662	3 to 10 years
Laboratory and manufacturing equipment	4,532	4,545	4 to 10 years
Leasehold improvements	18,412	18,026	2 to 12 years
Software and computer equipment	5,780	5,778	3 years
	30,422	30,011	
Less accumulated depreciation and amortization	(27,637	) (27,405	)
	\$2,785	\$2,606	

During the years ended December 31, 2013 and 2012, plant and equipment with a net book value of approximately \$59,000 and \$11,000, respectively, was retired from service and disposed. During the year ended December 31, 2012, we extended the lease of our facility in Lexington, MA as allowed in our lease agreement and accordingly extended the amortization period related to the existing leasehold improvements.

## (5) Income Taxes

We are subject to taxation in the U.S. and various state, local, and foreign jurisdictions. We remain subject to examination by U.S. Federal, state, local, and foreign tax authorities for tax years 2010 through 2013. 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 2009 and prior. However, net operating losses from the tax year 2009 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, 2013, we have available net operating loss carryforwards of \$515.8 million and \$63.9 million for Federal and state income tax purposes, respectively, which are available to offset future Federal and state taxable income, if any, and expire between 2014 and 2033. 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 \$8.9 million and \$7.1 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 2014 and 2033 and 2017 and 2028, respectively. 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, 2013 and 2012 are presented below (in thousands).

Table of Contents

	2013	2012
Deferred tax assets:		
Net operating loss carryforwards	\$177,589	\$178,966
Research and development tax credits	13,674	12,747
Contingent royalty obligation	7,384	—
Other	14,230	12,606
Total deferred tax assets	212,877	204,319
Less: valuation allowance	(212,577)	(203,016)
Net deferred tax assets	300	1,303
Deferred tax liabilities	(300)	(1,303)
Net deferred tax	\$—	\$—

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 \$9.6 million and \$2.9 million during the years ended December 31, 2013 and 2012, respectively. The net operating loss includes amounts pertaining to tax deductions relating to stock exercises for which any subsequently recognized tax benefit will be recorded as an increase to additional paid-in capital.

Income tax benefit was nil for each of the years ended December 31, 2013, 2012, and 2011, and differed from the amounts computed by applying the U.S. Federal income tax rate of 34% to loss before income taxes as a result of the following (in thousands).

	2013	2012	2011
Computed “expected” Federal tax benefit	\$(10,225)	\$(3,850)	\$(7,912)
(Increase) reduction in income taxes benefit resulting from:			
Change in valuation allowance	9,561	2,944	5,033
Increase due to uncertain tax positions	102	26	59
State and local income benefit, net of Federal income tax benefit	(1,359)	(581)	(1,182)
Net operating loss expirations	1,778	821	1,979
Increase due to debt discount adjustment	—	—	2,192
Other, net	143	640	(169)
	\$—	\$—	\$—

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

Balance, December 31, 2012	\$5,533
Increase related to current year positions	78
Increase related to previously recognized positions	38
Balance, December 31, 2013	\$5,649

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.



Table of Contents

## (6) Accrued Liabilities

Accrued liabilities consist of the following as of December 31, 2013 and 2012 (in thousands):

	2013	2012
Professional fees	\$1,121	\$919
Payroll	1,635	592
Clinical trials	1,021	291
Other	438	366
	\$4,215	\$2,168

## (7) Equity

Effective June 15, 2012, our certificate of incorporation was amended to decrease our authorized capital stock from 250,000,000 shares to 70,000,000 shares of common stock, \$0.01 par value per share, and from 25,000,000 shares to 5,000,000 shares of preferred stock, \$0.01 par value per share. Our Board of Directors is authorized to issue the preferred stock and to set the voting, conversion, and other rights.

In a private placement in September 2003, we sold 31,620 shares of our series A convertible preferred stock, par value \$0.01 per share, ("Series A Preferred Stock") for net proceeds of \$31.6 million. In February 2013, we entered into a Securities Exchange Agreement (the "Exchange Agreement") with the holder of our Series A Preferred Stock pursuant to which the holder exchanged all 31,620 of the outstanding shares of our Series A Preferred Stock for an equivalent number of shares of our Series A-1 Preferred Stock to be issued by us. The terms of the Series A-1 Preferred Stock are materially identical to the Series A Preferred Stock, except that the Series A-1 Preferred Stock accrues a 0.63% annual dividend, as compared to a 2.5% annual dividend for the Series A Preferred Stock. In exchange for this reduction in dividend obligations, we issued to the holder 666,666 shares of our common stock. After giving effect to the transactions contemplated by the Exchange Agreement, no shares of Series A Preferred Stock remain outstanding.

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, on or after September 24, 2013. The Certificate of Designation does not contemplate a sinking fund. The Series A-1 Preferred Stock ranks senior to our common stock. In a liquidation, dissolution, or winding up of the Company, the Series A-1 Preferred Stock's liquidation preference must be fully satisfied before any distribution could be made to the holders of the common stock. Other than in such a liquidation, no terms of the Series A-1 Preferred Stock affect our ability to declare or pay dividends on our common stock as long as the Series A-1 Preferred Stock's dividends are accruing. The liquidation value of this Series A-1 Preferred stock is equal to \$1,000 per share outstanding plus any accrued unpaid dividends. Dividends in arrears with respect to the Series A-1 Preferred Stock were approximately \$650,000 or \$20.56 per share, at December 31, 2013, and dividends in arrears with respect to the Series A Preferred Stock were approximately \$396,000, or \$12.54 per share, at December 31, 2012.

In September 2007, we issued 270,562 shares of our common stock at a price of \$18.48 per share to a single institutional investor. In conjunction with this transaction, we also issued to the investor 10,000 shares of our new series B1 convertible preferred stock and 5,250 shares of our new series B2 convertible preferred stock. All shares of the series B1 convertible preferred stock have been converted. Shares of the series B2 convertible preferred stock permit the investor to purchase common shares for consideration of up to 35 percent of the total dollar amount previously invested pursuant to the agreement with the investor, including conversions of the series B1 convertible preferred stock, at a purchase price equal to the lesser of \$24.96 per common share or a price calculated based on the then-prevailing price of our common stock, and such right expires seven years from the date of issuance. In April 2009, we issued 988,202 shares of our common stock upon conversion of 2,145 shares of our series B2 convertible preferred stock via cashless conversions. Upon completion of the conversions, 3,105 shares of our series B2 convertible preferred stock are still outstanding although no further shares can be converted into shares of common stock (other than in the event of a change of control) as the maximum number of shares (as defined in the agreement) have been issued. The total number of shares of common stock issued or issuable to the holder of the class B convertible preferred stock cannot exceed 19.9% of our outstanding common stock. No dividends are paid on the class

B convertible preferred stock and there are no liquidation preferences.

