

AGENUS INC  
Form 424B3  
March 06, 2012  
Table of Contents

Filed Pursuant to Rule 424(b)(3) and Rule 424(c)

Registration No. 333-150326

March 6, 2012

**PROSPECTUS SUPPLEMENT NO. 56**

**2,333,332 SHARES OF COMMON STOCK**

**AGENUS INC.**

This prospectus supplement amends the prospectus dated March 16, 2009 (as supplemented on April 15, 2009, April 17, 2009, April 22, 2009, April 27, 2009, May 4, 2009, May 11, 2009, May 27, 2009, June 4, 2009, June 8, 2009, June 9, 2009, June 11, 2009, June 15, 2009, July 7, 2009, July 15, 2009, August 3, 2009, August 5, 2009, September 11, 2009, September 18, 2009, November 12, 2009, January 5, 2010, March 1, 2010, March 25, 2010, April 26, 2010, May 11, 2010, May 18, 2010, July 23, 2010, August 9, 2010, August 25, 2010, November 3, 2010, November 10, 2010, December 30, 2010, January 7, 2011, January 14, 2011, January 28, 2011, March 1, 2011, March 8, 2011, March 18, 2011, April 18, 2011, May 5, 2011, May 9, 2011, June 8, 2011, June 17, 2011, August 8, 2011, August 16, 2011, September 7, 2011, September 27, 2011, September 30, 2011, October 11, 2011, October 20, 2011, November 7, 2011, November 17, 2011, December 12, 2011, December 21, 2011, and March 5, 2012) to allow certain stockholders or their pledgees, donees, transferees, or other successors in interest (the "Selling Stockholders"), to sell, from time to time, up to 1,166,666 shares of our common stock, which they have acquired in a private placement in the United States, and up to 1,166,666 shares of our common stock issuable upon the exercise of warrants which are held by the Selling Stockholders named in the prospectus.

We would not receive any proceeds from any such sale of these shares. To the extent any of the warrants are exercised for cash, if at all, we will receive the exercise price for those warrants.

This prospectus supplement is being filed to include the information set forth in the Annual Report on Form 10-K filed on March 6, 2012, which is set forth below. This prospectus supplement should be read in conjunction with the prospectus dated March 16, 2009, Prospectus Supplement No. 1 dated April 15, 2009, Prospectus Supplement No. 2 dated April 17, 2009, Prospectus Supplement No. 3 dated April 22, 2009, Prospectus Supplement No. 4 dated April 27, 2009, Prospectus Supplement No. 5 dated May 4, 2009, Prospectus Supplement No. 6 dated May 11, 2009, Prospectus Supplement No. 7 dated May 27, 2009, Prospectus Supplement No. 8 dated June 4, 2009, Prospectus Supplement No. 9 dated June 8, 2009, Prospectus Supplement No. 10 dated June 9, 2009, Prospectus Supplement No. 11 dated June 11, 2009, Prospectus Supplement No. 12 dated June 15, 2009, Prospectus Supplement No. 13 dated July 7, 2009, Prospectus Supplement No. 14 dated July 15, 2009, Prospectus Supplement No. 15 dated August 3, 2009, Prospectus Supplement No. 16 dated August 5, 2009, Prospectus Supplement No. 17 dated September 11, 2009, Prospectus Supplement No. 18 dated September 18, 2009, Prospectus Supplement No. 19 dated November 12, 2009, Prospectus Supplement No. 20 dated January 5, 2010, Prospectus Supplement No. 21 dated March 1, 2010, Prospectus Supplement No. 23 dated March 25, 2010, Prospectus Supplement No. 24 dated April 26, 2010, Prospectus Supplement No. 25 dated May 11, 2010, Prospectus Supplement No. 26 dated May 18, 2010, Prospectus Supplement No. 27 dated July 23, 2010, Prospectus Supplement No. 28 dated August 9, 2010, Prospectus Supplement No. 29 dated August 25, 2010, Prospectus Supplement No. 30 dated November 3, 2010, Prospectus Supplement No. 31 dated November 10, 2010, Prospectus Supplement No. 32 dated December 30, 2010, Prospectus Supplement No. 33 dated January 7, 2011, Prospectus Supplement No. 34 dated January 14, 2011, Prospectus Supplement No. 35 dated January 28, 2011, Prospectus Supplement No. 36 dated March 1, 2011, Prospectus Supplement No. 37 dated March 8, 2011, Prospectus Supplement No. 38 dated March 18, 2011, Prospectus Supplement No. 39 dated April 18, 2011, Prospectus Supplement No. 40 dated May 5, 2011, Prospectus Supplement No. 41 dated May 9, 2011, Prospectus Supplement No. 42 dated June 8, 2011, Prospectus Supplement No. 43 dated June 17, 2011, Prospectus Supplement No. 44 dated August 8, 2011, Prospectus Supplement No. 45 dated August 16, 2011, Prospectus Supplement No. 46 dated September 7, 2011, Prospectus Supplement No. 47 dated September 27, 2011, Prospectus Supplement No. 48 dated September 30, 2011, Prospectus Supplement No. 49 dated October 11, 2011, Prospectus Supplement No. 50 dated October 20, 2011, Prospectus Supplement No. 51 dated November 7, 2011, Prospectus Supplement No. 52 dated November 17, 2011, Prospectus Supplement No. 53 dated December 12, 2011, Prospectus Supplement No. 54 dated December 21, 2011, and Prospectus Supplement No. 55 dated March 5, 2012, which are to be delivered with this prospectus supplement.

Our common stock is quoted on The NASDAQ Capital Market ( "NASDAQ" ) under the ticker symbol AGEN. On March 2, 2012, the last reported closing price per share of our common stock was \$3.23 per share.

Edgar Filing: AGENUS INC - Form 424B3

Investing in our securities involves a high degree of risk. Before investing in any of our securities, you should read the discussion of material risks in investing in our common stock. See **Risk Factors** on page 1 of the prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

**THE DATE OF THIS PROSPECTUS SUPPLEMENT NO. 56 IS MARCH 6, 2012**

Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K**

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

For the fiscal year ended December 31, 2011

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:**

**06-1562417**  
*(I.R.S. Employer*

*Identification No.)*

Edgar Filing: AGENUS INC - Form 424B3

(781) 674-4400

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

**Common Stock, \$.01 Par Value**

*(Title of each class)*

**The NASDAQ Capital Market**

*(Name of each exchange on which registered)*

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

**None**

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically 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, 2011 was: \$75.9 million. There were 22,492,667 shares of the registrant's Common Stock outstanding as of February 24, 2012.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement for the registrant's 2012 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, 2011, are incorporated by reference into Part III of this Annual Report on Form 10-K.

**Table of Contents****TABLE OF CONTENTS**

		<b>Page</b>
	<b>PART I</b>	
ITEM 1.	<u>BUSINESS</u>	3
	<u>Our Business</u>	3
	<u>Our Products and Technologies Under Development</u>	4
	<u>Intellectual Property Portfolio</u>	9
	<u>Regulatory Compliance</u>	11
	<u>Competition</u>	12
	<u>Employees</u>	13
	<u>Corporate History</u>	13
	<u>Availability of Periodic SEC Reports</u>	13
ITEM 1A.	<u>RISK FACTORS</u>	13
ITEM 1B.	<u>UNRESOLVED STAFF COMMENTS</u>	30
ITEM 2.	<u>PROPERTIES</u>	31
ITEM 3.	<u>LEGAL PROCEEDINGS</u>	31
ITEM 4.	<u>MINE SAFETY DISCLOSURES</u>	31
	<u>EXECUTIVE OFFICERS OF THE REGISTRANT</u>	31
	<b>PART II</b>	
ITEM 5.	<u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	33
ITEM 6.	<u>SELECTED FINANCIAL DATA</u>	34
ITEM 7.	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	36
ITEM 7A.	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	44
ITEM 8.	<u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	45
ITEM 9.	<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	75
ITEM 9A.	<u>CONTROLS AND PROCEDURES</u>	75
ITEM 9B.	<u>OTHER INFORMATION</u>	77
	<b>PART III</b>	
ITEM 10.	<u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	77
ITEM 11.	<u>EXECUTIVE COMPENSATION</u>	77
ITEM 12.	<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	77
ITEM 13.	<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	77
ITEM 14.	<u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	77
	<b>PART IV</b>	
ITEM 15.	<u>EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	78

**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, intend, plan, believe, will, potential, opportunity, future and other words and terms of similar meaning and expression in connection with 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 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, 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. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly under Part I-Item 1A. Risk Factors, that we believe could cause actual results to differ materially from any forward-looking statement.

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 have included more detailed descriptions of these risks and uncertainties and other risks and uncertainties applicable to our business in Part I-Item 1A. Risk Factors of 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® and Stimulon® are registered trademarks of Agenus Inc. and its subsidiaries. All rights reserved.

**Reverse Stock Split** Except as otherwise indicated, information in this Annual Report on Form 10-K reflects the one-for-six reverse stock split of our common stock effected on October 3, 2011.

## **Table of Contents**

### **PART I**

#### **Item 1. Business** **Our Business**

##### ***Overview***

Agenus Inc., including its subsidiaries, referred to in this Annual Report on Form 10-K as Agenus, the Company, we, us, and our, is a biotechnology company focused on the development and commercialization of technologies to treat cancers and infectious diseases. Our core technology portfolio consists of our Saponin Platform (based on our saponin adjuvant based technologies) and our Heat Shock Protein ( HSP ) Platform (based on our HSP based technologies).

Some of our key candidates from these technology platforms are highlighted below:

QS-21 Stimulon® adjuvant ( QS-21 ): QS-21, 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 are GlaxoSmithKline ( GSK ) and JANSSEN Alzheimer Immunotherapy ( JANSSEN AI ). There are approximately 15 vaccines containing QS-21 in clinical development by our licensees, including a total of four in Phase 3 testing for malaria, melanoma, non-small cell lung cancer and shingles. The first products containing QS-21 are anticipated to be launched in the 2013-2014 timeframe, and we are generally entitled to royalties for at least 10 years post-launch. However, there is no guarantee that we will be able to collect royalties in the future. The pipeline of product candidates containing QS-21 is extraordinarily 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.

The Prophage Series vaccines: The Prophage Series vaccines are a patient specific application of our HSP Platform. We believe that the collective results from our clinical trials to date with product candidates from the Prophage Series indicate a favorable safety profile and signals of efficacy in multiple cancer types. Although promising results have been observed to date, there can be no assurances that we will successfully complete all clinical trials or obtain regulatory approvals for these products. The Prophage Series vaccine R-100 is referred to as Oncophage® vaccine (vitespen) and is approved in Russia for the treatment of renal cell carcinoma ( RCC ; kidney cancer) in patients at intermediate risk of recurrence. In a registry following patients from a large randomized Phase 3 trial in non-metastatic RCC, patients at intermediate risk of recurrence who were in the treatment arm and received Prophage Series R-100, demonstrated an approximately 46 percent lower risk of death compared with those in the control arm (n = 362;  $P < 0.05$ ; hazard ratio = 0.54). In December 2011, we secured a local partner for Oncophage when we granted NewVac LLC (a subsidiary of ChemRar Ventures LLC, 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. In addition, Phase 2 trials are underway in the United States testing the Prophage Series vaccine candidates G-100 and G-200 in newly diagnosed and recurrent glioma, respectively.

HerpV: Also derived from our HSP Platform technologies, HerpV is a recombinantly (off-the-shelf) and synthetically produced therapeutic vaccine candidate for the treatment of genital herpes. It has completed Phase 1 testing, where it was shown to elicit both CD4 and CD8 positive T cell responses a first of its kind finding in genital herpes treatment. Because the product contains multiple antigens derived from the herpes simplex 2 virus (HSV-2), it may be applicable to a broader patient population and may have potential in managing outbreaks and disease transmission. We consider this to be a platform technology, since with the integration of heat shock proteins with antigenic peptides we could potentially create therapeutic vaccines for many infectious diseases. We plan to initiate a Phase 2 trial during the second half of 2012.

## **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 the Prophage G-Series vaccine candidates, G-100 and G-200, QS-21 and HerpV. We are also exploring in-licensing opportunities. Our business activities have included product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development, market development, business development, and support of our collaborations. Research and development expenses for the years ended December 31, 2011, 2010, and 2009, were \$11.0 million, \$12.9 million, and \$16.9 million, respectively.

Our common stock is currently listed on The Nasdaq Capital Market ( "Nasdaq" ) under the symbol AGEN . In April 2009, we moved from The Nasdaq Global Market to The Nasdaq Capital Market as part of our plan to regain compliance with minimum market value requirements. On March 3, 2011, we were notified by the Listing Qualifications Staff of Nasdaq (the "Staff" ) that we were not in compliance with the minimum bid price requirement set forth in Nasdaq Marketplace Rule 5550(a)(2) (the "Bid Price Requirement" ) because the bid price for our common stock had closed below the minimum \$1.00 per share requirement for 30 consecutive business days. Effective October 3, 2011, our certificate of incorporation was amended to effect a reverse stock split of our common stock on the basis of one post-split share for every six pre-split shares to, in part, regain compliance with the Bid Price Requirement. On October 17, 2011, we received notice from the Nasdaq Listing Qualifications Panel (the "Panel" ) that we had regained compliance with the Bid Price Requirement and otherwise satisfied all requirements for continued listing on Nasdaq.

## **Our Products and Technologies Under Development**

### **QS-21**

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 are GSK and JANSSEN AI. There are approximately 15 vaccines containing QS-21 in clinical development, including a total of four in Phase 3 testing for malaria, melanoma, non-small cell lung cancer and shingles. Assuming regulatory approval, the first products containing QS-21 are anticipated to be launched in the early 2013-2014 timeframe. The pipeline of product candidates containing QS-21 is diverse, encompassing prophylactic as well as therapeutic vaccines for infectious diseases, multiple cancer types, and Alzheimer's disease. The Company does not incur clinical development costs for these products.

QS-21 is best known for its ability to stimulate antibody, or humoral, immune response, and has also been shown to activate cellular immunity. A natural product, QS-21 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 has been tested in approximately 185 clinical trials involving, in the aggregate, over 40,000 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 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.

### ***Partnered QS-21 Programs***

A number of pharmaceutical and biotechnology companies have licensed QS-21 from us for use in vaccines to treat a wide variety of human diseases. Companies with QS-21 programs include GSK, and JANSSEN AI. In return for rights to use QS-21, these companies have generally agreed to pay us license fees, manufacturing payments, milestone payments, and royalties on product sales for a minimum of 10 years after commercial launch. 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.



## **Table of Contents**

*GSK.* In July 2006, we entered into a license agreement and a supply agreement with GSK for the use of QS-21. On January 16, 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. GSK is obligated to supply us (or our affiliates, licensees, or customers) certain quantities of commercial grade QS-21 for a stated period of time. On March 2, 2012 we entered into a First Right to Negotiate and Amendment Agreement amending the license agreement and Amended GSK supply agreement to clarify and include additional rights for the use of QS-21. In addition, we agreed to grant 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 this agreement, GSK is obligated to pay us an upfront, non-refundable payment of \$9.0 million, \$2.5 million of which is creditable toward future royalty payments. In addition, as of December 31, 2011, we have received \$10.5 million of a potential \$15.3 million in upfront and milestone payments related to these agreements (excluding the \$9.0 million upfront consideration due). We are 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 agreements may be terminated by either party upon a material breach if the breach is not cured within the time specified in the 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 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 understand that QS-21 is a key component included in several of GSK's proprietary adjuvant systems and a number of GSK's vaccine candidates currently under development are formulated using adjuvant systems containing QS-21. GSK has ongoing Phase 3 studies evaluating its investigational MAGE-A3 Antigen-Specific Cancer Immunotherapeutic containing QS-21 in melanoma and non-small cell lung cancer. Data from Phase 3 trials in melanoma, non-small cell lung cancer, malaria and shingles is anticipated to be reported within the next year or so.

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. 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. Data from a second Phase 3 trial of RTS,S is anticipated to be reported during the fourth quarter of 2012.