In January 2008, we entered into a private placement agreement (the “January 2008 private placement”) pursuant to which we sold 1,451,450 shares of common stock for \$18.00 for each share sold. Investors also received (i) 10-year warrants to

63

---



Table of Contents

purchase, at an exercise price of \$18.00 per share, up to 1,451,450 shares of common stock and (ii) unit warrants to purchase, at an exercise price of \$18.00 per unit, contingent upon a triggering event as defined in the January 2008 private placement documents, (a) up to 1,451,450 shares of common stock and (b) additional 10-year warrants to purchase, at an exercise price of \$18.00 per share, up to 1,451,450 additional shares of common stock. In accordance with the terms of the January 2008 private placement, the 10-year warrants became exercisable for a period of 9.5 years as of July 9, 2008. Our private placement in April 2008 qualified as a triggering event, and therefore the unit warrants became exercisable for a period of eighteen months as of July 9, 2008. The unit warrants expired unexercised in January 2010. In February 2008, we filed a registration statement covering the resale of the 1,451,450 shares of common stock issued and the 1,451,450 shares issuable upon the exercise of the 10-year warrants issued in the January 2008 private placement. The Securities and Exchange Commission (the "SEC") declared the resale registration statement effective on February 14, 2008.

In April 2008, we entered into a private placement agreement (the "April 2008 private placement") under which we sold (i) 1,166,666 shares of common stock and (ii) five-year warrants to acquire up to 1,166,666 shares of common stock at an exercise price of \$22.50 per share, for \$18.00 for each share and warrant sold. The warrants became exercisable for a period of 4.5 years as of October 10, 2008. In April 2008, we filed a registration statement covering the resale of the 1,166,666 shares of common stock issued and the 1,166,666 shares issuable upon the exercise of the related warrants issued in the April 2008 private placement. The SEC declared the resale registration statement effective on May 7, 2008. These warrants expired unexercised April 2013.

In July 2009, we entered into a private placement agreement under which we issued and sold (i) 833,333 shares of our common stock, (ii) six-month warrants to purchase up to 416,666 additional shares of common stock at an exercise price of \$12.00 per share, and (iii) four-year warrants to purchase up to 362,316 additional shares of common stock at an exercise price of \$13.80 per share, for \$12.00 for each share sold generating gross proceeds of \$10.0 million. The six-month and four-year warrants expired unexercised in January 2010 and October 2013, respectively. Subsequently, we filed, and the SEC declared effective, a registration statement covering the resale of the 833,333 shares of common stock issued and the 778,982 shares issuable upon the exercise of the related warrants issued in this private placement. In August 2009, we entered into a private placement agreement under which we issued and sold (i) 730,994 shares of our common stock, (ii) six-month warrants to purchase up to 365,495 additional shares of common stock at an exercise price of \$13.86 per share, and (iii) four-year warrants to purchase up to 328,946 additional shares of common stock at an exercise price of \$15.00 per share, for \$13.68 for each share sold generating gross proceeds of \$10.0 million. The warrants were not exercisable for the first six months following the closing, which occurred on August 4, 2009. The six-month warrants expired unexercised in July 2010. Subsequently, we filed, and the SEC declared effective, a registration statement covering the resale of the 730,994 shares of our common stock issued and the 694,441 shares issuable upon the exercise of the related warrants issued in this private placement.

As part of all private placement agreements, we agreed to register the shares of common stock and the shares of common stock underlying the warrants (with the exception of the unit warrants from the January 2008 private placement) issued to the investors with the SEC within contractually specified time periods. As noted above, we filed registration statements covering all required shares.

In December 2010, we entered into subscription agreements under which we issued and sold 2,552,492 shares of our common stock for the aggregate purchase price of \$7.5 million. Additionally, within 90 calendar days of the date of the subscription agreements, the investors had the right and option to purchase up to an additional 106,648 shares of our common stock for the aggregate purchase price of up to \$575,901. In March 2011, we issued and sold 88,333 shares based on the exercise of a purchase option and received net proceeds of \$477,000. The offering and sale of these common shares were made under an effective shelf registration statement.

During August 2011, we issued and sold 2,287,581 shares of our common stock in an underwritten offering. Net proceeds after deducting offering expenses were approximately \$6.3 million. These shares were issued pursuant to a shelf registration statement on Form S-3 filed with the SEC on January 22, 2010.

During the year ended December 31, 2011, we issued approximately 265,000 shares of our common stock under an At the Market Sales Agreement through our sales agents, McNicoll, Lewis & Vlak LLC and Wm Smith & Co. ("Sales Agent") and raised net proceeds of approximately \$1.2 million, after deducting offering costs of approximately

\$38,000. These offerings were made under effective shelf registration statements and proceeds from the offering were used for general corporate purposes.

During the quarter ended March 31, 2012, we terminated our existing At Market Issuance Sales Agreement with the Sales Agent, (the "Old ATM Program"), and entered into a new At Market Issuance Sales Agreement with MLV & Co. LLC, ("MLV") as sales agent, under which we may sell from time to time up to five million shares of our common stock (the "New ATM

Table of Contents

Program”). In December 2012, we entered into an Amended and Restated At Market Sales Issuance Agreement with MLV to increase the number of shares of common stock available for offer and sale under the New ATM Program to an aggregate of ten million shares.

During the year ended December 31, 2012, we sold an aggregate of approximately 952,000 shares of our common stock in at the market offerings under the Old ATM Program and received net proceeds of approximately \$2.8 million after deducting offering costs of approximately \$87,000, and an aggregate of approximately 1.5 million shares of our common stock in at the market offerings under the New ATM Program and received net proceeds of approximately \$7.7 million after deducting offering costs of approximately \$244,000. During the year ended December 31, 2013, we sold an aggregate of approximately 4.8 million shares of our common stock in at the market offerings under the New ATM Program and received net proceeds of approximately \$17.0 million after deducting offering costs of approximately \$499,000. These offerings were made under effective shelf registration statements and proceeds from the offerings will be used for general corporate purposes.

During September 2013, we sold approximately 3,333,000 shares of the 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 will be exercisable beginning six 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.

#### (8) 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, nonvested (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, nonvested (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, which we refer to collectively as Awards, for up to 4.2 million shares of our common stock (subject to adjustment in the event of stock splits and other similar events). On March 7, 2013, our Board of Directors adopted, and on June 12, 2013, our stockholders approved, an amendment to the 2009 EIP increasing shares available for award under the plan to 6.2 million. The Board of Directors appointed the Compensation Committee to administer the 1999 EIP and the 2009 EIP. No awards will be granted under the 2009 EIP after June 10, 2019.

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 are currently 166,666 shares of common stock reserved for issuance under the 2009 ESPP. Rights to purchase common stock under the 2009 ESPP are granted at the discretion of the Compensation Committee, which determines the frequency and duration of individual offerings under the plan and the dates when stock may be purchased. Eligible employees participate voluntarily and may withdraw from any offering at any time before the stock is purchased. Participation terminates automatically upon termination of employment. The purchase price per share of common stock in an offering is 85% of the lesser of its fair value at the beginning of the offering period or on the applicable exercise date and may be 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 acquire more than 3,333 shares of stock in any offering period. No participant is allowed to purchase shares under the 2009 ESPP if such employee would own or would be deemed to own stock possessing 5% or more of the total combined voting power or value of the Company.

No offerings will be made under the 2009 ESPP after June 10, 2019.

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 225,000 shares of our common stock reserved for issuance under this plan. As of December 31, 2013, 48,971 shares have 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

Table of Contents

conversion date as reported by The Nasdaq Capital Market. Pursuant to this plan, a total of 179,947 units, each representing a share of our common stock at a weighted average common stock price of \$6.28, have been credited to participants' stock accounts as of December 31, 2013. The compensation charges for this plan were immaterial for all periods presented.

We 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 non-cash charge to operations for the non-employee options with vesting or other performance criteria is affected each reporting period, until the non-employee options vest, by changes in the fair value of our common stock.

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

	2013		2012		2011	
Expected volatility	87	%	96	%	103	%
Expected term in years	6		6		6	
Risk-free interest rate	1.5	%	0.9	%	1.6	%
Dividend yield	—	%	—	%	—	%

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 2013 is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2012	2,748,883	\$7.07		
Granted	1,482,800	3.40		
Exercised	(4,503)	) 3.36		
Forfeited	(47,386)	) 9.86		
Expired	(16,694)	) 10.91		
Outstanding at December 31, 2013	4,163,100	\$5.72	7.70	\$2,324
Vested or expected to vest at December 31, 2013	3,946,623	\$5.82	7.70	\$2,138
Exercisable at December 31, 2013	2,195,726	\$7.33	6.50	\$1,396

The weighted average grant-date fair values of options granted during the years ended December 31, 2013, 2012, and 2011, was \$2.42, \$3.94, and \$3.61, respectively.

The aggregate intrinsic value in the table above represents the difference between our closing stock price on the last trading day of fiscal 2013 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, 2013 (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, 2013, 2012, and 2011, determined on the dates of exercise, was \$5,000, \$12,000, and \$0, respectively. During 2013, 2012, and 2011, all options were granted with exercise prices equal to the market value of the underlying shares of common stock on the grant date.

As of December 31, 2013, there was \$4.3 million of total unrecognized compensation cost, \$793,000 of which pertains to performance awards for which performance has not yet been achieved, related to stock options granted to employees and directors expected to be recognized over a weighted average period of 2.0 years.

Table of Contents

As of December 31, 2013, unrecognized expense for options granted to outside advisors for which performance (vesting) has not yet been completed but the exercise price of the option is known is \$15,000. Such amount is subject to change each reporting period based upon changes in the fair value of our common stock, expected volatility, and the risk-free interest rate, until the outside advisor completes his or her performance under the option agreement. Certain employees and consultants have been granted nonvested stock. The fair value of nonvested stock is calculated based on the closing sale price of our common stock on the date of issuance.

A summary of nonvested stock activity for 2013 is presented below:

	Nonvested Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2012	249,968	\$5.38
Granted	237,552	3.70
Vested	(339,800 )	4.73
Forfeited	(446 )	6.30
Outstanding at December 31, 2013	147,274	3.99

As of December 31, 2013, there was \$346,000 of unrecognized share-based compensation expense related to these nonvested shares. The remaining cost is expected to be recognized over a weighted average period of 2.6 years. The total intrinsic value of shares vested during the years ended December 31, 2013, 2012, and 2011, was \$1.6 million, \$2.1 million, and \$330,000, respectively.

Cash received from option exercises and purchases under our 2009 ESPP for the years ended December 31, 2013, 2012, and 2011, was \$104,000, \$79,000, and \$83,000, respectively. We issue new shares upon option exercises, purchases under our 2009 ESPP, vesting of nonvested stock, and under the Director's Deferred Compensation Plan. During the years ended December 31, 2013, 2012, and 2011, 26,758 shares, 28,859 shares, and 20,524 shares, were issued under the 2009 ESPP, respectively. During the years ended December 31, 2013, 2012, and 2011, 339,800 shares, 523,210 shares and 165,586 shares, respectively were issued as a result of the vesting of nonvested stock. The impact on our results of operations from share-based compensation for the years ended December 31, 2013, 2012, and 2011, was as follows (in thousands).

	2013	2012	2011
Research and development	\$1,147	\$1,138	\$765
General and administrative	2,981	3,166	1,882
Total share-based compensation expense	\$4,128	\$4,304	\$2,647

(9) License, Research, and Other Agreements

In November 1994, we entered into a patent license agreement with the Mount Sinai School of Medicine, or Mount Sinai (the "Mount Sinai Agreement"). Through the Mount Sinai Agreement, we obtained an exclusive worldwide license to patent rights relating to the heat shock protein technology that resulted from the research and development performed by our founding scientist. We agreed to pay Mount Sinai a royalty on the net sales of products covered by the licensed patent rights and also provided Mount Sinai with a 0.45% equity interest in the Company (approximately 10,000 shares valued at \$90,000 at the time of issuance). The term of the Mount Sinai Agreement ends when the last of the licensed patents expires (2016) or becomes no longer valid. If we fail to pay royalties that are due under the agreement, Mount Sinai may issue written notice to us. If we continue to fail to pay royalties after 60 days from receipt of the written notice, Mount Sinai can terminate the agreement. The Mount Sinai Agreement requires us to use due diligence to make the products covered by the licensed patent rights commercially available, including a requirement for us to use best efforts to reach a number of developmental milestones which have been achieved. If we fail to comply with the due diligence provisions of the agreement, Mount Sinai could take actions to convert our exclusive license to a non-exclusive license after six months written notice. The Mount Sinai Agreement does not

contain any milestone payment provisions.

During 1995, our founding scientist moved his research to Fordham University (“Fordham”). We entered into a sponsored research and technology license agreement with Fordham (the “Fordham Agreement”) in March 1995 relating to the continued development of the heat shock protein technology and agreed to make payments to Fordham to sponsor research.

67

---



Table of Contents

Through the Fordham Agreement, we obtained an exclusive, perpetual, worldwide license to all of the intellectual property, including all the patent rights which resulted from such research and development performed at Fordham. We also agreed to pay Fordham a royalty on the net sales of products covered by the Fordham Agreement through the last expiration date on the patents under the agreement (2018) or when the patents become no longer valid. The agreement does not contain any milestone payment provisions or any diligence provisions. During 1997, research was moved to the University of Connecticut Health Center (“UConn”) and accordingly, the parts of the agreement related to payments for sponsored research at Fordham terminated in mid-1997. During the term of the agreement, we paid \$2.4 million to Fordham.

In May 2001, we entered into a license agreement with UConn which was amended in March 2003 and June 2009. Through the license agreement, we obtained an exclusive license to patent rights resulting from inventions discovered under a research agreement that was effective from February 1998 until December 2006. The term of the license agreement ends when the last of the licensed patents expires (2024) or becomes no longer valid. UConn may terminate the agreement: (1) if, after 30 days written notice for breach, we continue to fail to make any payments due under the license agreement, or (2) we cease to carry on our business related to the patent rights or if we initiate or conduct actions in order to declare bankruptcy. We may terminate the agreement upon 90 days written notice. We are still required to make royalty payments on any obligations created prior to the effective date of termination of the license agreement. Upon expiration or termination of the license agreement due to breach, we have the right to continue to manufacture and sell products covered under the license agreement which are considered to be works in progress for a period of 6 months. The license agreement contains aggregate milestone payments of \$1.2 million for each product we develop covered by the licensed patent rights. These milestone payments are contingent upon regulatory filings, regulatory approvals and commercial sales of products. We have also agreed to pay UConn a royalty on the net sales of products covered by the license agreement as well as annual license maintenance fees beginning in May 2006. Royalties otherwise due on the net sales of products covered by the license agreement may be credited against the annual license maintenance fee obligations. As of December 31, 2013, we have paid \$535,000 to UConn under the license agreement. The license agreement gives us complete discretion over the commercialization of products covered by the licensed patent rights, but also requires us to use commercially reasonable diligent efforts to introduce commercial products within and outside the United States. If we fail to meet these diligence requirements, UConn may be able to terminate the license agreement.