*Elan/JANSSEN Alzheimer's Immunotherapy.* Elan Pharmaceuticals, Inc. and/or its affiliates ("Elan") had a commercial license for the use of QS-21 in the research and commercialization of Elan's Alzheimer's disease vaccine candidate that contains QS-21 ("Licensed Product"). Effective September 14, 2009, we entered into an Amended and Restated License Agreement ("Amended License Agreement") with Elan, and on September 17, 2009, the Amended License Agreement was assigned to JANSSEN AI. Under the terms of the Amended License Agreement, JANSSEN AI has the right to develop, make, have made, use, sell, offer for sale, import, and have sold, the Licensed Product. In addition, pursuant to the terms of the Amended License Agreement, JANSSEN AI has the right to manufacture all of its requirements of QS-21 for use in the Licensed Product and we have no further supply obligations. Assuming all benchmarks are met under this agreement, we could receive up to \$11.5 million in future milestone payments; \$1.5 million has been received as of December 31, 2011. Furthermore, under the terms of the Amended License Agreement, we are entitled to receive mid single-digit royalties on net sales of the Licensed Product for a period of at least 10 years after the first commercial sale of such product, if any. Expiration or termination of the Amended 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 Amended License Agreement, JANSSEN AI will have a royalty-free license. Upon early termination of the Amended License Agreement, JANSSEN AI license rights terminate and future payment obligations do not accrue.

## **Table of Contents**

### ***Manufacturing***

Except in the case of GSK and JANSSEN AI, we have retained worldwide manufacturing rights for QS-21. We have the right to subcontract manufacturing for QS-21 and we have a supply agreement with a contract manufacturer for the production of QS-21 through September 2012. In addition, under the terms of our agreement with GSK, GSK is contractually committed to supply certain quantities of commercial grade QS-21 to us and our licensees in the future.

### **Heat Shock Protein Technology**

Heat shock proteins, also known as HSPs, are also called stress proteins, as their expression is increased when cells experience various stresses like extremes of temperature (hot or cold) and oxygen deprivation. HSPs are present in all cells in all life forms from bacteria to mammals, and their structure and function are similar across these diverse life forms. Under normal conditions, HSPs play a major role in protein folding and transport of protein fragments called peptides within a cell, and are thus also known as chaperones. Antigenic peptides, those portions of a protein that stimulate immune responses when recognized by the immune cells, are also transported by these chaperones. Because HSPs interact with and bind many cellular proteins and peptides, they chaperone a broad array of antigenic peptides to facilitate their recognition by the immune system. Thus, HSPs play an integral role in capturing and presenting the antigenic fingerprint of a cell to a host's immune system.

Although HSPs are normally found inside cells, they also provide important danger signals when found outside of cells. Detection of HSPs outside of cells is indicative that cell death has occurred. This may have been caused by disease, mutation, or injury, whereby a cell's contents are spilled into body tissue. These HSPs send powerful danger signals to the immune system that initiate a cascade of events capable of generating a targeted immune response against the infection or disease-related cell death.

Combined, these functions of HSPs form the basis of our technology. The chaperoning nature of HSPs allows us to produce vaccines containing the antigenic fingerprint of a given disease. In the case of cancer, the vaccines are patient-specific, consisting of heat shock protein-peptide complexes, also known as HSPPCs, purified from a patient's tumor cells. These HSPPCs, when injected into the skin, are expected to stimulate a powerful cellular immune response potentially capable of targeting and killing the cancer cells from which these complexes were derived. 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, 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***

The Prophage Series vaccines describe our portfolio of patient-specific HSP-based therapeutic cancer vaccines, including the R-Series candidates in RCC, M-Series candidates in melanoma, and G-Series candidates in glioma. The first product derived from the R-Series (R-100, registered in Russia as Oncophage), represents the only approved treatment for adjuvant or non-metastatic kidney cancer patients at intermediate risk for disease recurrence.

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

## **Table of Contents**

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. Unless the NewVac Agreement is earlier terminated or extended, 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 through December 2014. Upon termination of the NewVac Agreement, all activity under the agreement immediately ceases.

Each Prophage Series vaccine candidate is made from a patient's tumor tissue. After a surgeon removes a patient's tumor, the majority of that tumor tissue is frozen and shipped to our manufacturing facility. Using a proprietary manufacturing process that takes approximately eight to 10 hours per individual patient lot, we isolate the HSPPCs from the tumor tissue. Through this isolation process, the HSPPCs are extracted, purified, and sterile-filtered from the tumor tissue, then formulated in solution and packaged in standard single-injection vials. After the performance of quality control testing, including sterility testing, we ship the frozen vaccine back to the hospital or clinic for administration. Medical professionals administer the vaccine by injecting the product into the skin.

Although we believe that our technology is applicable to all cancer types, our initial focus with the Prophage Series vaccines is on cancers that have limited or no available treatment options and in cancers that typically yield sufficient quantities of tumor tissue from the surgical procedure to allow for manufacture.

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 clinical trials. Collectively, results across all trials provided evidence of manufacturing and logistical feasibility as well as an initial demonstration of safety and signals of efficacy, which included patients who had complete disappearance (a complete response), substantial shrinkage (partial response), minor shrinkage (minor response), or no change in the size (disease stabilization) of tumor lesions. Median overall survival results exceeded historical controls that were relevant at the time when the studies were performed. Additionally, tumor-specific T-cell responses were noted in studies where they were measured, namely melanoma and colorectal 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.

### ***Phase 3 Renal Cell Carcinoma Program***

Renal cell carcinoma is the most common type of kidney cancer. The American Cancer Society estimates that there will be 64,770 new cases of kidney cancer and 13,570 people will die from the disease in the United States in 2012. The Kidney Cancer Research Bureau, a Russian non-profit, non-government research organization, estimated that in 2008, approximately 16,000 Russians would be diagnosed with kidney cancer and approximately 50% of those diagnosed would die of the disease.

We initiated a Phase 3, multicenter, international trial for non-metastatic RCC into which the first patient was randomized in February 2001. As announced on March 24, 2006, the trial did not reach statistical significance in its primary endpoint of recurrence-free survival in the total patient population, though a positive trend was observed. During the protocol design process in 1999 and 2000, key opinion leaders were consulted, and the non-metastatic RCC patient population designated for enrollment in the trial was thought to be a relatively uniform group. In 2006, the Eastern Cooperative Oncology Group (ECOG) initiated a trial in adjuvant RCC with sorafenib and sunitinib that stratified their patient population into intermediate-risk, high-risk, and very high-risk recurrence categories. Using these ECOG defined criteria, analysis of the intermediate risk patients (362 of the 604 eligible patients in the trial) in the trial showed a statistically significant difference in recurrence-free survival in favor of the Oncophage arm. In part because the intermediate-risk category was not

---

## **Table of Contents**

prospectively delineated prior to the trial's initiation, the Food & Drug Administration (FDA) has indicated that, by itself, part I of our Phase 3 clinical trial in renal cell carcinoma is not sufficient to support a biologics license application (BLA) filing.

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, as noted above, we out-licensed this program to NewVac.

In 2008, we announced the submission of a marketing authorization application (MAA) to the European Medicines Agency (EMA) requesting conditional authorization of Oncophage in earlier-stage, localized kidney cancer. On November 20, 2009, we announced that the Committee for Medicinal Products for Human Use (CHMP) of the EMA formally adopted a negative opinion on our MAA. Subsequently we withdrew our application and we are no longer actively pursuing activities in the European market. Although we are no longer in active discussions with a potential partner for the European market, we continue to actively seek partnership discussions for multiple products generated from our portfolio of Prophage Series vaccines.

### ***Glioma***

Glioma is a cancer affecting the central nervous system that begins in glial cells (connective tissue cells that surround and support nerve cells). Malignant glioma is currently a fatal disease. The American Cancer Society estimates that 22,910 new cases of the brain and other nervous system cancers will be diagnosed during 2012 in the U.S., and that about 13,700 people will die from these tumors.

Phase 2 trials testing the Prophage Series candidates G-100 and G-200 are underway in both newly diagnosed and recurrent glioma, respectively, where promising data has been generated to date. A Phase 2 clinical trial with Prophage Series vaccine G-200 in recurrent, high-grade glioma is currently ongoing. This study is being led by the Brain Tumor Research Center at the University of California, San Francisco (UCSF), with grants from the American Brain Tumor Association and the National Cancer Institute Special Programs of Research Excellence. The study, which is designed to enroll approximately 50 patients, has expanded to include New York-Presbyterian Hospital/Columbia University Medical Center and University Hospitals/Case Western Reserve.

On June 6, 2011, results from the ongoing Phase 2 clinical trial were presented at the 47<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Illinois. Results from this trial showed that 93 percent of the patients were alive at  $\geq 26$  weeks after surgery and a median overall survival of 11 months (47.6 weeks). Results from pre-defined exploratory analyses of disease progression showed a median progression free survival (PFS) of approximately 5 months (20 weeks). Importantly, measures of immune response post vaccination with Prophage Series G-200 demonstrated a significant tumor-specific CD8<sup>+</sup> T-cell response as well as innate immune responses as marked by a significant increase in levels of circulating NK cells.

UCSF also initiated an additional Phase 2 clinical trial in newly diagnosed glioma testing Prophage Series vaccine G-100 in combination with Temodar<sup>®</sup> (temozolomide). This trial is currently enrolling, with a target of 50 patients.

### ***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.

## **Table of Contents**

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 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 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 multivalent vaccine containing multiple synthetic HSV-2 peptides, which means that it may be applicable to a broader patient population and may have potential in managing outbreaks and disease transmission.

According to the Centers for Disease Control, genital herpes affects more than 60 million Americans or 1 in 6 people between the ages 14 and 49 with an additional 1.5 million new cases contracted each year. 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.

Based on the results of completed toxicology studies and other preclinical activities, we submitted to the FDA an investigational new drug application (IND) for HerpV during the second quarter of 2005. In October 2005, we initiated a multicenter Phase 1 clinical trial of HerpV in genital herpes. In this four-arm, phase 1 study, 35 HSV-2 seropositive patients received HerpV with QS-21, HerpV alone, QS-21 alone, or placebo. The vaccine was well tolerated, with injection site pain as the most common reported adverse event. All patients who were evaluable for immune response and received HerpV with QS-21 showed a statistically significant CD4+ T cell response (100%; 7/7) to HSV-2 antigens as detected by IFN $\gamma$  Elispot, and the majority of those patients demonstrated a CD8+ T cell response (75%; 6/8). This study is the first to demonstrate that HSPs complexed to viral antigens induce an antigen-specific T cell response in humans. The results from this study were published in the peer-reviewed journal *Vaccine* in September 2011.

We believe this is a first of its kind finding in genital herpes treatment. 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 many infectious diseases. We plan to advance HerpV into a Phase 2 study in 2012 that will measure the effect of vaccination on viral shedding in individuals infected with HSV-2. Experts in HSV-2 clinical research believe that a reduction in viral shedding could translate into clinical benefit.

### **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 74 issued United States patents and 113 issued foreign patents. We also have exclusive rights to 6 pending United States patent applications and 25 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.

## **Table of Contents**

The issued patents that cover the Prophage Series vaccines expire at various dates between 2015 and 2024. The issued patents to HerpV expire at various dates between 2014 and 2017. Our patent to purified QS-21 expired in most territories in 2008. Additional protection for QS-21 in combination with other agents is provided by our other issued patents which expire between 2016 and 2019.

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 Agreement ends when the last of the licensed patents expires (2018) 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 (2022) 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. 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

## **Table of Contents**

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, 2011, we have paid approximately \$340,000 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-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 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 is 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

---

## **Table of Contents**

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.

### **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 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 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 markets Gliadel, both for treatment of recurrent glioma. In addition, TVAX Biomedical is developing an immunotherapy candidate (TVI-Brain-1) 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) and Celldex (CDX-110). One or more of these companies may also develop product candidates for recurrent glioma.

Valtrex (GSK) and Famvir (Novartis) are small molecule drugs marketed for treatment of genital herpes. Other companies are engaged in research for vaccines for treatment of genital herpes. 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 identical to QS-21 that are being used in clinical trials. Several other vaccine adjuvants are in development and could compete with QS-21 for inclusion in vaccines in development. These adjuvants include, but are not limited to, oligonucleotides, under development by Pfizer, Idera, Juvaris, and Dynavax, MF59 under development by Novartis, IC31, under development by Intercell, and



---

## **Table of Contents**

MPL, under development by GSK. Companies such as Adjuvance Technologies, Inc. and CSL Limited, as well as academic institutions, are developing saponin adjuvants, including derivatives and synthetic formulations. It is possible that these compounds could be substituted for the Company's QS-21.

The existence of products developed by these and other competitors, or other products of which we are not aware or which other companies may develop in the future, may adversely affect the marketability of products we develop.

### **Employees**

As of February 24, 2012, we had approximately 54 employees, of whom 8 were Ph.D.s and 2 were MDs. None of our employees are subject to a collective bargaining agreement. We believe that we have good relations with our employees.

### **Corporate History**

Antigenics L.L.C. was formed as a Delaware limited liability company in 1994 and was converted to Antigenics Inc., a Delaware corporation, in February 2000 in conjunction with our initial public offering of common stock. As of January 6, 2011, we changed our name from Antigenics Inc. to Agenesis Inc. to more accurately reflect our existing product pipeline, which has expanded over the years beyond antigen-based vaccines, as well as to highlight our business strategy as we seek partnering opportunities to grow and diversify our business.

### **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.

### **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. 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.*

From our inception through December 31, 2011, we have incurred net losses totaling \$607.7 million. Our net losses for the years ended December 31, 2011, 2010, and 2009, were \$23.3 million, \$21.9 million, and \$30.3 million, respectively. We expect to incur significant losses over the next several years as we continue research and clinical development of our technologies, apply for regulatory approvals, and pursue partnering opportunities, commercialization, and related activities. 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 QS-21, our Prophage Series vaccines and our other product candidates. 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.

## **Table of Contents**

On December 31, 2011, we had \$10.7 million in cash and cash equivalents. We believe that, based on our current plans and activities, our working capital resources at December 31, 2011 and the net proceeds raised from equity sales and license agreements since year-end, along with the estimated proceeds from our license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements through 2013 based on our estimated annual use of cash of \$13-16 million during 2012. 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, 2011, our average monthly cash used in operating activities was \$1.4 million. We do not anticipate significant capital expenditures during 2012.

We have financed our operations primarily through the sale of equity and convertible notes. 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, we will be required to delay, reduce, or eliminate some or all of our development, commercialization and clinical trial programs. 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. We may also be unable to continue our operations, or we may become insolvent.

The weakness of the United States economy and the global economy 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 further deterioration in the credit markets and related financial crisis 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.***

As of December 31, 2011, we had debt outstanding of \$37.9 million in principal, including \$37.5 million in principal of our 8% senior secured convertible notes due August 2014 (the "2006 Notes") and \$100,000 in principal of our 5.25% convertible senior notes due February 2025 (the "2005 Notes"). The 2005 Notes are currently subject to redemption at our option or at the options of the holders on each of February 1, 2015 and February 1, 2020.

Our ability to satisfy our obligations 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.

To date, we have had negative cash flows from operations. For the years ended December 31, 2011, 2010, and 2009, net cash used in operating activities was \$16.2 million, \$14.8 million, and \$24.2 million, respectively.

### ***Our 2006 Notes contain restrictive covenants and are convertible into equity interests in one of our subsidiaries that holds important rights to certain of our QS-21 Stimulon® adjuvant and HerpV technology.***

Our 2006 Notes are secured by the equity of our wholly-owned subsidiary that holds the QS-21 and HerpV technologies. At the option of the holders, our 2006 Notes can be converted in whole or in part into an equity interest in this subsidiary, subject to our ability to preempt the conversion by redeeming the 2006 Notes to be so



## Table of Contents

converted at a price equal to the conversion amount of such notes plus an amount that, when taken together with any cash interest payments previously made with respect to such 2006 Notes, would generate a 30% annual internal rate of return to the holders. If converted into an equity interest of this subsidiary, the ownership interest in the subsidiary will be determined by multiplying (x) the quotient of the conversion amount divided by \$25.0 million, by (y) 30%. In addition, our 2006 Notes grant holders a right of first refusal in any future equity issuance in this subsidiary so that holders of our 2006 Notes may purchase up to 50% of any newly issued equity in this subsidiary. In addition, our 2006 Notes contain a number of restrictions and covenants, including, but not limited to, restrictions and covenants that limit our ability, and the ability of our subsidiary mentioned above, to:

incur certain additional indebtedness;

make certain investments;

enter into certain affiliated party transactions;

create certain liens;

consolidate, merge, sell or otherwise dispose of our assets; and/or

change our line of business.