In March 2003, we entered into an amendment agreement that amended certain provisions of the license agreement. The amendment agreement granted us a license to additional patent rights. In consideration for execution of the amendment agreement, we agreed to pay UConn an upfront payment and to make future payments for licensed patents or patent applications. Through December 31, 2013, we have paid approximately \$100,000 to UConn under the license agreement, as amended.

In December 2011, we signed a license, development and manufacturing technology transfer agreement (“NewVac Agreement”) for Oncophage with NewVac LLC (a subsidiary of ChemRar Ventures LLC, “NewVac”), a company focused on the development of innovative technology for cancer immunotherapy. Under the NewVac Agreement, we granted NewVac an exclusive license to manufacture, market and sell Oncophage as well as pursue a development program in the Russian Federation and certain other CIS countries. The NewVac Agreement may be terminated by either party upon a material breach if the breach is not cured within the time specified in the agreement. The NewVac Agreement may also be terminated by us if certain milestones are not achieved and by NewVac without cause. The NewVac Agreement has an initial term of three years and may be extended under certain terms for a period ending the later of December 2021, or the expiration of the last valid claim of the licensed patent rights, as defined. During the term of the NewVac Agreement we are entitled to receive modest milestone payments in addition to payments for supply of Oncophage and/or royalties in the low double-digits on net sales of Oncophage. Upon termination of the NewVac Agreement, all activity under the agreement immediately ceases.

We have entered into various agreements with institutions and contract research organizations to conduct clinical studies. Under these agreements, subject to the enrollment of patients and performance by the institution of certain services, we have estimated our payments to be \$52.6 million over the term of the studies. For the years ended December 31, 2013, 2012, and 2011, \$2,720,000, \$654,000, and \$623,000, respectively, have been expensed in the

accompanying consolidated statements of operations related to these clinical studies. Through December 31, 2013, \$49.4 million of this estimate has been paid. The timing of our expense recognition and future payments related to these agreements is dependent on the enrollment of patients and documentation received from the institutions.

We have various comprehensive agreements with collaborative partners that allow for the use of QS-21 Stimulon, an investigational adjuvant used in numerous vaccines under development for a variety of diseases including, but not limited to, hepatitis, HIV, influenza, cancer, Alzheimer's disease, malaria, and tuberculosis. These agreements grant exclusive worldwide rights in some fields of use, and co-exclusive or non-exclusive rights in others. The agreements call for royalties to be paid to us by the collaborative partner on the future sales of licensed vaccines that include QS-21 Stimulon.

Table of Contents

In July 2006, we entered into a license agreement and a supply agreement with GlaxoSmithKline ("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. 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 the Company or certain of our assets. The first right to negotiate will expire after five years. 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. We sometimes refer to the GSK License Agreement, the Amended GSK Supply Agreement and the GSK First Right to Negotiate Agreement, from time to time as the "GSK Agreements". As of December 31, 2013, we have received \$21.3 million of a potential \$24.3 million in upfront and milestone payments related to the GSK Agreements. We are generally entitled to receive low single-digit royalties on net sales for a period of 7-10 years after the first commercial sale of a resulting GSK product. 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 milestone payment obligations survive termination or expiration of the GSK Agreements for any reason, and 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.

During each of the years ended December 31, 2013, 2012, and 2011, we recognized revenue of \$1.3 million related to payments received under our GSK License and Amended GSK Supply Agreements. As we have no future service obligation under the GSK First Right to Negotiate Agreement, we recognized \$6.5 million in revenue during the year ended December 31, 2012. Deferred revenue of \$3.8 million related to the GSK Agreements is included in deferred revenue on our consolidated balance sheet as of December 31, 2013.

Elan Pharmaceuticals, Inc. and/or its affiliates ("Elan") had a commercial license for the use of QS-21 Stimulon in the research and commercialization of Elan's Alzheimer's disease vaccine candidate that contains QS-21 Stimulon ("JANSSEN Product"). Effective September 14, 2009, we entered into an Amended and Restated License Agreement with Elan, which was assigned by Elan to JANSSEN AI on September 17, 2009 (the "JANSSEN AI License Agreement"). Under the terms of the JANSSEN AI License Agreement, JANSSEN AI has the right to develop, make, have made, use, sell, offer for sale, import, and have sold, the JANSSEN Product. In addition, pursuant to the terms of the JANSSEN AI License Agreement, JANSSEN AI has the right to manufacture all of its requirements of QS-21 Stimulon for use in the JANSSEN Product. We have no further supply obligations to JANSSEN AI. If all benchmarks are met under the JANSSEN AI License Agreement, we could receive up to \$11.5 million in future milestone payments; \$1.5 million has been received as of December 31, 2013. Furthermore, under the terms of the JANSSEN AI License Agreement, we are entitled to receive mid-single-digit royalties on net sales of the JANSSEN Product for a period of at least 10 years after the first commercial sale of such product, if any. Expiration or termination of the JANSSEN AI License Agreement is without prejudice to any rights that accrued to the benefit of the parties prior to the date of such expiration or termination. Upon expiration of the JANSSEN AI License Agreement, JANSSEN AI will have a royalty-free license. JANSSEN may terminate the JANSSEN AI License Agreement by giving us written notice. If a material breach is not cured within the time specified in the JANSSEN AI License Agreement, either party may terminate. Upon early termination of the JANSSEN AI License Agreement, JANSSEN AI's license rights terminate and future payment obligations do not accrue. The termination or expiration of the JANSSEN AI License Agreement will not relieve either party from any obligation which accrued prior to the termination or expiration. However, in the event that JANSSEN elects an early termination of the JANSSEN AI License Agreement, all rights to

know-how, manufacturing technology and patents covered under the JANSSEN AI License Agreement will revert back to us. Deferred revenue of \$797,000 related to the JANSSEN AI License Agreement is included in deferred revenue on our consolidated balance sheet as of December 31, 2013.

During March 2012, we received \$6.25 million through an amended license of non-core technologies with an existing licensee. This amendment converted the license grant from non-exclusive to exclusive and enabled the licensee to buy-out the current royalty stream structure. As we have no future service obligation under this agreement, we recognized the \$6.25 million in revenue during the year ended December 31, 2012.

(10) Certain Related Party Transactions

On January 9, 2008, we entered into the January 2008 private placement that included (i) 1,451,450 shares of common stock, (ii) 10-year warrants to acquire up to 1,451,450 shares of common stock at \$18.00 per share, and (iii) unit warrants,

Table of Contents

which, if exercisable due to a triggering event as that term is defined in the applicable warrant, permit a holder to acquire up to 1,451,450 shares of common stock at \$18.00 per share and additional ten-year warrants to acquire up to an additional 1,451,450 shares of common stock at \$18.00 per share. In conjunction with this private placement, we sold 90,341 shares of common stock to Garo H. Armen, Ph.D., our Chairman and Chief Executive Officer (“CEO”), and 194,444 shares of common stock to Armen Partners LP. Garo H. Armen is general partner of Armen Partners LP and owns a controlling interest therein. In addition to the common stock acquired by Garo H. Armen and Armen Partners LP, each acquired an equal number of both warrants and unit warrants. The unit warrants expired unexercised on January 9, 2010.

In April 2011, we entered into an arrangement with Timothy Wright, a member of our Board of Directors, pursuant to which he assisted the company in business development and partnering efforts. As compensation for these services, we awarded him options to purchase 20,501 common shares at an exercise price of \$5.70 per share vesting in six equal monthly installments. The grant date fair value of this award was \$100,000.

In August 2011, we issued and sold 2,287,581 shares of our common stock in an underwritten offering for net proceeds of approximately \$6.3 million. 358,496 of these shares of common stock were issued and sold to our CEO.

(11) Leases

We lease manufacturing, research and development, and office facilities under various long-term lease arrangements. Rent expense (before sublease income) was \$1.6 million, \$1.0 million, and \$1.7 million, for the years ended December 31, 2013, 2012, and 2011, respectively.

We lease a facility in Lexington, Massachusetts for our manufacturing, research and development, and corporate offices. During April 2011, we executed a Fifth Amendment of Lease reducing our occupied space in this facility from approximately 162,000 square feet to approximately 82,000 square feet. During December 2012 we entered into a commercial lease for approximately 5,600 square feet of office space in New York, New York for use as corporate offices.

The future minimum rental payments under our leases of our New York City facility, which expires in 2020, and our Lexington headquarters, which expires in 2023, are as follows (in thousands).

Year ending December 31,	
2014	\$ 1,407
2015	1,447
2016	1,489
2017	1,544
2018	1,600
Thereafter	6,960
Total	\$ 14,447

In connection with the Lexington facility, we maintain a fully collateralized letter of credit of \$1.0 million. No amounts have been drawn on the letter of credit as of December 31, 2013. In addition, for the office space in New York City, we are required to deposit \$204,000 with the landlord as an interest-bearing security deposit pursuant to our obligations under the lease.

We sublet a portion of our facilities and received rental payments of \$481,000, \$399,000, and \$541,000 for the years ended December 31, 2013, 2012, and 2011, respectively. We are contractually entitled to receive rental payments of \$365,000 and \$185,000 in 2014 and 2015, respectively.

(12) Debt

As of December 31, 2013, we have \$9.6 million in principal of debt outstanding: \$9.4 million of notes, \$146,000 of debentures and \$39,000 of equipment financing.

Convertible Notes—2006 Notes

On October 30, 2006 (the “Issuance Date”), we issued \$25.0 million of the 2006 Notes to a group of accredited investors (“Investors”). These 2006 Notes bore interest at 8% (an effective rate of 8.10%) payable semi-annually on December 30

and June 30 in cash or, at our option, in additional notes or a combination thereof and had an original maturity date of August 30,

70

---

Table of Contents

2011. During the years ended December 31, 2012, and 2011, we issued additional 2006 Notes in the amount of \$1.5 million, and \$2.8 million, respectively, as payment for interest due.

On February 23, 2011, we entered into a Ninth Amendment of Rights Agreement (the “Amendment”) to the 2006 Notes. The Amendment extended the maturity date of the 2006 Notes to August 31, 2014, and waived the rights of the note holders to convert the 2006 Notes into our common stock. The Amendment also removed substantially all restrictions on us incurring indebtedness subordinate to the 2006 Notes and substantially all restrictions to issue our common stock. We also agreed to waive our right to prepay these notes in the event that our shares trade at a weighted average price over \$42.00 for a 30-day period.

On April 15, 2013, we entered into a Securities Exchange Agreement (the “Exchange”) with the holders of all of our 2006 Notes which were due August 2014 (outstanding principal of \$39.0 million). The holders exchanged the 2006 Notes, including all accrued interest thereon, for \$10.0 million in cash, 2,500,000 shares of our common stock (for purpose of the Exchange, valued at \$4.51 per share) (the “Shares”), and a contractual right to the proceeds of 20% of our revenue interests from certain QS-21 Stimulon partnered programs and a 0.5% royalty on net sales of HerpV. The rights are governed by a Revenue Interests Assignment Agreement dated as of April 15, 2013 between us and the holders of the 2006 Notes. The rights were valued at \$19.1 million on April 15, 2013, (\$18.8 million at December 31, 2013) based on management's estimate with the assistance of a third party valuation and are reflected in the consolidated balance sheet as contingent royalty consideration. We recorded a loss of \$3.3 million in non-operating (loss) income based on the Exchange and eliminated \$5.6 million of non-controlling interest.

## Notes—2013 Notes

In connection with the Exchange, we entered into a Loan and Security Agreement with Silicon Valley Bank for senior secured debt in the aggregate principal amount of \$5.0 million (the “SVB Loan”). The SVB Loan bears interest at a rate of 6.75% per annum, payable in cash on the first day of each month. Principal payments of approximately \$278,000 are due monthly beginning November 2013 and ending in April 2015. The SVB Loan is secured by a lien against substantially all of our assets and contains a number of restrictions and covenants, including, but not limited to, restrictions and covenants that limit our ability to incur certain additional indebtedness, make certain investments, pay dividends other than dividends required pursuant to pre-existing commitments, make payments on subordinated indebtedness other than regularly scheduled payments of interest, create certain liens, consolidate, merge, sell or otherwise dispose of our assets, and/or change our line of business. The SVB Loan also specifies a number of events of default (some of which are subject to applicable cure periods), including, among other things, covenant defaults, other non-payment defaults, bankruptcy, certain penalties and judgments from a governmental authority, cross-defaults in respect of indebtedness over \$50,000, and insolvency defaults.

Additionally, any material adverse change with respect to us or our subsidiary, Antigenics Inc., constitutes an event of default. Upon the occurrence of an event of default under the SVB Loan, subject to cure periods in certain circumstances, Silicon Valley Bank may declare all amounts outstanding to be immediately due and payable and may foreclose upon our assets that secure the SVB Loan. During the continuance of an event of default which does not accelerate the maturity of the SVB Loan, interest will accrue at a default rate equal to the otherwise applicable rate plus 5%. We may prepay the SVB Loan at any time, in full, subject to certain notice requirements and a prepayment premium equal to 4% of the outstanding principal amount of the SVB Loan.

In addition, in connection with the Exchange, we also entered into a Note Purchase Agreement, dated as of April 15, 2013 with various investors to issue senior subordinated notes (the “Subordinated Notes”) in the aggregate principal amount of \$5.0 million and four year warrants to purchase 500,000 unregistered shares of our common stock at an exercise price of \$4.41 per share. We recorded a debt discount of \$1.1 million based on the relative fair values of the Subordinated Notes and four year warrants. The Subordinated Notes bear interest at a rate of 10% per annum, payable in cash on the first day of each month in arrears and are due April 2015. The Subordinated Notes include default provisions which allow for the acceleration of the principal payment of the 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 Subordinated Notes, default on other indebtedness with an aggregate principal balance of \$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 \$5 million if such amount

will not be covered by third-party insurance. The debt discount, and issuance costs of approximately \$178,000, are being amortized using the effective interest method over two years, the expected life of the SVB Loan and the Subordinated Notes.