If the holders elect not to convert into the subsidiary, then at the maturity of the 2006 Notes, we may elect to repay the then outstanding balance in cash or in common stock, subject to certain limitations. If we elect to repay the notes in common stock, we are limited to the number of shares we can issue, whereby the note holders cannot beneficially own in excess of 9.99% of our outstanding common stock at any given time. At December 31, 2011, the outstanding principal balance of the 2006 Notes was \$37.5 million.

***Our licensee may not be able to successfully commercialize Oncophage in Russia and/or we may not receive any revenue from Oncophage sales or related efforts in Russia or certain other CIS countries.***

In April 2008, the Russian Ministry of Public Health issued a registration certificate for the use of Prophage Series vaccine R-100 (Oncophage) for the treatment of kidney cancer patients at intermediate-risk for disease recurrence. The Russian registration was our first product approval from a regulatory authority.

Since approval, minimal sales have occurred in Russia. In December 2011, we secured a partner for Oncophage when we granted NewVac LLC (a subsidiary of ChemRar Ventures LLC, 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. There is no guarantee that NewVac's efforts will be successful, or that we will receive any financial or other benefits from this arrangement. In addition, NewVac has the right to terminate its agreement with us at any time without cause. See Manufacturing problems may cause delays, unanticipated costs, or loss of revenue streams.

While NewVac is establishing manufacturing capabilities in Russia, we are obligated to continue Oncophage manufacturing supply in our Lexington, MA, facility. As long as we manufacture Oncophage in the United States for importation into Russia, complexities unique to the logistics of this product may delay shipments and limit our ability to move commercial product in an efficient manner without incident.

In addition, to date we have not been able to secure government reimbursement and there is no guarantee that NewVac will be able to do so. There appears to be a limited private-pay market in Russia, and many patients will not be capable of paying for Oncophage without third party reimbursement. The reimbursement system in Russia is uncertain and has experienced serious funding and administrative problems in its national and regional reimbursement programs. See If we 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.



## **Table of Contents**

***If we 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 or our licensees' product candidates. 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 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.

***We may not be able to make vaccines from the Prophage Series available in countries other than Russia or in indications other than adjuvant renal cell carcinoma.***

Oncophage is currently only approved for marketing in Russia for the adjuvant treatment of kidney cancer patients at intermediate-risk for disease recurrence and is the only product from our Prophage Series vaccines that is approved for marketing anywhere. The probability and timing of submissions and/or approval of Prophage Series vaccines in any other jurisdiction or indication is uncertain. Phase 2 trials testing the Prophage Series vaccine candidates G-100 and G-200 are currently underway in both newly diagnosed and recurrent glioma, respectively. There can be no assurance that these trials will support BLA filings.

In 2008, we submitted a marketing authorization application ( MAA ), to the European Medicines Agency ( EMA ), requesting conditional authorization of Oncophage in earlier-stage, localized kidney cancer. After its review, the Committee for Medicinal Products for Human Use ( CHMP ) of the EMA adopted a negative opinion on our MAA. Subsequently we withdrew our application and we are no longer actively pursuing opportunities in this territory.

The FDA has indicated that our Phase 3 clinical trials of Oncophage and Prophage Series vaccine M-200 cannot, by themselves, support BLA filings in the studies' indications (renal cell carcinoma and metastatic melanoma). Furthermore, our existing data may not support registration or approval in other territories outside of Russia, including in Europe, as this Phase 3 trial did not reach statistical significance in its primary endpoint of recurrence-free survival in the total patient population.

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 FDA and foreign regulatory agencies, including the EMA, 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.

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

Oncophage is currently only approved for sale in Russia. Russia is an evolving market and regulatory, legal, and commercial structures are less predictable than in more mature markets. This unpredictability, as well as potential geopolitical instability in the Russian region, could negatively impact the regulatory and/or commercial environment there, which in turn could have an adverse effect on our business.

## **Table of Contents**

In addition, various other 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 product and service needs of foreign customers, difficulties in building and managing foreign relationships, the performance of our licensees or collaborators, and unexpected regulatory, economic, or political changes in foreign markets.

***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 intense 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. See Part I-Item 1 Business Competition in this Annual Report on Form 10-K.

Genentech markets Avastin and Eisai markets Gliadel, both for treatment of recurrent glioma. In addition, TVAX Biomedical is developing an immunotherapy candidate (TVI-Brain-1) 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) and Celldex (CDX-110). One or more of these companies may also develop product candidates for recurrent glioma.

There is no guarantee that our products or product candidates will be able to compete with potential future products being developed by our competitors. For example, Oncophage may compete with therapies currently in development for non-metastatic renal cell carcinoma, such as Willex AG's Rencarex (WX-G250), 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. 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.

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

Our patent to purified QS-21 expired in most territories in 2008. Additional protection for our QS-21 proprietary adjuvant in combination with other agents is provided by our other patents. Our license and manufacturing agreements for QS-21 typically provide royalties for at least 10 years after commercial launch independent of patent expiry. However, there is no guarantee that we will be able to collect royalties in the future.

We are aware of compounds that claim to be identical to QS-21 that are being used in clinical trials. Several other vaccine adjuvants are in development and could compete with QS-21 for inclusion in vaccines in development. These adjuvants include, but are not limited to, oligonucleotides, under development by Pfizer, Idera, Juvaris, 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 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. Companies such as Adjuvance Technologies, Inc. and CSL

---

## **Table of Contents**

Limited, as well as academic institutions, are developing saponin adjuvants, including derivatives and synthetic formulations. It is possible that these compounds could be substituted for the Company's QS-21 in partnered programs.

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.

***Our commercial and international operations experience and resources are limited and may need to be developed or acquired. If we fail to do so, our revenues may be limited or nonexistent. In addition, we may be required to incur significant costs and devote significant efforts to augment our existing capabilities.***

As we have limited experience with commercial and international operations, it may be difficult to accurately estimate our costs. We currently do not have employees, manufacturing, or business operations facilities outside of the United States and we will rely significantly on consultants, partners, and other third parties to conduct our sales, marketing, and distribution operations. If these third parties are unable to fulfill their obligations this could have a material adverse effect on our commercialization efforts. If in the future we elect to perform sales, marketing, and distribution functions ourselves, we will face a number of additional risks, including the need to recruit experienced marketing and sales personnel, or incur significant expenditures. In addition, we may need to compete with other companies that have more experienced and better-funded operations. Where we have licensed our products to third-party collaborators or licensees, we will be dependent on their commercial operations, sales and marketing expertise and resources, and any revenues we receive from those products will depend primarily on the sales and marketing efforts of others.

***Manufacturing problems may cause delays, unanticipated costs, or loss of revenue streams.***

If the future commercial demand for our Prophage Series vaccine Oncophage or clinical demand for other 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, Massachusetts 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.





---

## **Table of Contents**

Except in the case of GSK and JANSSEN AI, we have retained worldwide manufacturing rights for QS-21. We have the right to subcontract manufacturing for QS-21 for our other existing and future QS-21 manufacturing and supply needs, and we have a supply agreement with a contract manufacturer for the production of QS-21 through September 2012. If we are not able to renew this agreement we may not be able to supply QS-21 to meet future supply obligations on favorable terms or at all. For example, although GSK is a source of QS-21 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 never have the ability to manufacture commercial grade QS-21

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.

Manufacturing is also subject to extensive government regulation. Regulatory authorities must approve the facilities in which human health care products are produced. 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.

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

We currently rely upon and expect to continue to rely upon third party licensees, particularly GSK and JANSSEN AI, to develop, test, market and manufacture vaccines that utilize our QS-21 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, our licensees have generally agreed to pay us license fees, supply payments, milestone payments and royalties on product sales for a minimum of 10 years after commercial launch of a vaccine that utilizes QS-21. As each licensee controls its own product development process, we cannot predict our licensees' requirements for QS-21 in the future or to what extent, if any, they will develop vaccines that use QS-21 as an adjuvant. Our licensees may initiate or cease programs containing QS-21 at any time. In the event that our licensees develop vaccines using QS-21, 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 commercial grade QS-21, we have amended our agreements so that they are permitted to manufacture their own QS-21. We are unable to predict what amount of QS-21, if any, will be purchased from us by other licensees or collaborators in the future. Any such inability to receive anticipated QS-21 revenues would have a material adverse effect on our business, financial condition and results of operations.

## **Table of Contents**

***Our patent on QS-21 composition of matter has already expired in virtually all territories and we rely on unpatented technology and know-how to protect our rights to QS-21.***

Our patent on QS-21 composition of matter has already expired in virtually all territories, and our patent rights are limited to protecting certain combinations of QS-21 with other adjuvants or formulations of QS-21 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, therefore, 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.

***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. 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. As of December 31, 2011, we have spent approximately 17 years and \$292.0 million on our research and development program in heat shock proteins for cancer.

The timing and success of a clinical trial is dependent on 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.

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 timeframe anticipated, and our business will suffer.



## **Table of Contents**

***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 United States 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.

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.

***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.

## **Table of Contents**

***Failure to enter into significant licensing, distribution and/or collaboration agreements may hinder our efforts to develop and commercialize our product candidates and will increase 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 Oncophage or any of the other Prophage Series vaccines other than the recent 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. Due to the announcements in March 2006 that part I of our Phase 3 trial in renal cell carcinoma did not achieve its primary endpoint in the intent to treat population, and in November 2009, that the CHMP adopted a negative opinion on our MAA, and because companies may be skeptical regarding the potential success of a patient-specific product candidate, 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. This product is at an early stage and collaborative partners or licensees may defer discussions until results from early clinical trials become available, or they may not engage in such discussions at all.

***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 large part on the efforts of our institutional collaborators, such as the Brain Tumor Research Center at the UCSF, which is conducting Phase 2 clinical trials of Prophage Series vaccines G-100 and G-200 for the treatment of glioma. In addition, substantially all product candidates containing QS-21, other than HerpV, depend on the success of our collaborative partners or licensees, and the Company's 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. In addition, 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.

Development activities 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

## **Table of Contents**

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.

***If we or our licensee are unable to purify heat shock proteins we may have difficulty successfully initiating or completing clinical trial or supporting commercial sales of Oncophage in Russia. Even if we or our licensees do successfully complete ongoing or future clinical trials or are successful manufacturing Oncophage commercially we may have difficulty generating a sizable market or commercial sales.***

Depending on the type and stage of cancer and the patient population, the 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 our licensee, their ability to purify heat shock proteins from that type of cancer. If we or our licensee 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 enrolment 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. 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 in our ongoing Phase 2 clinical trials in glioma. We expect to continue to devote resources to allow for a better evaluation of tumor characteristics and screening methods in an attempt to increase manufacturing success rates.

In December 2011, we granted NewVac LLC (a subsidiary of ChemRar Ventures LLC, 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. To be successful, NewVac will have to build and equip a manufacturing facility, hire, train and retain staff, and validate the facility systems and process. There is no guarantee that NewVac will be able to accomplish these tasks and if they are unable or delayed in becoming operational, the commercial and developmental efforts may be delayed or limited. 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 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.

***If we fail to sustain and further build our intellectual property rights, competitors may be able to take advantage of our research and development efforts to develop competing products.***

If we are not able to protect our proprietary technology, trade secrets, and know-how, our competitors may use our past developments and technologies to develop competing products. We have exclusive rights to 74 issued United States patents and 113 issued foreign patents. We also have exclusive rights to 6 pending United States patent applications and 25 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,

## **Table of Contents**

are generally uncertain and involve complex legal, scientific, and factual questions. The standards which the United States Patent and Trademark Office 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.

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 composition of matter has already expired in virtually all territories, our patent rights are limited to protecting certain combinations of QS-21 with other adjuvants or formulations of QS-21 with other agents, e.g., excipients that improve performance of the compound. However, there is no guarantee that a third party would necessarily choose to use QS-21 in combination with such adjuvants or formulate it with the excipients covered by our patents. We are aware of at least one other party that makes a synthetic version of QS-21, claimed by such party to be equivalent in activity to natural QS-21, and has also developed derivatives of QS-21, which have shown biological activity.

In addition to our patented technology, we also rely on unpatented technology, trade secrets, and confidential information. We may not be able to effectively protect our rights to this technology or information. Other parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We generally require each of our employees, consultants, collaborators, and certain contractors to execute a confidentiality agreement at the commencement of an employment, consulting, collaborative, or contractual relationship with us. However, these agreements may not provide effective protection of our technology or information, or in the event of unauthorized use or disclosure, they may not provide adequate remedies.

***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights in, or to use, our technology.***

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask a court to rule that our patents are invalid and should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of our patents. In addition, there is a risk that the court will decide that our patents are not valid and that we do not have the right to stop the other party from using the claimed inventions. There is also the risk that, even if the validity of our patents is upheld, the court will refuse to stop the other party on the grounds that such other party's activities do not infringe our patents.

We may not have rights under some patents or patent applications related to some of our existing and proposed products or processes. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, such as those described below, in order to develop, use, manufacture, sell, or import some of our existing or proposed products, or develop or use some of our existing or proposed processes, we or our collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad, or those that might issue from United States and foreign patent applications. In such an event, we likely would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to exploit these products or processes.



## **Table of Contents**

Furthermore, a third party may claim that we are using inventions covered by such third-party's patents or other intellectual property rights and may go to court to stop us from engaging in our normal operations and activities. These lawsuits are expensive. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. There is a risk that a court would decide that we are infringing the third-party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party substantial damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. Moreover, patent holders sometimes send communications to a number of companies in related fields suggesting possible infringement, and we, like a number of biotechnology companies, have received such communications in the past and may receive others in the future. If we are sued for patent infringement, we would need to demonstrate that our products either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, which we may not be able to do. Proving invalidity, in particular, is difficult, since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

If patent litigation or other proceeding is resolved against us, we or our licensees or collaborators may be enjoined from using, manufacturing, selling, or importing our products or processes without a license from the other party, and we may be held liable for significant damages. We may not be able to obtain any required licenses on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to enter into collaborations with other entities, obtain financing, or compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time and other resources.

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

We are a party to various license agreements under which we receive the right to practice and use important third-party patent rights and we may enter into additional licenses in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

***If we fail to retain the services of our key employees and external consultants 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 severed 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.

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

## **Table of Contents**

rely more heavily on outside consultants and third parties. 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.

***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.

Our directors and officers insurance policies provide \$30.0 million of coverage. This insurance coverage may not be sufficient to cover us for future claims.

***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 Oncophage in other territories and/or sell our other product candidates commercially. An individual may bring a product liability claim against us if Oncophage or one of our product candidates causes, or merely appears to have caused, an injury. Product liability claims may result in:

decreased demand for Oncophage or 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. To date, we have obtained transportation insurance coverage for commercial Oncophage being shipped to Russia. 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.

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

## Edgar Filing: AGENUS INC - Form 424B3

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

## **Table of Contents**

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.

### **Risks Related to our Common Stock**

*Unaffiliated holders of certain convertible securities may convert such securities into a substantial percentage of our outstanding common stock.*

According to publicly filed documents, Mr. Brad M. Kelley beneficially owns approximately 924,000 shares of our outstanding common stock and 31,620 shares of our series A convertible preferred stock. The shares of preferred stock are currently convertible at any time into approximately 333,000 shares of common stock at an initial conversion price of \$94.86, are non-voting, and carry a 2.5% annual dividend yield. If Mr. Kelley had converted all of the shares of preferred stock on December 31, 2011, he would have held approximately 6% of our outstanding common stock. We currently have a right of first refusal agreement with Mr. Kelley that provides us with limited rights to purchase certain of Mr. Kelley's shares if he proposes to sell them to a third party.

According to publicly filed documents, Ingalls & Snyder, LLC beneficially owns 1,282,517 shares of our common stock, representing approximately 6% of our outstanding common stock. In addition, Ingalls & Snyder LLC holds \$30.0 million aggregate principal amount of our 2006 Notes. Upon maturity in 2014, we may elect to repay the outstanding balance of our 2006 Notes in cash or in common stock, subject to certain limitations. If we elect to satisfy the outstanding balance with common stock at maturity (August 2014), the number of shares issued will be determined by dividing the cash obligation by 90 percent of the weighted average price of the common shares for the 20 trading days preceding the maturity date of the 2006 Notes. This right is subject to our market capitalization exceeding \$300 million at such time. In no event will the note holder be obligated to accept equity that would result in them owning in excess of 9.99% of the Company's outstanding common stock at any given time in connection with any conversion, redemption, or repayment of the 2006 Notes.

Collectively, Mr. Kelley, Ingalls & Snyder LLC, and Dr. Armen, our Chief Executive Officer, control approximately 17% of our outstanding common stock as of December 31, 2011, providing the ability, if they vote in the same manner, to determine the outcome of matters submitted to a stockholder vote. If Mr. Kelley were to convert all of his preferred stock into common stock, the combined total would increase to 19%. Additional purchases of our common stock by Mr. Kelley also would increase both his percentage of outstanding voting rights and the percentage combined with our Chief Executive Officer. While Mr. Kelley's shares of preferred stock do not carry voting rights, the shares of common stock issuable upon conversion carry the same voting rights as other shares of common stock.

## **Table of Contents**

### ***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 The Nasdaq Capital Market.

On March 3, 2011, we were notified by the Listing Qualifications Staff that we were not in compliance with the minimum bid price requirement set forth in Nasdaq Marketplace Rule 5550(a)(2) (the Bid Price Requirement ) because the bid price for our common stock had closed below the minimum \$1.00 per share requirement for 30 consecutive business days.

On October 3, 2011, we effected a one-for-six reverse stock split of our common stock to, in part, regain compliance with the Bid Price Requirement. On October 17, 2011, we received notice from the Nasdaq Listing Qualification Panel (the Panel ) that we had regained compliance with the Bid Price Requirement and otherwise satisfied all requirements for continued listing on Nasdaq. Though the bid price of our common stock has remained above \$1.00 per share since the reverse split, we cannot guarantee that it will remain at or above \$1.00 per share. If the bid price drops below \$1.00 per share, our common stock could become subject to delisting again, and we may need to seek shareholder approval for an additional reverse split. A second reverse split could produce negative effects and we cannot provide any assurance that it would result in a long-term or permanent increase in the bid price of our common stock. For example, a second reverse split could make it more difficult for us to comply with other listing standards of Nasdaq, including requirements related to the minimum number of shares that must be in the public float, the minimum market value of publicly held shares and the minimum number of round lot holders. In addition, investors might consider the increased proportion of unissued authorized shares of common stock to issued shares of common stock to have an anti-takeover effect under certain circumstances by allowing for dilutive issuances which could prevent certain shareholders from changing the composition of our Board of Directors. 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. This was the third time we were non-compliant with the Bid Price Requirement since our move to The Nasdaq Capital Market in April 2009.

### ***We have implemented a reverse stock split, which has reduced our trading volume and may result in a decrease in our market capitalization.***

On October 3, 2011, we implemented a one-for-six reverse stock split of our common stock to, in part, regain compliance with the Nasdaq Bid Price Requirement. We cannot guarantee that the increase of our common stock price resulting from the reverse split will be proportionate to the reverse split ratio, will last in the marketplace for any length of time, will remain at a price sufficient to meet the listing requirements of Nasdaq or will be sufficient to facilitate raising capital.

### ***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

## **Table of Contents**

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 the 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 ensuing 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, 2011, and for the year ended December 31, 2011, the closing price of our common stock has fluctuated between \$1.80 and \$315.78 per share and \$2.00 and \$6.66 per share, respectively. The average daily trading volume for the year ended December 31, 2011 was approximately 79,000 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:

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;

developments concerning proprietary rights, including patent and litigation matters;

publicity regarding actual or potential results with respect to product candidates under development; and

quarterly fluctuations in our financial results.

## **Table of Contents**

### ***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, 2011, we had approximately 21,492,000 shares of common stock outstanding. All of these shares are eligible for sale on The Nasdaq Capital Market, although certain of the shares are subject to sales volume and other limitations. We have filed registration statements to permit the sale of approximately 4,167,000 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 125,000 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 3,333,000 shares of our common stock pursuant to our At the Market Sales Agreement. As of December 31, 2011, an aggregate of 7.3 million shares remain available for sale under these registration statements. The market price of our common stock may decrease based on the expectation of such sales.

As of December 31, 2011, options to purchase 1,814,161 shares of our common stock with a weighted average exercise price per share of \$8.38 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, 2011, we have 135,791 nonvested shares outstanding.

### ***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 Securities and Exchange Commission and the 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, 2011, our procedures are subject to the risk that our controls may become inadequate because of changes in conditions or as a result of a deterioration in compliance with such procedures. No assurance is given that our procedures and processes for detecting weaknesses in our internal control over financial reporting will be effective.

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

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

None



**Table of Contents****Item 2. Properties**

We maintain our 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 2013 with an option to renew for two additional ten-year periods. We have sublet a portion of this facility under a lease that expires in July 2012.

We also lease approximately 5,400 square feet in an office building in New York, New York. Our New York lease terminates in April 2012.

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**

Agenus, our Chairman and Chief Executive Officer ( CEO ), Garo H. Armen, Ph.D., and two investment banking firms that served as underwriters in our initial public offering were named as defendants in a federal civil class action lawsuit in the United States District Court for the Southern District of New York. Substantially similar actions were filed concerning the initial public offerings for more than 300 different issuers, and the cases were coordinated for pre-trial purposes as In re Initial Public Offering Securities Litigation, 21 MC 92. The suit alleged that the brokerage arms of the investment banking firms charged secret excessive commissions to certain of their customers in return for allocations of our stock in the offering. The suit also alleged that shares of our stock were allocated to certain of the investment banking firms customers based upon agreements by such customers to purchase additional shares of our stock in the secondary market. These coordinated lawsuits were resolved pursuant to a global settlement. Any portion of the settlement attributable to Agenus has been funded by insurance, and Agenus bears no financial liability. Appeals filed by various objectors to the settlement have been dismissed.

We may currently be a party, or may become a party, to other 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, as well. 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.

**Item 4. Mine Safety Disclosures**

Not applicable

**Executive Officers of the Registrant**

Set forth below is certain information regarding our current and certain former executive officers, including their age, as of March 1, 2012:

Name	Age	Title
Garo H. Armen, Ph.D.	59	Chairman of the Board and Chief Executive Officer
Shalini Sharp	37	Vice President and Chief Financial Officer
Christine M. Klaskin	46	Vice President, Finance and Principal Accounting Officer
Karen H. Valentine	40	Vice President and General Counsel
Kerry A. Wentworth	39	Vice President, Clinical, Regulatory & Quality

---

**Table of Contents**

***Garo H. Armen, PhD*** Dr. Armen is Chairman and CEO of Agenesis Inc., the biotechnology company he co-founded with Pramod Srivastava in 1994. From mid-2002 through 2004, he was Chairman of the Board of Directors for the biopharmaceutical company Elan Corporation, plc. Dr. Armen is also the founder and President of the Children of Armenia Fund, a charitable organization established in 2000 that is dedicated to the positive development of the children and youth of Armenia.

***Shalini Sharp*** Ms. Sharp is Chief Financial Officer of Agenesis Inc. Prior to joining Agenesis Inc. in 2003, Ms. Sharp was director of strategic planning at Elan Corporation, plc., where she served as chief of staff to the chairman of the board during the restructuring process and drove to completion a number of strategic corporate and financial transactions. Ms. Sharp was previously a management consultant at McKinsey & Company, specializing in pharmaceuticals and medical devices. Ms. Sharp received her BA and MBA from Harvard University.

***Christine M. Klaskin*** Christine M. Klaskin is Vice President, Finance and Principal Accounting Officer. Since joining Agenesis 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 to joining Agenesis, Ms. Klaskin was employed by Arthur Andersen as an audit manager. Ms. Klaskin received her Bachelor of Accountancy from The George Washington University.

***Karen H. Valentine*** Karen Higgins Valentine is Vice President and General Counsel and also serves as Secretary and Chief Compliance Officer of the Company. Prior to joining Agenesis Inc. in 2004, Ms. Valentine was an associate in the biotechnology practice of Palmer & Dodge LLP (now Edwards, Wildman Palmer LLP). While at the law firm, she provided corporate law services to a broad range of both public and private corporations, and developed an expertise in the areas of licensing and strategic collaborations. 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 is Vice President, Clinical, Regulatory & Quality. Before joining Agenesis 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
<b>2010</b>		
First Quarter	\$ 7.20	\$ 3.60
Second Quarter	10.32	4.20
Third Quarter	6.72	4.38
Fourth Quarter	6.72	5.22
<b>2011</b>		
First Quarter	6.96	5.16
Second Quarter	6.72	4.62
Third Quarter	5.10	2.76
Fourth Quarter	4.43	1.92

As of February 16, 2012, there were approximately 1,700 holders of record and approximately 21,000 beneficial holders of our common stock.

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

**Stock Performance**

The following graph shows the cumulative total stockholder return on our common stock over the period from December 31, 2006 to December 31, 2011, 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, 2006. 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 Contents**

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

	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/31/2011
Agenus Inc.	100.00	111.48	26.23	34.97	55.19	18.21
NASDAQ Stock Market (U.S. Companies) Index	100.00	109.81	65.29	93.95	109.84	107.86
NASDAQ Biotechnology Index	100.00	104.58	91.38	105.66	121.52	135.86

***Recent Sales of Unregistered Securities*** *None*

Information concerning our equity compensation plans is set forth in our Definitive Proxy Statement with respect to our 2012 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.

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

We have derived the consolidated balance sheet data set forth below as of December 31, 2011 and 2010, and the consolidated statement of operations data for each of the years in the three-year period ended December 31, 2011, 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.

**Table of Contents**

Given our history of incurring operating losses, management believes that it is more likely than not that any deferred tax assets will not be realized through future earnings. Therefore, no income tax benefit has been recognized in the consolidated 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 (see Note (1) below).

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 \$8.1 million, \$11.6 million, \$18.7 million, \$46.9 million, and \$4.6 million in the years ended December 31, 2011, 2010, 2009, 2008, and 2007, respectively.

	2011	For the Year Ended December 31,			2007
		2010	2009	2008	
		(In thousands, except per share data)			
Consolidated Statement of Operations Data:					
Revenue	\$ 2,756	\$ 3,360	\$ 3,334	\$ 2,651	\$ 5,552
Operating expenses:					
Cost of goods sold		(123)			
Research and development	(11,023)	(12,878)	(16,903)	(20,663)	(21,789)
General and administrative	(10,820)	(12,112)	(14,110)	(19,832)	(17,041)
Loss from operations	(19,087)	(21,753)	(27,679)	(37,844)	(33,278)
Non-operating income	2	4,680	2,568	12,356	1
Interest expense, net	(4,191)	(4,834)	(5,207)	(5,313)	(4,658)
Net loss (1)	(23,276)	(21,907)	(30,318)	(30,801)	(37,935)
Dividends on series A convertible preferred stock	(790)	(790)	(790)	(790)	(790)
Net loss attributable to common stockholders	(24,066)	\$ (22,697)	\$ (31,108)	\$ (31,591)	\$ (38,725)
Net loss attributable to common stockholders per common share, basic and diluted					
	\$ (1.21)	\$ (1.41)	\$ (2.36)	\$ (3.00)	\$ (5.00)
Weighted average number of shares outstanding, basic and diluted	19,899	16,108	13,170	10,542	7,752

	2011	2010	December 31, 2009	2008	2007
			(In thousands)		
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents, and short-term investments	\$ 10,748	\$ 19,782	\$ 30,065	\$ 34,463	\$ 18,679
Total current assets	12,004	20,854	31,533	35,486	20,782
Total assets	19,808	30,907	45,874	56,822	44,351
Total current liabilities	4,754	5,416	5,355	6,997	8,383
Long-term debt, less current portion	32,726	34,050	49,494	64,126	71,524
Stockholders' deficit	(20,831)	(14,707)	(16,975)	(20,330)	(41,370)

- (1) Given our history of incurring operating losses, no income tax benefit has been recognized in our consolidated 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 Contents**

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

Our current research and/or development activities are focused on developing technologies and product candidates to treat cancers and infectious diseases. Our core technology portfolio consists of our Saponin Platform (based on our saponin adjuvant based technologies) and our Heat Shock Protein ( HSP ) Platform (based on our HSP based technologies). Some of our key candidates from these technology platforms are QS-21 Stimulon® adjuvant ( QS-21 ), the Prophage Series vaccines and HerpV.

QS-21 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 are GlaxoSmithKline (GSK) and JANSSEN Alzheimer Immunotherapy ( JANSSEN AI ). There are approximately 15 vaccines containing QS-21 in clinical development by our licensees, including a total of four in Phase 3 testing for malaria, melanoma, non-small cell lung cancer and shingles. The first products containing QS-21 are anticipated to be launched in the 2013-2014 timeframe, and we are entitled to royalties for at least 10 years post-launch.

The Prophage Series vaccines are a patient specific application of our HSP Platform. The Prophage Series vaccine R-100 is referred to as Oncophage® vaccine (vitespen) and is approved in Russia for the treatment of renal cell carcinoma ( RCC ; kidney cancer) in patients at intermediate risk of recurrence. In December 2011, we granted NewVac LLC (a subsidiary of ChemRar Ventures LLC) 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. In addition, Phase 2 trials are underway in the United States testing the Prophage Series vaccine candidates G-100 and G-200 in newly diagnosed and recurrent glioma, respectively.

Also derived from our HSP Platform technologies, HerpV is a recombinant, synthetic, non-patient specific therapeutic vaccine candidate for the treatment of genital herpes. It has completed Phase 1 testing, where it was shown to elicit both CD4 and CD8 positive T cell responses a first of its kind finding in genital herpes treatment. Because the product contains multiple antigens derived from the herpes simplex 2 virus (HSV-2), it may be applicable to a broader patient population and may have potential in managing outbreaks and disease transmission. We consider this to be a platform technology, since with the integration of heat shock proteins with antigenic peptides we could potentially create therapeutic vaccines for various infectious diseases. We plan to initiate a Phase 2 trial during the second half of 2012.

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 the Prophage G-Series vaccines, G-100 and G-200, QS-21, and HerpV. We are also exploring in-licensing opportunities. Our business activities have included product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development, market development, business development, and support of our collaborations. Research and development expenses for the years ended December 31, 2011, 2010, and 2009, were \$11.0 million, \$12.9 million, and \$16.9 million, respectively. We have incurred significant losses since our inception. As of December 31, 2011, we had an accumulated deficit of \$607.7 million.

We have financed our operations primarily through the sale of equity and convertible notes. We believe that, based on our current plans and activities, our working capital resources at December 31, 2011 and the net proceeds raised from equity sales and license agreements since year-end, along with the estimated proceeds from our license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements through 2013 based on our estimated annual use of cash of \$13-16 million during 2012. We expect to attempt to raise additional funds in advance of depleting our funds. We may attempt to raise additional 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) our product, Oncophage and/or our other Prophage Series vaccines, (2) vaccines containing QS-21 under development by our licensees, and/or (3) potentially other product candidates, each of which will require additional capital.