**Convertible Notes—Conversion Option**

As a result of the adoption of revised guidance for evaluating when adjustment features within contracts are considered to be equity-indexed, as of January 1, 2009, the conversion feature embedded in our 2006 Notes was treated as a derivative



Table of Contents

liability and recorded at its fair value, with period to period changes in the fair value recorded as a gain or loss in our consolidated statement of operations. Accordingly, upon adoption we recorded a reduction to additional paid-in capital of \$1.4 million, an increase to debt discount of \$1.3 million, a derivative liability of \$2.7 million, and a charge to opening accumulated deficit of \$21,000. As amended, the 2006 Notes no longer fell within this guidance since they were no longer convertible into our common stock, therefore, the conversion option was no longer valued as a derivative liability. Accordingly, during 2011, the value of the derivative was reduced to zero with a corresponding increase to additional paid-in capital of \$755,000. Also, as the Amendment did not modify our ability to settle the 2006 Notes in cash, the 2006 Notes were within the guidance of ASC 470-20, Debt with Conversion and Other Options. In accordance with this guidance, the debt and equity components of the 2006 Notes were bifurcated and accounted for separately based on the value and related interest rate of a non-convertible debt security with the same terms. The fair value of the 2006 Notes at February 23, 2011 (the date of the Amendment) was determined to be \$28.5 million. The equity (conversion option) component of the notes was classified as noncontrolling interest on our consolidated balance sheet and accordingly, the carrying value of the 2006 Notes was reduced by approximately \$5.6 million, the calculated value of the conversion option. As of December 31, 2012, our debt discount balance was \$3.3 million and was being amortized until August 31, 2014, the maturity date of the 2006 Notes.

**Other**

At December 31, 2013, 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 part of the current portion of long-term debt.

During 2011 we entered into an equipment purchase financing arrangement for approximately \$154,000 payable in monthly installments over three years. At December 31, 2013, approximately \$39,000 remains outstanding with approximately \$39,000 classified in current liabilities on our consolidated balance sheet.

**(13) Fair Value Measurements**

We measure fair value based on a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1-Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access;

Level 2-Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly; and

Level 3-Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement.

The estimated fair values of all of our financial instruments, excluding long-term debt, approximate their carrying amounts in the consolidated balance sheets. The fair value of our long-term debt was derived by evaluating the nature and terms of the note and considering the prevailing economic and market conditions at the balance sheet date.

We measure our contingent royalty consideration at fair value. The fair value of our contingent royalty consideration, \$18.8 million at December 31, 2013, is based on significant inputs not observable in the market, which require it to be reported as a Level 3 liability within the fair value hierarchy. The valuation uses assumptions we believe would be made by a market participant. In particular, the valuation analysis used the Income Approach based on the sum of the economic income that an asset is anticipated to produce in the future. In this case that asset is the potential royalty income to be paid to us as a result of certain license agreements for QS-21 Stimulon and the potential net sales generated from HerpV. The fair value of the contingent royalty consideration is estimated by applying a risk adjusted discount rate (12.7%) to the probability adjusted royalty revenue stream based on expected approval dates. These fair

value estimates are most sensitive to changes in the probability of regulatory approvals. The Discounted Cash Flow method of the Income Approach was chosen as the method best suited to valuing the contingent royalty consideration.

72

---

Table of Contents

The following table presents our liability measured at fair value using significant unobservable inputs (Level 3), as of December 31, 2013 (amounts in thousands):

Balance, December 31, 2012	\$—	
Contingent royalty consideration	19,091	
Decrease in fair value during the year ended December 31, 2013	(292	)
Balance, December 31, 2013	\$18,799	

The decrease in fair value of the contingent royalty consideration liability is included in non-operating (loss) income in our consolidated statement of operations for the year ended December 31, 2013. 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 estimated fair values of all of our financial instruments, excluding long-term debt, approximate their carrying amounts in the consolidated balance sheets. The fair value of our long-term debt 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 fair value of the SVB Note and the Subordinated Notes at December 31, 2013, was \$9.6 million combined, and the fair value of the debt portion of the 2006 Notes as of December 31, 2012, was \$32.1 million, both based on the level 2 valuation hierarchy of the fair value measurements standard using a present value methodology.

**(14) 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.

**(15) 401(k) Plan**

We sponsor a defined contribution 401(k) savings plan for all eligible employees, as defined. Participants may contribute up to 60% of their compensation, as defined in the savings plan, with a maximum contribution of \$17,500 for individuals under 50 years old and \$23,000 for individuals 50 years old and older in 2013. Each participant is fully vested in his or her contributions and related earnings and losses. In 2012 we made discretionary contributions to the savings plan of approximately \$48,000. For the year ended December 31, 2012, we expensed \$48,000 related to this discretionary contribution. No discretionary contributions or expense was recorded for the years ended December 31, 2013 and 2011.

**(16) Quarterly Financial Data (Unaudited)**

	Quarter Ended,			
	March 31,	June 30,	September 30,	December 31,
	(In thousands, except per share data)			
2013				
Revenue	\$1,109	\$807	\$736	\$393
Net loss	(5,835	) (11,142	) (7,319	) (5,777
Net loss attributable to common stockholders	(8,842	) (11,193	) (7,370	) (5,827
Per common share, basic and diluted:				
Basic and diluted net loss attributable to common stockholders	\$(0.35	) \$(0.40	) \$(0.24	) \$(0.16

Table of Contents

	Quarter Ended,			
	March 31,	June 30,	September 30,	December 31,
	(In thousands, except per share data)			
2012				
Revenue	\$13,375	\$627	\$869	\$1,090
Net income (loss)	6,768	(6,923	) (5,729	) (5,441
Net income (loss) attributable to common stockholders	6,570	(7,121	) (5,927	) (5,639
Per common share, basic and diluted:				
Basic net income (loss) attributable to common stockholders	\$0.29	\$(0.31	) \$(0.24	) \$(0.23
Diluted net income (loss) attributable to common stockholders	\$0.29	\$(0.31	) \$(0.24	) \$(0.23

Net income (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.

(17) Subsequent Events

In January 2014, we entered into a Share Exchange Agreement (the "Exchange Agreement") pursuant to which we agreed to acquire all of the outstanding capital stock of 4-Antibody AG, a joint stock company formed under the laws of Switzerland ("4-AB"), from the shareholders of 4-AB (the "4-AB Shareholders") in exchange for \$10 million of our common stock payable upon closing, together with contingent milestone payments, payable in cash or shares of our common stock, at our discretion, that may exceed \$40 million. In addition, we agreed to assume certain 4-AB liabilities, including approximately \$1 million of obligations relating to transaction-related payments and certain 4-AB indebtedness totaling approximately \$500,000, which may be settled in shares of our common stock or cash. The Acquisition was completed on February 12, 2014. We issued 3,334,079 shares of our common stock to the 4-AB Shareholders, such shares of the Company's common stock having a value of \$10 million as calculated pursuant to the terms of the Exchange Agreement.

The 4-AB acquisition will be accounted and reported for in accordance with ASC Topic 805, "Business Combinations" by the acquisition method of accounting. Accordingly, the assets and liabilities of 4-AB as of February 12, 2014 will be recorded at their respective fair values. The calculations to determine fair values are incomplete at this time. Until the determination of the fair value measurements are complete, it is impractical to include disclosures related to the fair value of the assets acquired and liabilities assumed as required by the accounting guidance.

In February 2014, we issued and sold 22,236,000 shares of our common stock in a public underwritten offering. Net proceeds after deducting offering expenses were approximately \$56.0 million. These offerings were made under effective shelf registration statements and proceeds from the offerings will be used for general corporate purposes. In February 2014, our Board of Directors retired and returned to authorized and unissued the 43,490 shares of our treasury stock outstanding as of December 31, 2013.