## **Table of Contents**

Our common stock is currently listed on The Nasdaq Capital Market under the symbol AGEN. In April 2009, we moved from The Nasdaq Global Market to The Nasdaq Capital Market as part of our plan to regain compliance with minimum market value requirements. On March 3, 2011, we were notified by the Listing Qualifications Staff of Nasdaq (the Staff) that we were not in compliance with the minimum bid requirement set forth in Nasdaq Marketplace Rule 5550(a)(2) (the Bid Price Requirement) because the bid price for our common stock had closed below the minimum \$1.00 per share requirement for 30 consecutive business days. Effective October 3, 2011, our certificate of incorporation was amended to effect a reverse stock split of our common stock on the basis of one post-split share for every six pre-split shares to, in part, regain compliance with the Bid Price Requirement. On October 17, 2011, we received notice from the Nasdaq Listing Qualifications Panel (the Panel) that we had regained compliance with the Bid Price Requirement and otherwise satisfied the requirements for continued listing on Nasdaq.

## **Historical Results of Operations**

### ***Year Ended December 31, 2011 Compared to the Year Ended December 31, 2010***

**Revenue:** We generated revenue of \$2.8 million and \$3.4 million during the years ended December 31, 2011 and 2010, respectively. Revenue includes license fees and royalties earned, and in 2010, revenue earned on shipments of QS-21 to our QS-21 licensees, grants earned and Oncophage sales. In the years ended December 31, 2011 and 2010, we recorded revenue of \$1.6 million and \$1.5 million, respectively, from the amortization of deferred revenue related to our QS-21 partnered programs.

**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 decreased 15% to \$11.0 million for the year ended December 31, 2011 from \$12.9 million for the year ended December 31, 2010. The decrease is primarily due to the overall status of our development programs and includes \$1.3 million for amortization and depreciation expense, \$495,000 related to our noncash share-based compensation expense, and \$230,000 related to the reduced production of clinical product to our licensees due to the transfer of manufacturing rights.

**General and Administrative:** General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses decreased 11% to \$10.8 million for the year ended December 31, 2011 from \$12.1 million for the year ended December 31, 2010. This decrease is largely due to the status of our development programs and our cost containment efforts and includes \$600,000 related to our employee and director noncash share-based compensation expense, \$400,000 for amortization and depreciation expense, and \$200,000 for personnel related expenses.

**Non-operating Income:** Non-operating income of \$4.7 million for the year ended December 31, 2010 consists of a net gain of \$2.8 million on the extinguishment of a portion of our 2005 Notes and the change in the fair value of our derivative liability since December 31, 2009 of \$1.9 million.

**Interest Expense:** Interest expense decreased to \$4.2 million for the year ended December 31, 2011 from \$4.9 million for the year ended December 31, 2010. This decrease is related to the repurchase of substantially all of our 2005 Notes during the year ended December 31, 2010. Interest on our 2006 Notes is payable semi-annually on December 30 and June 30 in cash or, at our option, in additional notes or a combination thereof. During the years ended December 31, 2011 and 2010, interest expense included \$2.8 million and \$2.6 million, respectively, paid in the form of additional 2006 Notes.

### ***Year Ended December 31, 2010 Compared to the Year Ended December 31, 2009***

**Revenue:** We generated revenue of \$3.4 million and \$3.3 million during the years ended December 31, 2010 and 2009, respectively. Revenue includes revenue earned on shipments of QS-21 to our QS-21 licensees, license fees, royalties earned, and in 2010, grants earned and Oncophage sales. In the years ended December 31, 2010 and 2009, we recorded \$1.5 million each period from the amortization of deferred revenue related to our QS-21 partnered programs.

**Table of Contents**

**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 decreased 24% to \$12.9 million for the year ended December 31, 2010 from \$16.9 million for the year ended December 31, 2009. The decrease included declines of \$1.7 million for personnel related expenses and \$367,000 for facility related costs primarily due to cost containment efforts, and \$1.8 million for various outside services primarily related to the status of our efforts in Russia and other territories.

**General and Administrative:** General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses decreased 14% to \$12.1 million for the year ended December 31, 2010 from \$14.1 million for the year ended December 31, 2009. This decrease is largely attributable to declines of \$1.5 million for various outside services primarily relating to the status of our efforts in Russia and other territories, and \$145,000 in employee and director noncash share-based compensation expense.

**Interest Expense:** Interest expense decreased to \$4.9 million for the year ended December 31, 2010 from \$5.3 million for the year ended December 31, 2009. This decrease is related to the repurchase of a portion of our 2005 Notes. Interest on our 2006 Notes is payable semi-annually on December 30 and June 30 in cash or, at our option, in additional notes or a combination thereof. During the years ended December 31, 2010 and 2009, interest expense included \$2.6 million and \$2.4 million, respectively, paid in the form of additional 2006 Notes.

**Interest Income:** Interest income decreased 73% to \$38,000 for the year ended December 31, 2010 from \$137,000 for the year ended December 31, 2009. This decrease is primarily attributable to a decrease in our average cash, cash equivalents and short-term investments balance coupled with declining interest rates earned on our cash, cash equivalents, and short-term investments. Our average interest rate earned decreased from 0.49% for the year ended December 31, 2009 to 0.15% for the year ended December 31, 2010.

**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 2011, these research and development programs consisted largely of our Prophage Series vaccines and QS-21, as indicated in the following table (in thousands).

Research and Development Program	Product	Year Ended December 31,			Prior to 2009	Total
		2011	2010	2009		
Heat shock proteins for cancer	Prophage Series Vaccines	\$ 10,182	\$ 10,960	\$ 15,309	\$ 255,582	\$ 292,033
Heat shock proteins for infectious diseases	HerpV	734	644	262	17,448	19,088
Vaccine adjuvant *	QS-21	94	1,185	1,071	10,148	12,498
Other research and development programs		13	89	261	33,177	33,540
Total research and development expenses		\$ 11,023	\$ 12,878	\$ 16,903	\$ 316,355	\$ 357,159

\* 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 Prophage Series vaccines are in various stages of development as described below. Significant additional expenditures will be required if we start new trials, encounter delays in our programs, apply for regulatory approvals, continue



## **Table of Contents**

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 the further development of our Prophage Series vaccines is subject to evaluation and uncertainty, and because HerpV is an early-stage clinical development candidate, 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 depend on our collaborative partners or licensees successfully completing clinical trials, successfully manufacturing QS-21 to meet demand, obtaining regulatory approvals and successfully commercializing product candidates containing QS-21.

### ***Product Development Portfolio***

#### ***QS-21***

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 are GSK and JANSSEN AI. There are 15 vaccines containing QS-21 in clinical development, including a total of four in Phase 3 testing for malaria, melanoma, non-small cell lung cancer and shingles. The first products containing QS-21 are anticipated to be launched in the 2013-2014 timeframe. The pipeline of product candidates containing QS-21 is extraordinarily diverse, encompassing prophylactic as well as therapeutic vaccines for infectious diseases, multiple cancer types, and Alzheimer's disease. The Company does not incur clinical development costs for these products. For additional information regarding QS-21, please read Part I-Item 1. **Business** of this Annual Report on Form 10-K.

#### ***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. 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.

We believe that the collective results from clinical trials thus far show that the vaccine candidates that have been clinically evaluated have a favorable safety profile. We also believe that available results from clinical trials suggest that treatment with the Prophage Series vaccines can generate immunological and anti-tumor responses. For additional information regarding our Prophage Series vaccines, 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 \$607.7 million as of December 31, 2011. We expect to incur significant losses over the next several years as we continue clinical trials, apply for regulatory approvals, prepare for commercialization, and continue development of our technologies. 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. From our inception through December 31, 2011, we have raised aggregate net proceeds of \$514.4 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 notes. During February 2010, we entered into an At the Market Sales Agreement (the "2010 ATM") with McNicoll, Lewis & Vlak LLC and Wm Smith & Co (the "Sales Agents") under which we were able to sell an aggregate of up to 3,333,333 shares of our common stock from

## **Table of Contents**

time to time through the Sales Agents. As of February 29, 2012, we issued approximately 2.4 million shares of our common stock in at the market offerings through the Sales Agents and raised net proceeds of approximately \$12.6 million after deducting offering costs of approximately \$450,000. As of December 31, 2011, we had debt outstanding of \$37.9 million in principal, including \$37.5 million in principal of our 2006 Notes maturing August 31, 2014 and \$100,000 in principal of our 2005 Notes maturing February 20, 2025. The 2005 Notes are currently redeemable by us or at the option of the holders on February 1, 2015 and 2020.

Our cash, cash equivalents, and short-term investments at December 31, 2011 were \$10.7 million, a decrease of \$9.0 million from December 31, 2010. We believe that, based on our current plans and activities, our cash balance of \$10.7 million as of December 31, 2011, plus the \$18 million net proceeds from equity offerings and license agreements since year-end, along with the estimated additional proceeds from our license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements through 2013 based on our estimated annual use of cash of \$13-16 million during 2012. 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 believe that, based on our current plans and activities, our working capital resources at December 31, 2011 and the net proceeds raised from equity sales and license agreements since year-end, along with the estimated proceeds from our license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements into 2013. We closely monitor our cash needs. 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 commercially feasible. In addition, we will continue to adjust other spending as needed in order to preserve liquidity. We expect to attempt to raise additional funds in advance of depleting our current funds. In order to fund our operations through 2012 and beyond, we will need to contain costs and raise additional funds. We may attempt to raise additional 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 additional 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. As noted above, we expect to attempt to raise additional funds in advance of depleting our funds; however, 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 of Oncophage and/or one or more partnering arrangements for our other Prophage Series vaccines, successful commercialization of vaccines containing QS-21 under development by our licensees, and potentially successful commercialization of other product candidates, each of which will require additional capital, as discussed above. We hope to earn royalties from our QS-21 product in the 2013-2014 timeframe. Please see Note Regarding Forward-Looking Statements on page 2 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.

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 payments to be \$47.6 million over the term of the studies. Through December 31, 2011, we have expensed \$47.1 million as research and development expenses and \$46.8 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 \$6.5 million, all of which has been paid as of December 31, 2011. We plan to enter into additional sponsored research agreements, and we anticipate significant additional expenditures will be required to advance

**Table of Contents**

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 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. We have various agreements, for example, with collaborative partners and/or licensees, which allow the use of our QS-21 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 provide us with rights to manufacture and supply QS-21 to the collaborative partner or licensee and also call for royalties to be paid to us on future sales of licensed vaccines that include QS-21, 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, 2011 and 2010 was \$16.2 million and \$14.8 million, respectively. We continue to support and develop our QS-21 partnering collaborations, with the goal of earning royalties from this product in the 2013-2014 timeframe. Our future ability to generate cash from operations will depend on achieving regulatory approval of our product candidates, and market acceptance of Oncophage and our product candidates, achieving benchmarks as defined in existing collaborative agreements, and our ability to enter into new collaborations. Please see **Note Regarding Forward-Looking Statements** on page 2 of this Annual Report on Form 10-K section 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, 2011 (in thousands).

	Total	Less than 1 Year	Payments Due by Period			More than 5 Years
			1	3 Years	3	5 Years
Long-term debt (1)	\$ 46,710	\$ 268	\$ 46,339	\$ 103	\$	
Operating leases (2)	1,861	1,137	724			
<b>Total</b>	<b>\$ 48,571</b>	<b>\$ 1,405</b>	<b>\$ 47,063</b>	<b>\$ 103</b>	<b>\$</b>	

- (1) Assumes the 2006 Notes are not converted and are paid at maturity on August 31, 2014. In certain circumstances, the 2006 Notes could be converted before then. Also includes fixed interest payments, some of which may be paid in kind, and assumes that the 2005 Notes are not converted and are paid on February 1, 2015. In certain circumstances, the 2005 Notes could be converted before then. In addition, the holders of the 2005 Notes can require us to purchase debt from them at certain dates between 2012 and 2020. If the 2005 Notes are not converted and we are not required to purchase the debt, the 2005 Notes mature on February 1, 2025. If the 2005 Notes were outstanding until maturity, there would be additional interest payments of \$68,000 for the period 2012 through 2025.
- (2) Effective July 30, 2010, we sublet part of our Lexington facility to Cubist Pharmaceuticals, Inc. whose lease expires in July 2012. Our Lexington facility and New York office leases expire August 2013 and April 2012, respectively.

**Inflation**

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

**Off-Balance Sheet Arrangements**

At December 31, 2011, we had no off-balance sheet arrangements.

## **Table of Contents**

### **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. 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 ASC 718, *Compensation - Stock Compensation*, we recognize share-based 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 9 of the notes to our consolidated financial statements for a further discussion on share-based compensation.

#### ***Fair Value Accounting - Derivative Liability***

As a result of the adoption of certain guidance within ASC 815-40, *Derivatives and Hedging- Contracts In Entity's Own Equity*, as of January 1, 2009, the conversion feature embedded in our 2006 Notes was treated as a derivative and recorded at its fair value, with period changes in the fair value recorded as a gain or loss in our consolidated statement of operations. In February 2011, we entered into a Ninth Amendment of Rights Agreement for the 2006 Notes and as amended, the 2006 Notes no longer fall within this guidance since they are no longer convertible into our common stock, therefore the conversion option is no longer a derivative liability.

## **Table of Contents**

We measured 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. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. Our derivative liability was valued based on significant unobservable inputs.

### ***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 Accounting Standards Codification (ASC) 605-25, *Revenue Recognition - Multiple Element Arrangements*, as amended by Accounting Standards Update 2009-13.

### **Recent Accounting Pronouncements**

In December 2010, the Financial Accounting Standards Board (FASB) issued additional guidance on when to perform Step 2 of the goodwill impairment test for reporting units with zero or negative carrying amounts. The criteria for evaluating Step 1 of the goodwill impairment test and proceeding to Step 2 was amended for reporting units with zero or negative carrying amounts and requires performing Step 2 if qualitative factors indicate that it is more likely than not that a goodwill impairment exists. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Upon adoption of this guidance on January 1, 2011, we had a negative carrying value but determined there were no qualitative factors that indicated it was more likely than not that a goodwill impairment existed and accordingly, Step 2 of the goodwill impairment test was not required to be performed. The adoption of this amended guidance did not have any impact on our consolidated financial statements.

In September 2011, the FASB amended the guidance on the annual testing of goodwill for impairment. This amended guidance permits companies to assess qualitative factors to determine whether to perform the two-step goodwill impairment test. This amendment is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. We do not anticipate any material impact of this guidance on our consolidated financial statements.

In June 2011, the FASB issued Accounting Standard Update No. 2011-05, *Comprehensive Income* (ASU 2011-05) which increases the prominence of other comprehensive income in financial statements. Under this standard, the components of net income and other comprehensive income must be presented in either one or two consecutive financial statements. The standard eliminates the option to present other comprehensive income in the statement of changes in equity. ASU 2011-05 is effective for fiscal years beginning after December 15, 2011 and interim and annual periods thereafter. The standard should be applied retrospectively and early adoption is permitted. Adoption of this standard will impact only the presentation of our financial information. In December 2011, the FASB decided to defer the effective date of those changes in ASU 2011-05 that relate only to the presentation of reclassification adjustments in the statement of income by issuing ASU 2011-12, *Comprehensive Income*.

In December 2011, the FASB issued ASU No. 2011-11, *Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities* (ASU 2011-11). The amendments in ASU 2011-11 require companies to disclose information about offsetting and related arrangements to enable users of their financial statements to understand the effects of those arrangements on its financial position. ASU 2011-11 is required to be applied retrospectively for all prior periods presented and is effective for fiscal years, and interim periods within those years, beginning on or after January 1, 2013. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

**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, 2011, there has been no material change with respect to our interest rate and foreign currency exposures or our approach toward those exposures. However, we are exploring possible commercialization of Oncophage outside of the U.S., which could result in increased foreign currency exposure.

The information below summarizes our market risks associated with debt obligations as of December 31, 2011. Fair value included herein has been estimated taking into consideration the nature and terms of each instrument and the prevailing economic and market conditions at December 31, 2011. The table presents principal payments by year of maturity based on the terms of the debt (in thousands).

	Estimated Fair Value (2)	Outstanding Principal Amount	Year of Maturity				
		December 31, 2011	2012	2013	2014	2015	
Long-term debt (1)	\$ 30,837	\$ 37,885	\$ 198	\$ 87	\$ 37,500	\$ 100	

- (1) Fixed interest rates range from 5.25% to 8%. The above table is based on the assumptions that future interest on the 2006 Notes is paid in cash and that these notes are not converted at maturity August 31, 2014. In certain circumstances, the 2006 Notes could be converted before then. In addition, the table is based on the assumption that the 2005 Notes are redeemed on February 1, 2015. In certain circumstances, the 2005 Notes could be converted on or before February 1, 2015. The note holders of our 2005 Notes can require us to redeem debt at certain dates between 2015 and 2020. If the 2005 Notes are not converted and we are not required to purchase the notes, they mature on February 1, 2025.
- (2) The estimated 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. In addition, the fair value of our 2005 Notes was estimated based on the most recent market transactions.

We had cash and cash equivalents at December 31, 2011 of \$10.7 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, 2011, however, we are subject to investment risk.

We invest our cash, cash equivalents, and short-term investments 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. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. 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>	46
<u>Consolidated Balance Sheets as of December 31, 2011 and 2010</u>	47
<u>Consolidated Statements of Operations for the years ended December 31, 2011, 2010, and 2009</u>	48
<u>Consolidated Statements of Stockholders' Equity (Deficit) and Comprehensive Loss for the years ended December 31, 2011, 2010, and 2009</u>	49
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2011, 2010, and 2009</u>	52
<u>Notes to Consolidated Financial Statements</u>	53

**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, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity (deficit) and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2011. 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, 2011 and 2010, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2011, 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, 2011, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 6, 2012, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Boston, Massachusetts

March 6, 2012



**Table of Contents**

**AGENUS INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**

	December 31, 2011	December 31, 2010
<b>ASSETS</b>		
Cash and cash equivalents	\$ 10,747,951	\$ 19,781,976
Inventories	20,072	26,432
Accounts receivable		35,000
Prepaid expenses	536,270	704,744
Other current assets	699,786	306,008
Total current assets	12,004,079	20,854,160
Plant and equipment, net of accumulated amortization and depreciation of \$26,081,778 and \$24,993,225 at December 31, 2011 and 2010, respectively	4,136,699	6,194,465
Goodwill	2,572,203	2,572,203
Other long-term assets	1,094,549	1,285,831
Total assets	\$ 19,807,530	\$ 30,906,659
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current portion, long-term debt	\$ 197,684	\$ 146,061
Current portion, deferred revenue	1,542,395	1,540,385
Accounts payable	807,928	698,554
Accrued liabilities	1,730,290	2,684,609
Other current liabilities	475,342	346,314
Total current liabilities	4,753,639	5,415,923
Convertible notes	32,637,757	34,050,033
Other long-term debt	88,247	
Deferred revenue	2,078,651	3,612,156
Derivative liability		755,000
Other long-term liabilities	1,080,201	1,780,759
Commitments and contingencies (Notes 12 and 15)		
<b>STOCKHOLDERS DEFICIT</b>		
Preferred stock, par value \$0.01 per share; 25,000,000 shares authorized:		
Series A convertible preferred stock; 31,620 shares designated, issued, and outstanding at December 31, 2011 and 2010; liquidation value of \$31,817,625 at December 31, 2011	316	316
Series B2 convertible preferred stock; 3,105 shares designated, issued, and outstanding at December 31, 2011 and 2010	31	31
Common stock, par value \$0.01 per share; 250,000,000 shares authorized; 21,535,037 and 18,647,626 shares issued at December 31, 2011 and 2010, respectively (Note 1)	215,350	186,476
Additional paid-in capital (Note 1)	581,392,602	569,849,178
Treasury stock, at cost; 43,490 shares of common stock at December 31, 2011 and 2010 (Note 1)	(324,792)	(324,792)
Accumulated deficit	(607,694,596)	(584,418,421)
Noncontrolling interest	5,580,124	
Total stockholders deficit	(20,830,965)	(14,707,212)
Total liabilities and stockholders deficit	\$ 19,807,530	\$ 30,906,659

See accompanying notes to consolidated financial statements.



**Table of Contents****AGENUS INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS****For the Years Ended December 31, 2011, 2010, and 2009**

	2011	2010	2009
Revenue:			
Product revenue	\$	\$ 52,500	\$
Grant revenue		424,720	
Research and development revenue	2,755,772	2,882,391	3,334,444
Total revenues	2,755,772	3,359,611	3,334,444
Operating expenses:			
Cost of goods sold		(122,946)	
Research and development	(11,022,391)	(12,877,695)	(16,902,537)
General and administrative	(10,820,187)	(12,111,507)	(14,110,514)
Operating loss	(19,086,806)	(21,752,537)	(27,678,607)
Other income (expense):			
Non-operating income	1,941	4,680,120	2,568,545
Interest expense	(4,210,097)	(4,871,446)	(5,344,713)
Interest income	18,787	37,560	137,482
Net loss	(23,276,175)	(21,906,303)	(30,317,293)
Dividends on series A convertible preferred stock	(790,500)	(790,500)	(790,500)
Net loss attributable to common stockholders	\$ (24,066,675)	\$ (22,696,803)	\$ (31,107,793)
Per common share data, basic and diluted:			
Net loss attributable to common stockholders	\$ (1.21)	\$ (1.41)	\$ (2.36)
Weighted average number of common shares outstanding, basic and diluted	19,898,632	16,108,353	13,169,524

See accompanying notes to consolidated financial statements.

**Table of Contents****AGENUS INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) AND COMPREHENSIVE LOSS****For the Years Ended December 31, 2011, 2010, and 2009**

	Series A Convertible Preferred Stock		Series B2 Convertible Preferred Stock		Common Stock		Additional	Treasury Stock		Accumulated	Noncontrolling	
	Number of	Par	Number of	Par	Number of	Par	Paid-In	Number of	Amount	Deficit	Interest	Total
	Shares	Value	Shares	Value	Shares	Value	Capital	Shares				
Balance January 1, 2009	31,620	\$ 316	5,250	\$ 53	11,082,956	\$ 110,830	\$ 512,001,800	23,838	\$ (269,849)	\$ (532,173,577)	\$	\$ (20,330,427)
Net loss and comprehensive loss										(30,317,293)		(30,317,293)
Adoption of EITF 07-5							(1,352,317)			(21,248)		(1,373,565)
Share-based compensation							3,115,642					3,115,642
Shares issued in private placements					1,564,327	15,643	18,557,012					18,572,655
Conversion of series B2 preferred shares			(2,145)	(22)	988,202	9,882	(9,860)					
Shares issued to repurchase convertible senior notes					932,893	9,329	14,124,860					14,134,189
Exercise of stock options					13,212	132	141,180					141,312
Employee share purchases					6,883	69	16,864					16,933
Shares issued under Directors Deferred Compensation Plan					2,562	26	21,474					21,500
Shares issued to CEO in lieu of cash compensation					21,690	217	109,783					110,000
Reclassification of liability classified option grants							(220,470)					(220,470)
Vesting of nonvested shares					389,848	3,898	(3,898)					
Treasury stock received for vested share tax payments								19,652	(54,943)			(54,943)
Dividends on series A convertible preferred stock (\$25 per share)							(790,500)					(790,500)
	31,620	\$ 316	3,105	\$ 31	15,002,573	\$ 150,026	\$ 545,711,570	43,490	\$ (324,792)	\$ (562,512,118)	\$	\$ (16,974,967)

## Edgar Filing: AGENUS INC - Form 424B3

Balance at  
December 31,  
2009

See accompanying notes to consolidated financial statements.

**Table of Contents****AGENUS INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) AND COMPREHENSIVE LOSS (Continued)****For the Years Ended December 31, 2011, 2010, and 2009**

	Series A Convertible Preferred Stock		Series B2 Convertible Preferred Stock		Common Stock		Additional	Treasury Stock		Accumulated	Noncontrolling	
	Number of	Par	Number of	Par	Number of	Par	Paid-In	Number of	Amount	Deficit	Interest	Total
	Shares	Value	Shares	Value	Shares	Value	Capital	Shares				
Net loss and comprehensive loss										(21,906,303)		(21,906,303)
Share-based compensation							2,813,304					2,813,304
Shares issued in private placements					533,241	5,332	2,874,174					2,879,506
Shares sold at the market					1,136,678	11,367	8,634,363					8,645,730
Shares issued to repurchase convertible senior notes					1,642,544	16,425	10,345,495					10,361,920
Exercise of stock options					159	2	717					719
Employee share purchases					14,954	149	48,454					48,603
Shares issued to consultants for services					27,676	277	149,723					150,000
Shares issued to CEO in lieu of cash compensation					25,484	255	131,745					132,000
Reclassification of liability classified option grants							(67,224)					(67,224)
Vesting of nonvested shares					264,317	2,643	(2,643)					
Dividends on series A convertible preferred stock (\$25 per share)							(790,500)					(790,500)
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)	\$	\$ (14,707,212)

See accompanying notes to consolidated financial statements.

**Table of Contents****AGENUS INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) AND COMPREHENSIVE LOSS (Continued)****For the Years Ended December 31, 2011, 2010, and 2009**

	Series A Convertible Preferred Stock		Series B2 Convertible Preferred Stock		Common Stock		Additional	Treasury Stock		Accumulated	Noncontrolling	Total
	Number of	Par	Number of	Par	Number of	Value	Paid-In	Number of	Amount	Deficit	Interest	
	Shares	Value	Shares	Value	Shares		Capital	Shares				
ss and prehensive loss										(23,276,175)		(23,276,175)
Note												
ndment conversion							755,000				5,580,124	6,335,124
valuation												
s sold at the					2,552,492	25,525	7,477,850					7,503,375
t												
s issued in private					88,333	883	476,117					477,000
ments												
-based							3,335,066					3,335,066
ensation												
ssification of							(78,079)					(78,079)
ty classified												
grants												
ng of nonvested					165,586	1,656	(1,656)					
s issued to CEO												
o of cash					36,577	366	155,834					156,200
ensation												
s issued to					16,192	162	94,538					94,700
stants for services												
ise of stock					319	3	1,435					1,438
s												
oyee share					20,524	205	80,893					81,098
ases												
s issued to					7,388	74	36,926					37,100
or for services												
ends on series A							(790,500)					(790,500)
rtible preferred												
(\$25 per share)												
ce at												
ber 31, 2011	31,620	\$ 316	3,105	\$ 31	21,535,037	\$ 215,350	\$ 581,392,602	43,490	\$ (324,792)	\$ (607,694,596)	\$ 5,580,124	\$ (20,830,762)

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, 2011, 2010, and 2009**

	2011	2010	2009
Cash flows from operating activities:			
Net loss	\$ (23,276,175)	\$ (21,906,303)	\$ (30,317,293)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,252,412	3,437,767	4,108,538
Share-based compensation	2,646,767	3,151,537	3,130,804
Noncash interest expense	4,167,849	4,053,272	4,014,840
Loss on monetization of receivable			317,512
Gain on extinguishment of debt		(2,761,426)	(2,653,387)
Asset impairment		629,382	
Change in fair value of derivative liability		(1,910,156)	(47,707)
Loss on disposal of assets	37,447	161,188	51,584
Changes in operating assets and liabilities:			
Accounts receivable	35,000	(35,000)	
Inventories	6,360	297,603	(97,659)
Prepaid expenses	168,474	47,216	(141,498)
Accounts payable	105,667	(198,116)	296,094
Deferred revenue	(1,531,495)	674,101	(440,404)
Accrued liabilities and other current liabilities	(269,713)	(246,879)	(2,120,876)
Other operating assets and liabilities	(591,504)	(152,221)	(293,559)
Net cash used in operating activities	(16,248,911)	(14,758,035)	(24,193,011)
Cash flows from investing activities:			
Proceeds from maturities of available-for-sale securities	5,000,000	40,000,000	30,000,000
Purchases of available-for-sale securities	(4,998,799)	(29,989,763)	(29,986,794)
Proceeds from sale of equipment	23,884	50,299	53,550
Purchases of plant and equipment	(54,547)	(130,437)	(243,868)
Collection of receivable from sale of patent applications			2,337,475
Net cash (used in) provided by investing activities	(29,462)	9,930,099	2,160,363
Cash flows from financing activities:			
Net proceeds from sales of equity	7,980,375	11,525,236	18,572,655
Proceeds from exercise of stock options	1,438	719	141,312
Proceeds from employee stock purchases	81,098	48,603	16,933
Treasury stock received to satisfy minimum tax withholding requirements			(54,943)
Payments of series A convertible preferred stock dividends	(790,500)	(790,500)	(790,500)
Payments of long-term debt	(28,063)	(6,240,963)	(255,000)
Net cash provided by financing activities	7,244,348	4,543,095	17,630,457
Net decrease in cash and cash equivalents	(9,034,025)	(284,841)	(4,402,191)
Cash and cash equivalents, beginning of year	19,781,976	20,066,817	24,469,008
Cash and cash equivalents, end of year	\$ 10,747,951	\$ 19,781,976	\$ 20,066,817



## Edgar Filing: AGENUS INC - Form 424B3

### Supplemental cash flow information:

Cash paid for interest	\$ 12,458	\$ 1,122,473	\$ 1,573,906
------------------------	-----------	--------------	--------------

### Non-cash investing and financing activities:

Issuance of senior secured convertible notes as payment in-kind for interest	\$ 2,829,105	\$ 2,615,667	\$ 2,418,332
--	--------------	--------------	--------------

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		10,361,920	14,134,189
--	--	------------	------------

See accompanying notes to consolidated financial statements.

**Table of Contents**

**AGENUS INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(1) Description of Business**

Agenus Inc. (including its subsidiaries, also referred to as Agenus, the Company, we, us, and our ) is a biotechnology company developing and commercializing technologies to treat cancers and infectious diseases, primarily based on immunological approaches. Our technology portfolio consists of our Saponin Platform (based on our saponin adjuvant based technologies) and our Heat Shock Protein ( HSP ) Platform (based on our HSP based technologies). Within our Saponin Platform is QS-21 Stimulon® adjuvant, or QS-21, 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 human immunodeficiency virus, cancer, Alzheimer's disease, malaria, shingles, and tuberculosis. From our HSP Platform we are developing our Prophage Series vaccines. We have tested product candidates from our Prophage Series 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 (vitespen). Product candidates from our Prophage G-Series are currently in Phase 2 clinical trials in glioma, a type of brain cancer. Within our HSP Platform we are also developing recombinant HSP based technologies (the Recombinant Series). HerpV, a therapeutic vaccine candidate from the Recombinant Series has been tested in a Phase 1 clinical trial for the treatment of genital herpes. Our business activities have included product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development activities, market development, 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, 2011, we had an accumulated deficit of \$607.7 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 \$10.7 million as of December 31, 2011, plus the \$18 million net proceeds from equity offerings and license agreements since year-end, along with the estimated additional proceeds from our license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements into 2013 based on our estimated annual use of cash of \$13-16 million during 2012. 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 the development of our Prophage Series vaccines is subject to further evaluation and uncertainty, and because HerpV is in early-stage clinical development and requires a partner for further development, 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, 2011, we had debt outstanding of \$37.9 million in principal, including \$37.5 million in principal of our 8% senior secured convertible notes due August 2014 (the 2006 Notes ) and \$100,000 in

## **Table of Contents**

principal of our 5.25% convertible senior notes due February 2025 (the "2005 Notes"). The 2005 Notes are currently subject to redemption by us and at the option of the holders on February 1, 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) our product, Oncophage and/or our other Prophage Series vaccines, (2) vaccines containing QS-21 under development by our licensees and/or (3) potentially 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.

Effective October 3, 2011, our certificate of incorporation was amended to effect a reverse stock split of our common stock on the basis of one post-split share for every six pre-split shares to, in part, regain compliance with Nasdaq Marketplace Rule 550(a)(2) ("the Bid Price Requirement"). All references in these consolidated financial statements and notes thereto to shares, share price, and earnings per share, have been retroactively restated to reflect the reverse stock split.

### **(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 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.

**Table of Contents*****(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. Credit risk on accounts receivable is minimized by the financial position of the entities with which we do business. Credit losses from our customers have been immaterial.