Table of Contents

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 Securities 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 Securities 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 (1992) 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, 2013.

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 were no changes in our internal control over financial reporting that occurred during the fourth quarter of 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Agenus Inc.:

We have audited Agenus Inc. and subsidiaries' internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control-Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Agenus Inc.'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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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 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.

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.

In our opinion, Agenus Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control-Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Agenus Inc. and subsidiaries as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2013, and our report dated March 7, 2014 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Boston, Massachusetts

March 7, 2014

Table of Contents

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The response to this item is incorporated by reference from “Executive Officers of the Registrant” found in Part I of this Annual Report on Form 10-K, following Item 4 of this Annual Report on Form 10-K, and from sections entitled “Proposal 1 – Election of Directors,” “Our Corporate Governance,” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our Proxy Statement relating to our 2014 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our 2013 fiscal year (the “2014 Proxy Statement”).

Item 11. Executive Compensation

The response to this item is incorporated by reference into this Annual Report on Form 10-K from sections entitled “Our Corporate Governance,” “Compensation Discussion and Analysis,” “Compensation Committee Report,” “Compensation of Executive Officers,” and “Director Compensation” in our 2014 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The response to this item is incorporated by reference into this Annual Report on Form 10-K from sections entitled “Equity Plans” and “Ownership of Our Common Stock” in our 2014 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The response to this item is incorporated by reference into this Annual Report on Form 10-K from the sections entitled “Our Corporate Governance” and “Certain Relationships and Related Transactions” in our 2014 Proxy Statement.

Item 14. Principal Accounting Fees and Services

The response to this item is incorporated by reference into this Annual Report on Form 10-K from the section entitled “Proposal 3—To Ratify the Appointment of KPMG LLP as our Independent Registered Public Accounting Firm for the Fiscal Year Ending December 31, 2014” in our 2014 Proxy Statement.

Table of Contents

## 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 Index

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.
3.2	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.



Edgar Filing: AGENUS INC - Form 10-K

0-29089) filed on February 5, 2013 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 Form of Amended and Restated Note under the Securities Purchase Agreement dated as of October 30, 2006 (as amended), by and among Agenus Inc., a Delaware corporation and the investors listed on the Schedule of Buyers thereto. Filed as Exhibit 4.4 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.

78

---

Table of Contents

- 4.3 Form of Warrant under the Securities Purchase Agreement dated January 9, 2008. Filed as Exhibit 4.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 11, 2008 and incorporated herein by reference.
- 4.4 Purchase Agreement dated August 31, 2007 by and between Agenus Inc. and Fletcher International. Filed as Exhibit 99.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 5, 2007 and incorporated herein by reference.
- 4.5 Securities Purchase Agreement dated April 8, 2008. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on April 10, 2008 and incorporated herein by reference.
- 4.6 Form of Warrant to purchase common stock dated April 9, 2008. Filed as Exhibit 4.1 to our Current Report on Form 8-K (File No. 0-29089) filed on April 10, 2008 and incorporated herein by reference.
- 4.7 Securities Purchase Agreement by and between Agenus Inc. and the investors identified on Schedule I attached to the agreement, dated January 9, 2008. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 11, 2008 and incorporated herein by reference.
- 4.8 Form of 4 Year Warrant under the Securities Purchase Agreement dated July 30, 2009. Filed as Exhibit 4.2 to our Current Report on Form 8-K (File No. 0-29089) filed on August 3, 2009 and incorporated herein by reference.
- 4.9 Form of 4 Year Warrant under the Securities Purchase Agreement dated August 3, 2009. Filed as Exhibit 4.2 to our Current Report on Form 8-K (File No. 0-29089) filed on August 5, 2009 and incorporated herein by reference.
- 4.10 Securities Purchase Agreement dated as of July 30, 2009 by and among Agenus Inc. and the investors listed on the Schedule of Buyers thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on August 3, 2009 and incorporated herein by reference.
- 4.11 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.
- 4.12 Note Purchase Agreement dated as of April 15, 2013 by and between Agenus Inc., and the Purchasers listed on Schedule 1.1 thereto. Filed as Exhibit 4.1 to our Quarterly Report on Form 10-Q (File No. 0-029089) for the quarter ended March 31, 2013 and incorporated herein by reference.
- 4.13 Form of Senior Subordinated Note under the Note Purchase Agreement dated as of April 15, 2013 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. 0-029089) for the quarter ended March 31, 2013 and incorporated herein by reference.
- 4.14 Form of Warrant under the Note Purchase Agreement dated as of April 15, 2013 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. 0-029089) for the quarter ended March 31, 2013 and incorporated herein by reference.

4.15 Loan and Security Agreement dated as of April 15, 2013 by and among Agenus Inc., Antigenics Inc., a Massachusetts corporation (and wholly-owned subsidiary of Agenus Inc.), and Silicon Valley Bank, a California corporation. Filed as Exhibit 4.4 to our Quarterly Report on Form 10-Q (File No. 0-029089) for the quarter ended March 31, 2013 and incorporated herein by reference.

4.16 Securities Exchange Agreement dated as of April 15, 2013 by and among Agenus Inc., Ingalls & Snyder Value Partners L.P. and Arthur Koenig. Filed as Exhibit 4.5 to our Quarterly Report on Form 10-Q (File No. 0-029089) for the quarter ended March 31, 2013 and incorporated herein by reference.

4.17 Securities Purchase Agreement, dated September 18, 2013, as amended, by and between Agenus Inc. and the investors party thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 19, 2013 and incorporated herein by reference.

4.18 Form of Warrant under the Securities Purchase Agreement, dated September 18, 2013, as amended, by and between Agenus Inc. and the investors party thereto. Filed as Exhibit 4.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 19, 2013 and incorporated herein by reference.

4.19 Share Exchange Agreement, dated January 10, 2014, by and among Agenus Inc., 4-Antibody AG, certain shareholders of 4-Antibody AG and Vischer AG. Filed as Exhibit 2.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 13, 2014 and incorporated herein by reference.

Table of Contents

4.17	Securities Purchase Agreement dated as of August 3, 2009 by and among Agenus Inc. and the investors listed on the Schedule of Buyers thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on August 5, 2009 and incorporated herein by reference.
	Employment Agreements and Compensation Plans
10.1*	1999 Equity Incentive Plan, as amended. Filed as Exhibit 10.1 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2008 and incorporated herein by reference.
10.1.2*	Form of Non-Statutory Stock Option. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on December 15, 2004 and incorporated herein by reference.
10.1.3*	Form of 2007 Restricted Stock Award Agreement. Filed as Exhibit 10.1.5 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2007 and incorporated herein by reference.
10.1.4*	Form of 2008 Restricted Stock Award Agreement. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on March 11, 2008 and incorporated herein by reference.
10.1.5*	Sixth Amendment to the Agenus Inc. 1999 Equity Incentive Plan. Filed as Appendix D to our Definitive Proxy Statement on Schedule 14A filed on April 27, 2009 and incorporated herein by reference.
10.2*	Agenus Inc. 2009 Equity Incentive Plan, as amended to date. Filed as Exhibit 10.2 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*	Form of Restricted Stock Agreement for the Agenus Inc. Agenus Inc. 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.
10.2.2*	Form of Stock Option Agreement for the Agenus Inc. 2009 Equity Incentive Plan. Filed as Exhibit 10.3 to our Current Report on Form 8-K (File No. 0-29089) filed on June 15, 2009 and incorporated herein by reference.
10.3*	Agenus Inc. 2009 Employee Stock Purchase Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed on April 27, 2009 and incorporated herein by reference.
10.4	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.
10.5*	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.