***(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, 2011 and 2010 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 \$2.2 million, \$2.6 million, and \$2.8 million, for the years ended December 31, 2011, 2010, and 2009, 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. As of December 31, 2011, the fair value of our 2005 Notes was estimated based on the most recent market transactions. The fair value of our 2006 Notes exclusive of the conversion option is based on a present value methodology. The outstanding principal amount of debt, including the current portion, is \$37.9 million and \$34.9 million at December 31, 2011 and 2010, respectively.

***(j) 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. Product revenue is recognized as product is shipped. For the years ended December 31, 2011, 2010, and 2009, 48%, 39%, and 51%, respectively, of our revenue was earned from one research partner. In addition, 43%, 31%, and 32% of our revenue for the years ended December 31, 2011, 2010, and 2009 was earned from one of our licensees. These revenues will not continue past 2011 due to the amended license agreement of non-core technologies (See Note 19).

***(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, \$45,000, and \$32,000, for the years ended December 31, 2011, 2010, and 2009, respectively. Such losses are included as a component of operating expenses.

**Table of Contents*****(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 9 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, 2011, 2010, and 2009, as they would be anti-dilutive:

	At December 31,		
	2011	2010	2009
Warrants	3,309,378	3,309,378	6,994,453
Stock options	1,814,161	1,212,095	1,024,770
Nonvested shares	135,791	85,564	33,338
Convertible preferred stock	333,333	333,333	333,333
Convertible notes		1,926,134	2,090,261

## **Table of Contents**

### ***(p) Goodwill and Acquired Intangible Assets***

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. Intangible assets with estimable useful lives are amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment as deemed necessary.

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. We consider ourselves a single reporting unit for purposes of the impairment test. We determine our fair value using the quoted market price of our common stock, adjusted for certain factors, and compare it to our net book value at the date of our evaluation. To the extent our net book value exceeds the fair value, there is an indication that the reporting unit goodwill may be impaired and a second step of the impairment test is performed to determine the amount of the impairment to be recognized, if any.

The costs of core and developed technology are presented at their estimated fair value as of their acquisition date. These costs were being amortized on a straight-line basis over their estimated useful lives of 10 years.

### ***(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 December 2010, the Financial Accounting Standards Board ( FASB ) issued additional guidance on when to perform Step 2 of the goodwill impairment test for reporting units with zero or negative carrying amounts. The criteria for evaluating Step 1 of the goodwill impairment test and proceeding to Step 2 was amended for reporting units with zero or negative carrying amounts and requires performing Step 2 if qualitative factors indicate that it is more likely than not that a goodwill impairment exists. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Upon adoption of this guidance on January 1, 2011, we had a negative carrying value but determined there were no qualitative factors that indicated it was more likely than not that a goodwill impairment exists and accordingly, Step 2 of the goodwill impairment test was not required to be performed. The adoption of this amended guidance did not have any impact on our consolidated financial statements.

**Table of Contents**

In September 2011, the FASB amended the guidance on the annual testing of goodwill for impairment. This amended guidance permits companies to assess qualitative factors to determine whether to perform the two-step goodwill impairment test. This amendment is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. We do not anticipate any material impact of this guidance on our consolidated financial statements.

In June 2011, the FASB issued Accounting Standard Update No. 2011-05, Comprehensive Income ( ASU 2011-05 ) which increases the prominence of other comprehensive income in financial statements. Under this standard, the components of net income and other comprehensive income must be presented in either one or two consecutive financial statements. The standard eliminates the option to present other comprehensive income in the statement of changes in equity. ASU 2011-05 is effective for fiscal years beginning after December 15, 2011 and interim and annual periods thereafter. The standard should be applied retrospectively and early adoption is permitted. Adoption of this standard will impact only the presentation of our financial information. In December 2011, the FASB decided to defer the effective date of those changes in ASU 2011-05 that relate only to the presentation of reclassification adjustments in the statement of income by issuing ASU 2011-12, Comprehensive Income.

In December 2011, the FASB issued ASU No. 2011-11, Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities ( ASU 2011-11 ). The amendments in ASU 2011-11 require companies to disclose information about offsetting and related arrangements to enable users of their financial statements to understand the effects of those arrangements on its financial position. ASU 2011-11 is required to be applied retrospectively for all prior periods presented and is effective for fiscal years, and interim periods within those years, beginning on or after January 1, 2013. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

**(3) Investments*****Cash Equivalents and Short-term Investments***

Cash equivalents and short-term investments consisted of the following as of December 31, 2011 and 2010 consisted solely of institutional money market funds with cost approximating the estimated fair value.

Proceeds from maturities of available-for-sale securities amounted to \$5.0 million, \$ 40.0 million, and \$30.0 million, for the years ended December 31, 2011, 2010, and 2009, respectively. No available-for-sale securities were sold before their maturity in 2011, 2010 or 2009. Gross realized gains and gross realized losses included in net loss as a result of those maturities were immaterial for each of the years in the three-year period ended December 31, 2011. As a result of the short-term nature of our investments, there were no unrealized holding gains or losses as of December 31, 2011, 2010, and 2009.

**(4) Plant and Equipment**

Plant and equipment as of December 31, 2011 and 2010 consists of the following (in thousands).

	2011	2010	Estimated Depreciable Lives
Furniture, fixtures, and other	\$ 1,643	\$ 1,649	3 to 10 years
Laboratory and manufacturing equipment	4,547	5,546	4 to 10 years
Leasehold improvements	18,254	18,218	2 to 12 years
Software and computer equipment	5,774	5,774	3 years
	30,218	31,187	
Less accumulated depreciation and amortization	(26,081)	(24,993)	
	\$ 4,137	\$ 6,194	

**Table of Contents**

During the years ended December 31, 2011 and 2010, plant and equipment with a net book value of approximately \$37,000 and \$155,000, respectively, was retired from service and disposed.

**(5) Other Intangible Assets**

The following table presents certain information on our intangible assets as of December 31, 2011 and 2010 (in thousands).

	Weighted Average Amortization Period	Gross Carrying Amount	As of December 31, 2010		Net Carrying Amount
			Impairment Charge	Accumulated Amortization	

**Amortizing intangible assets:**

Core and developed technology	10 years	\$ 11,073	\$ 630	\$ 10,443	\$
-------------------------------	----------	-----------	--------	-----------	----

Our intangible assets were being amortized over their estimated useful lives of 10 years, with no estimated residual values. Amortization expense related to core and developed technology was \$690,000, and \$1.1 million, in 2010 and 2009 respectively. As further development of Aroplatin, a liposomal chemotherapeutic tested in a Phase 1 clinical trial for the treatment of solid malignancies and B-cell lymphomas, was discontinued, we determined that an impairment had occurred and accordingly recorded a loss of approximately \$630,000 during the year ended December 31, 2010, representing the net carrying value of the intangible asset related to liposomal technology at the time development was discontinued. This impairment charge is included in research and development expenses.

**(6) 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 2008 through 2011. 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 2007 and prior. However, net operating losses from the tax year 2007 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, 2011, we have available net operating loss carryforwards of \$497.3 million and \$130.1 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 2012 and 2031. 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 \$8.2 million and \$6.6 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 2012 and 2031 and 2015 and 2026, respectively. The potential impacts of such provisions are among the items considered and reflected in management's assessment of our valuation allowance requirements.



**Table of Contents**

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, 2011 and 2010 are presented below (in thousands).

	2011	2010
Deferred tax assets:		
Net operating loss carryforwards	\$ 175,965	\$ 170,171
Research and development tax credits	12,546	12,122
Other	13,510	13,042
Total deferred tax assets	202,021	195,335
Less: valuation allowance	(200,072)	(195,052)
Net deferred tax assets	1,949	283
Deferred tax liabilities	(1,949)	(283)
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 \$5.0 million and \$2.8 million during the years ended December 31, 2011 and 2010, 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, 2011, 2011, and 2009, 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).

	2011	2010	2009
Computed expected Federal tax benefit	\$ (7,912)	\$ (7,451)	\$ (10,308)
(Increase) reduction in income taxes benefit resulting from:			
Change in valuation allowance	5,033	2,760	(3,415)
Increase due to uncertain tax positions	59	67	241
State and local income benefit, net of Federal income tax benefit	(1,182)	(534)	(1,498)
Net operating loss expirations	1,979	4,363	14,759
Increase due to debt discount adjustment	2,192		
Other, net	(169)	795	221
	\$	\$	\$

As of December 31, 2011 and 2010, our gross unrecognized tax benefits totaled \$5.4 million. 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**

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

Balance, December 31, 2010	\$ 5,429
Increase related to current year positions	64
Decrease related to previously recognized positions	(5)
Balance, December 31, 2011	\$ 5,488

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

Accrued liabilities consist of the following as of December 31, 2011 and 2010 (in thousands)

	2011	2010
Professional fees	\$ 892	\$ 888
Payroll	184	1,086
Other	654	711
	\$ 1,730	\$ 2,685

Other current liabilities consist of the following as of December 31, 2011 and 2010 (in thousands)

	2011	2010
Deferred rent expense	\$ 405	\$ 44
Value of liability classified option grants	70	282
Other		20
	\$ 475	\$ 346

**(8) Equity**

Our authorized capital stock consists of 250,000,000 shares of \$0.01 par value per share of common stock and 25,000,000 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, for net proceeds of \$31.6 million. Under the terms and conditions of the Certificate of Designation creating the series A convertible preferred stock, this stock is convertible by the holder at any time into our common stock, is non-voting, carries a 2.5% annual dividend yield, 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) on or after September 24, 2013. The Certificate of Designation does not contemplate a sinking fund. The series A convertible preferred stock ranks senior to our common stock. In a liquidation, dissolution, or winding up of the Company, the series A convertible 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 convertible preferred stock affect our ability to declare or pay dividends on our common stock as long as the series A convertible preferred stock's dividends are accruing. The liquidation value of this series A convertible preferred stock is equal to \$1,000 per share outstanding plus any accrued unpaid dividends. Accrued and unpaid dividends of the series A convertible preferred stock aggregated \$197,625 or \$6.25 per share, at December 31, 2011.

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

## Edgar Filing: AGENUS INC - Form 424B3

series B2 convertible preferred stock. Shares of the series B1 convertible preferred stock permitted the investor, within one year of the anniversary of closing, to

**Table of Contents**

purchase up to an additional \$10.0 million of common shares at a purchase price equal to the lesser of \$18.48 per share or a price calculated based on the then-prevailing price of our common stock minus \$1.80 per share. Gross proceeds of \$5.0 million were received as a result of this transaction. Net proceeds, after deducting the placement agent fees and offering expenses paid by us, were \$4.7 million. The class B convertible preferred stock has been recorded as an equity classified instrument in accordance with the applicable authoritative guidance. In April 2008, we issued 264,199 shares of our common stock upon conversion of 10,000 shares of our series B1 convertible preferred stock via a cashless conversion. These shares were issued pursuant to an effective shelf registration statement. 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 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. Investors also received (i) 10-year warrants to 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.

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 warrants expired unexercised in January 2010. 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.

## **Table of Contents**

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. In connection with the two private placements during 2009, we raised net proceeds of \$18.6 million, after deducting offering costs of \$1.4 million.

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.

During the years ended December 31, 2011 and 2010, we issued approximately 265,000 and 1.1 million shares of our common stock, respectively, under an At the Market Sales Agreement through our sales agents, McNicoll, Lewis & Vlak LLC and Wm Smith & Co. and raised net proceeds of approximately \$1.2 million and \$8.6 million respectively, after deducting offering costs of approximately \$363,000. These offerings were made under effective shelf registration statements and proceeds from the offering were used for general corporate purposes.

In December 2010, we entered into subscription agreements under which we issued and sold 533,241 shares of our common stock for the aggregate purchase price of \$2,879,506. 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 approximately 2.3 million 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, 2009, certain employees, in lieu of paying withholding taxes on the vesting of nonvested stock awarded under our 1999 Equity Incentive Plan, as amended (the "1999 EIP"), authorized the withholding of an aggregate of 117,913 shares, of common stock to satisfy the minimum tax withholding requirements related to such vesting. We recorded these shares as treasury stock using the cost method at the market price of the common stock on the vesting dates.

### **(9) Share-based Compensation Plans**

Our 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 2,000,000 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 collectively as Awards, for

## **Table of Contents**

up to 2,166,666 shares of our common stock (subject to adjustment in the event of stock splits and other similar events). The Board of Directors appointed the Compensation Committee to administer the 1999 EIP and the 2009 EIP.

Under the 1999 Employee Stock Purchase Plan, as amended (the "1999 ESPP"), eligible employees purchased shares of common stock at a discount from fair value. There were 75,000 shares of common stock reserved for issuance under the 1999 ESPP. The 1999 ESPP, which terminated on November 15, 2009, was intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Code. 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 also designed to comply with Section 423 of the Code. There are 83,333 shares of common stock reserved for issuance under the 2009 ESPP subject to adjustment as defined in the plan. 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 125,000 shares of our common stock reserved for issuance under this plan. As of December 31, 2011, 15,491 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 conversion date as reported by The Nasdaq Capital Market. Pursuant to this plan, a total of 95,211 units, each representing a share of our common stock at a weighted average common stock price of \$8.23, have been credited to participants' stock accounts as of December 31, 2011. 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 four-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:

	2011	2010	2009
Expected volatility	103%	104%	94%
Expected term in years	6	6	6
Risk-free interest rate	1.6%	2.1%	2.7%
Dividend yield	0%	0%	0%

**Table of Contents**

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 2011 is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2010	1,212,095	\$ 13.43		
Granted	748,161	4.63		
Exercised	(319)	4.50		
Forfeited	(53,233)	9.03		
Expired	(92,543)	43.54		
Outstanding at December 31, 2011	1,814,161	\$ 8.38	7.6	\$ 41
Vested or expected to vest at December 31, 2011	1,761,439	\$ 8.49	7.6	\$ 40
Exercisable at December 31, 2011	1,160,421	\$ 10.31	6.8	\$ 20

The weighted average grant-date fair values of options granted during the years ended December 31, 2011, 2010, and 2009, was \$3.61, \$3.66, and \$7.26, respectively.

The aggregate intrinsic value in the table above represents the difference between our closing stock price on the last trading day of fiscal 2011 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, 2011 (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, 2011, 2010, and 2009, determined on the dates of exercise, was \$0, \$0 and \$54,000, respectively.

During 2011, 2010, and 2009, 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, 2011, \$1.9 million of total unrecognized compensation cost related to stock options granted to employees and directors is expected to be recognized over a weighted average period of 2.2 years.

As of December 31, 2011, 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 \$11,000. 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.

**Table of Contents**

A summary of nonvested stock activity for 2011 is presented below:

	<b>Nonvested Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Outstanding at December 31, 2010	85,564	\$ 5.28
Granted	224,618	6.19
Vested	(165,024)	6.03
Forfeited	(9,367)	5.64
Outstanding at December 31, 2011	135,791	5.85

As of December 31, 2011, there was \$362,000 of unrecognized share-based compensation expense related to these nonvested shares. This cost is expected to be recognized over a weighted average period of 1.5 years. The total intrinsic value of shares vested during the years ended December 31, 2011, 2010, and 2009, was \$330,000, \$1.6 million, and \$1.5 million, respectively.

Cash received from option exercises and purchases under our 2009 ESPP for the years ended December 31, 2011, 2010, and 2009, was \$83,000, \$49,000, and \$158,000, respectively. We issue new shares upon option exercises, purchases under our 2009 ESPP, vesting of nonvested stock, and under the Directors' Deferred Compensation Plan. During the years ended December 31, 2011, 2010, and 2009, 20,524 shares, 14,954 shares, and 6,883 shares, were issued under the 2009 ESPP, respectively. During the years ended December 31, 2011 and 2010, 165,586 shares and 264,317 shares, respectively were issued as a result of the vesting of nonvested stock. During the year ended December 31, 2009, 370,196 shares, net of 19,652 shares withheld to cover personal income tax withholding, were issued as a result of the vesting of nonvested stock. The shares withheld were recorded as treasury stock using the cost method, at weighted average prices of \$ 2.82 per share during the year ended December 31, 2009 based on the closing sale price of our common stock on the vesting dates, for a total of approximately \$55,000.