Edgar Filing: AGENUS INC - Form 10-K

- 10.5.1\* 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. 0-029089) for the quarter ended June 30, 2012 and incorporated herein by reference.
- 10.6\* 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.
- 10.7 Form of Indemnification Agreement between Agenus Inc. and its directors and executive officers. These agreements are materially different only as to the signatories and the dates of execution. Filed as Exhibit 10.4 to our registration statement on Form S-1 (File No. 333-91747) and incorporated herein by reference.
- 10.8 Current schedule identifying the directors and executive officers who are party to an Indemnification Agreement, the form of which was filed as Exhibit 10.4 to our registration statement on Form S-1 (File No. 333-91747). Filed herewith.
- 10.9\* Employment Agreement dated February 20, 2007 between Agenus Inc. and Kerry Wentworth. Filed as Exhibit 10.2 to our Current Report on Form 8-K (File No. 0-29089) filed on February 26, 2007 and incorporated herein by reference.

Table of Contents

- 10.9.1\* First Amendment to Employment Agreement dated July 2, 2009 between Agenus Inc. and Kerry Wentworth. Filed as Exhibit 10.4 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended September 30, 2009 and incorporated herein by reference.
- 10.9.2\* Second Amendment to Employment Agreement dated December 15, 2010 between Agenus Inc. and Kerry Wentworth. Filed as Exhibit 10.11.2 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.
- 10.10\* 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.
- 10.10.1\* 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.
- 10.10.2\* 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.
- 10.11\* Employment Agreement dated September 16, 2008 between Agenus Inc. and Karen Valentine. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 19, 2008 and incorporated herein by reference.
- 10.11.1\* First Amendment to Employment Agreement dated July 2, 2009 between Agenus Inc. and Karen Valentine. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended September 30, 2009 and incorporated herein by reference.
- 10.11.2\* Second Amendment to Employment Agreement dated December 15, 2010 between Agenus Inc. and Karen Valentine. Filed as Exhibit 10.20.2 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.
- License and Collaboration Agreements
- 10.12(1) Patent License Agreement between Agenus Inc. and Mount Sinai School of Medicine dated November 1, 1994, as amended on June 5, 1995. Filed as Exhibit 10.8 to our registration statement on Form S-1 (File No. 333-91747) and incorporated herein by reference.
- 10.13(1) Sponsored Research and Technology License Agreement between Agenus Inc. and Fordham University dated March 28, 1995, as amended on March 22, 1996. Filed as Exhibit 10.9 to our registration statement on Form S-1 (File No. 333-91747) and incorporated herein by reference.
- 10.14(1) License Agreement between the University of Connecticut Health Center and Agenus Inc. dated May 25, 2001, as amended on March 18, 2003. Filed as Exhibit 10.2 to the Amendment No. 1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2003 and incorporated herein by reference.
- 10.14.1(1)

Edgar Filing: AGENUS INC - Form 10-K

Letter Agreement by and between Agenus Inc. and The University of Connecticut Health Center dated May 11, 2009. Filed as Exhibit 10.5 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2009 and incorporated herein by reference.

10.14.2(1) Amendment Number Two to License Agreement by and between Agenus Inc. and The University of Connecticut Health Center dated June 5, 2009. Filed as Exhibit 10.6 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2009 and incorporated herein by reference.

10.15(1) License Agreement by and between Agenus Inc. and GlaxoSmithKline Biologicals SA dated July 6, 2006. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2006 and incorporated herein by reference.

10.16(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.

Table of Contents

- 10.17(1) First Right to Negotiate and Amendment Agreement between Agenus Inc., Antigenics Inc. 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.
- 10.18(1) Amended and Restated License Agreement by and between Antigenics Inc., a Massachusetts corporation and wholly owned subsidiary of Agenus Inc., Elan Pharma International Limited, and Elan Pharmaceuticals, Inc. dated September 14, 2009. Filed as Exhibit 10.5 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended September 30, 2009 and incorporated herein by reference.
- 10.19 License Agreement by and between Agenus Inc. and NewVac LLC dated December 19, 2011. Filed as Exhibit 10.42 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2011 and incorporated herein by reference.
- 10.20(1) Revenue Interests Assignment Agreement dated as of April 15, 2013 by and among Agenus Inc., Ingalls & Snyder Value Partners L.P., Arthur Koenig and Antigenics Inc., a Massachusetts corporation (and wholly-owned subsidiary of Agenus Inc.). Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-029089) for the quarter ended March 31, 2013.
- Real Estate Leases
- 10.21 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.
- 10.21.1 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.
- 10.21.2 Second Amendment of Lease dated as of March 7, 2007 from BHX, LLC as trustee of 3 Forbes Road Realty, to Agenus Inc. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2007 and incorporated herein by reference.
- 10.21.3 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.
- 10.21.4 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.
- 10.21.5 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



Edgar Filing: AGENUS INC - Form 10-K

Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2011 and incorporated herein by reference.

10.22 Standard Form of Office Lease dated December 13, 2012 between 149 Fifth Ave. Corp. and Agenus Inc. Filed as Exhibit 10.22 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2012 and incorporated herein by reference.

Sales Agreement

10.24 Amended and Restated At Market Issuance Sales Agreement, dated as of December 21, 2012, by and between Agenus Inc. and MLV & Co. LLC. Filed as Exhibit 10.1 to our Registration Statement on Form S-3 (File No. 333-185657) and incorporated herein by reference.

21 Subsidiaries of Agenus Inc. Filed herewith.

23 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.

82

---

Table of Contents

32.1(2)	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(3)
101.SCH	XBRL Taxonomy Extension Schema Document(3)
101.CAL	XBRL Calculation Linkbase Document(3)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document(3)
101.LAB	XBRL Label Linkbase Document(3)
101.PRE	XBRL Taxonomy Presentation Linkbase Document(3)

---

\*Indicates a management contract or compensatory plan.

Certain confidential material contained in the document has been omitted and filed separately with the Securities (1) and Exchange Commission pursuant to Rule 406 of the Securities Act or Rule 24b-2 of the Securities Exchange Act.

(2) This certification accompanies the Annual Report on Form 10-K and is not filed as part of it.

(3) XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

Table of Contents

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 7, 2014

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 7, 2014
/S/ CHRISTINE M. KLASKIN Christine M. Klaskin	Vice President, Finance (Principal Accounting and Financial Officer)	March 7, 2014
/S/ BRIAN CORVESE Brian Corvese	Director	March 7, 2014
/S/ TOM DECHAENE Tom Dechaene	Director	March 7, 2014
/S/ WADIH JORDAN Wadih Jordan	Director	March 7, 2014
/S/ SHAHZAD MALIK Shahzad Malik	Director	March 7, 2014
/S/ SHALINI SHARP Shalini Sharp	Director	March 7, 2014
/S/ TIMOTHY R. WRIGHT Timothy R. Wright	Director	March 7, 2014