For the year ended December 31, 2009, 2,562 shares were issued under our Directors' Deferred Compensation Plan. No shares were issued during the years ended December 31, 2011 and 2010.

The impact on our results of operations from share-based compensation for the years ended December 31, 2011, 2010, and 2009, was as follows (in thousands).

	<b>2011</b>	<b>2010</b>	<b>2009</b>
Research and development	\$ 765	\$ 1,058	\$ 864
General and administrative	1,882	2,094	2,267
Total share-based compensation expense	\$ 2,647	\$ 3,152	\$ 3,131

**(10) 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 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 10,000 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 (2018) 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



## **Table of Contents**

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, Dr. Srivastava 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 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 the agreement, we paid \$2.4 million to Fordham.

We entered into a license agreement with UConn in May 2001 (the License Agreement ) that provides us with the exclusive, worldwide rights to technologies discovered and developed under the research agreement. The term of the License Agreement ends when the last of the licensed patents expires (2019) or becomes no longer valid. UConn may terminate the License 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 License Agreement upon 90 days written notice. 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, 2011, we have paid \$340,000 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, 2011, 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. Unless the NewVac Agreement is earlier terminated, or extended, we are entitled to receive modest milestone payments in addition to payments for supply of Oncophage and/or

## **Table of Contents**

royalties in the low double-digits on net sales of Oncophage through December 2014. 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 \$47.6 million over the term of the studies. For the years ended December 31, 2011, 2010, and 2009, \$623,000, \$361,000, and \$170,000, respectively, have been expensed in the accompanying consolidated statements of operations related to these clinical studies. Through December 31, 2011, \$46.8 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, 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.

On January 16, 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. In addition, the parties have amended their purchase and supply obligations with respect to pre-commercial grade QS-21. In accordance with the terms of the Amended GSK Supply Agreement, upon our election, GSK is obligated to supply us (or our affiliates, licensees, or customers) certain quantities of commercial grade QS-21 for a stated period of time.

As consideration for our entering into the Amended GSK Supply Agreement, we received a \$2.0 million upfront non-refundable payment from GSK in lieu of a milestone payment that would have otherwise been payable under the original agreement. In addition, GSK is obligated to make payments to us totaling \$5.25 million through December 2012, of which \$3.5 million has been received, for manufacturing profits that were anticipated to have otherwise been earned under the original agreement. Except as expressly provided in the Amended GSK Supply Agreement, all other financial obligations of GSK under the original agreement, including royalty payments, remain unchanged. As of December 31, 2011, we have received \$10.5 million of a potential \$15.3 million in upfront and milestone payments related to our agreements with GSK. We are also entitled to receive low single-digit royalties on the net sales for a period of at least 10 years after the first commercial sale of a resulting GSK product.

During the years ended December 31, 2011, 2010, and 2009, we recognized revenue of \$1.3 million each year related to payments received under our license and supply agreements with GSK. Deferred revenue of \$2.2 million related to our agreements with GSK is included in deferred revenue on our consolidated balance sheet as of December 31, 2011.

Effective September 14, 2009, we entered into an Amended and Restated License Agreement ("Amended License Agreement") with Elan Corporation, plc and/or its affiliates ("Elan") and Elan Pharmaceuticals, Inc. for providing Elan a commercial license for the use of QS-21 in the research and commercialization of an Alzheimer's disease vaccine containing QS-21 ("Licensed Product"). On September 17, 2009, the Amended License Agreement was assigned to JANSSEN Alzheimer's Immunotherapy ("JANSSEN AI"), a subsidiary of Johnson & Johnson. Under the terms of the Amended License Agreement assigned to JANSSEN AI, they have the right to develop, make, have made, use, sell, offer for sale, import, and have sold the Licensed Product. In addition, pursuant to the terms of the Amended License Agreement, JANSSEN AI has the right to manufacture all of its requirements of QS-21 for use in the Licensed Product and we have no further supply obligations. As of December 31, 2011, we have received \$1.5 million in upfront and milestone payments under this agreement and are entitled to receive up to \$10 million in additional future payments contingent upon successful milestone achievements. In addition, we are entitled to

**Table of Contents**

receive mid single-digit royalties on a country-by-country basis on net sales of the Licensed Product for a period of at least 10 years after first commercial sale in that country. Deferred revenue of \$1.1 million related to this Amended License Agreement is included in deferred revenue on our consolidated balance sheet as of December 31, 2011.

**(11) Certain Related Party Transactions**

In March 1995, we entered into a consulting agreement with Dr. Pramod Srivastava, our scientific founder and a former member of our Board of Directors, and upon its expiration in March 2006, we entered into a new consulting agreement, effective March 28, 2006, with Dr. Srivastava. The agreement expired March 31, 2011. In exchange for the timely performance of services, as defined in the agreement, Dr. Srivastava was entitled to receive compensation to be established by the Compensation Committee of the Agenesis Board of Directors. For the twelve-month period ended March 31, 2011, Dr. Srivastava received \$50,000. Dr. Srivastava was also eligible to receive an annual bonus and stock options at the discretion of the Compensation Committee of our Board of Directors. During the year ended December 31, 2009, we paid Dr. Srivastava an additional \$50,000 for his work related to our marketing authorization application submitted to the European Medicines Agency.

On January 9, 2008, we entered into the January 2008 private placement that included (i) 1,451,450 shares of common stock, (ii) warrants to acquire up to 1,451,450 shares of common stock at \$18.00 per share, and (iii) unit warrants, 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 approximately 2.3 million 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.

**(12) Leases**

We lease manufacturing, research and development, and office facilities under various long-term lease arrangements. Rent expense (before sublease income) was \$1.7 million, \$2.6 million, and \$2.9 million, for the years ended December 31, 2011, 2010, and 2009, respectively.

We lease an 83,000 square foot facility 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. The future minimum rental payments under our leases of our New York City facility, which expires in 2012, and our Lexington headquarters, which expires in 2013, are as follows (in thousands).

Year ending December 31,	
2012	\$ 1,137
2013	724
Total	\$ 1,861

## **Table of Contents**

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, 2011. In addition, for the office space in New York City, we were required to deposit \$161,000 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 \$541,000, \$1.1 million and \$1.2 million for the years ended December 31, 2011, 2010, and 2009, respectively. We are contractually entitled to receive rental payments of \$320,000 in 2012.

### **(13) Debt**

As of December 31, 2011, we have \$37.9 million in principal of debt outstanding: \$37.5 million due in 2014 (2006 Notes), \$100,000 due in 2025 (2005 Notes), \$146,000 currently due and \$140,000 related to an equipment financing due in 2014.

#### *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 bear 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, 2011. During the years ended December 31, 2011, 2010, and 2009, we issued additional 2006 Notes in the amount of \$2.8 million, \$2.6 million, and \$2.4 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 have 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.

As of December 31, 2010, the 2006 Notes were convertible into our common stock at a fixed conversion price of \$18.00 per share at the option of the Investors. Effective with the Amendment this conversion provision is removed from the terms of the 2006 Notes. The 2006 Notes can be converted into an interest in one of our wholly-owned subsidiaries that holds the QS-21 and HerpV technologies. If converted into an interest of this subsidiary, the ownership interest in the subsidiary is determined by multiplying the quotient of the conversion amount divided by \$25.0 million, by 30%.

If the Investors elect at any time to convert the 2006 Notes into ownership of the subsidiary holding the QS-21 and HerpV technologies, we have the right, within 60 days, to redeem the 2006 Notes, including accrued interest, at a redemption price providing a 30-percent internal rate of return to the Investors. The 2006 Notes are secured by our equity ownership in this subsidiary. Upon the maturity of the 2006 Notes, we may elect to repay the outstanding balance in cash or in common stock, subject to certain limitations. If we elect to satisfy the outstanding balance with common stock at maturity, the number of shares issued will be determined by dividing the cash obligation by 90 percent of the weighted average price of the common shares for the 20 trading days preceding the maturity date of the 2006 Notes. This right is subject to our market capitalization exceeding \$300 million at such time.

In no event will any Investor be obligated to accept equity that would result in an Investor owning in excess of 9.99% of the Company's outstanding common stock at any given time in connection with any redemption or repayment of the 2006 Notes. The note agreements include a change of control provision whereby the holders of the 2006 Notes could require us to redeem all or a portion of the then outstanding 2006 Notes at a price equal to

## **Table of Contents**

101% of the conversion amount being redeemed and a right of first refusal provision for the holders of the 2006 Notes on any sales of equity of the subsidiary holding the QS-21 and HerpV technologies, to purchase up to 50% of such sales of equity on the same terms as the third-party purchaser.

### *Convertible Notes 2005 Notes*

On January 25, 2005, we issued \$50.0 million of our 2005 Notes. Proceeds from the sale of the 2005 Notes were approximately \$48.0 million net of issuance costs. Issuance costs are being amortized using the effective interest method over seven years, the expected life of the 2005 Notes based on the earliest date on which the holders can require redemption. During 2008, we repurchased \$11.8 million in principal of these 2005 Notes for \$2.9 million plus accrued interest of \$178,000. During 2009, we repurchased \$18.2 million in principal of our 2005 Notes for \$255,000 and approximately 5,482,000 shares of our common stock. In connection with these 2009 repurchases we recorded a net gain of \$2.7 million in non-operating income, which is comprised of inducement expense of \$9.8 million and a gain on extinguishment of debt of \$12.5 million. During 2010, we repurchased \$19.9 million in principal of the 2005 Notes for \$6.2 million and approximately 9,643,000 shares of our common stock. In connection with these 2010 repurchases we recorded a net gain of \$2.8 million in non-operating income, which is comprised of inducement expense of \$8.9 million and a gain on extinguishment of debt of \$11.7 million. At December 31, 2011, \$100,000 of the 2005 Notes remains outstanding.

The 2005 Notes, which mature in 2025, bear interest payable semi-annually on February 1 and August 1 of each year, at a rate of 5.25% per annum (an effective rate of 5.94%) and are convertible into common stock at an initial conversion price of \$64.56 per share. On or after February 1, 2012, we may redeem the 2005 Notes for cash, at a redemption price equal to 100% of the principal amount of the 2005 Notes, plus any accrued and unpaid interest. On each of February 1, 2015 and February 1, 2020, holders may require us to purchase their 2005 Notes for cash equal to 100% of the principal amount of the 2005 Notes, plus any accrued and unpaid interest. At December 31, 2011, \$100,000 of the 2005 Notes remain outstanding.

### *Convertible Notes Conversion Option*

As of January 1, 2009, we adopted revised guidance that addressed certain matters applicable to convertible debt instruments and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new guidance. Under this new method of accounting, the debt and equity components of our 2005 Notes and our 2006 Notes are bifurcated and accounted for separately based on the fair value and related interest rate of a non-convertible debt security with the same terms. The fair value of a non-convertible debt instrument at the original issuance dates of our 2005 Notes and our 2006 Notes was determined to be \$42.6 million and \$23.6 million, respectively. The equity (conversion options) components of our convertible debt securities have been included in additional paid-in capital on our consolidated balance sheet and, accordingly, the initial carrying value of the debt securities was reduced by \$8.8 million.

Additionally, 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 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 of December 31, 2010 and 2009, our debt discount balance was \$720,000, and \$2.5 million, respectively. During the year ended December 21, 2010, we recorded a gain of \$1.9 million due to the change in the fair value of the derivative. For the year ended December 31, 2009, we recorded a charge to other income of \$48,000 due to changes in the fair value of the derivative and noncash interest expense of \$1.3 million due to the adoption of this revised guidance. As amended, the 2006 Notes no longer fall within this guidance since they are no longer convertible into our common stock, therefore, the conversion option is no longer valued as a derivative liability. Accordingly, the value of the derivative has been reduced to zero with a corresponding increase to additional paid-in capital of

## **Table of Contents**

\$755,000. Also, as the Amendment did not modify our ability to settle the 2006 Notes in cash, the 2006 Notes are now 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 are 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 has been 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.

### *Other*

At December 31, 2011, 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, 2011, approximately \$140,000 remains outstanding with approximately \$52,000 classified as part of the current portion of long-term debt on our consolidated balance sheet.

### **(14) 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. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. 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.

We measure our derivative liability at fair value. Our derivative liability is classified within Level 3 because it is valued using a modified Black-Scholes model. Certain inputs into this model were valued using a combination of income and market approaches which are unobservable in the market and are significant.

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.

**Table of Contents**

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

Description	December 31, 2011		December 31, 2010	
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Unobservable Inputs (Level 3)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Unobservable Inputs (Level 3)
<b>Liabilities:</b>				
Derivative liability				\$ 755
The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3), as of December 31, 2011 (amounts in thousands):				

Balance, December 31, 2010	\$ 755
Decrease for reclassification as Equity (see Note 13)	(755)
Balance, December 31, 2011	\$

As of December 31, 2011 and 2010, \$37.5 million and \$34.7 million in principal of the 2006 Notes are outstanding respectively. The fair value of the debt portion of the 2006 Notes exclusive of the conversion option at December 31, 2011, and 2010, is \$30.8 million, based on a present value methodology. The fair value of the embedded conversion option at December 31, 2011, is \$988,000.

**(15) Contingencies**

Agenus, our Chairman and CEO, Garo H. Armen, Ph.D., and two investment banking firms that served as underwriters in our initial public offering were named as defendants in a federal civil class action lawsuit in the United States District Court for the Southern District of New York. Substantially similar actions were filed concerning the initial public offerings for more than 300 different issuers, and the cases were coordinated for pre-trial purposes as *In re Initial Public Offering Securities Litigation*, 21 MC 92. The suit alleged that the brokerage arms of the investment banking firms charged secret excessive commissions to certain of their customers in return for allocations of our stock in the offering. The suit also alleged that shares of our stock were allocated to certain of the investment banking firms' customers based upon agreements by such customers to purchase additional shares of our stock in the secondary market. These coordinated lawsuits were resolved pursuant to a global settlement. Any portion of the settlement attributable to Agenus has been funded by insurance, and Agenus bears no financial liability. Appeals filed by various objectors to the settlement have been dismissed. No accrual has been recorded at December 31, 2011 for this action.

We may currently be, or may become a party, to other legal proceedings as well. 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.

**(16) 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 \$16,500 for individuals under 50 years old and \$22,000 for individuals 50 years old and older in 2011. Each participant is fully vested in his or her contributions and related earnings and losses. The Company matched 50% of the participant's contribution, subject to a maximum of 6% of compensation through February 2009. Such matching contributions vest over four years. In 2010 we made a discretionary contribution to the savings plan of approximately \$42,000. For the years ended December 31, 2010, and 2009, we expensed \$42,000, and \$37,000, respectively, for the Company's contributions to the 401(k) plan.





**Table of Contents****(17) Restructuring Costs**

On February 2, 2009, we initiated a plan of restructuring that resulted in a reduction of our workforce by approximately 20%, or 19 positions. We engaged in this workforce reduction in order to reduce operating expenses in light of market conditions and to focus our resources on near-term commercial opportunities. This restructuring action resulted in total charges of approximately \$177,000 in severance and outplacement expenses in the quarter ended March 31, 2009, with \$42,000 included in research and development expenses and \$135,000 included in general and administrative expenses in our consolidated statement of operations. The charge to operations was reduced by \$10,000 during the quarter ended June 30, 2009 based on actual activities. All amounts were paid during 2009.

**(18) Quarterly Financial Data (Unaudited)**

	March 31,	June 30,	Quarter Ended, September 30,	December 31,
	(In thousands, except per share data)			
<b>2011</b>				
Revenue	\$ 672	\$ 786	\$ 654	\$ 644
Net loss	(5,963)	(5,759)	(5,534)	(6,020)
Net loss attributable to common stockholders	(6,161)	(5,957)	(5,732)	(6,217)
Per common share, basic and diluted:				
Net loss attributable to common stockholders	\$ (0.30)	\$ (0.30)	\$ (0.28)	\$ (0.29)

	March 31,	June 30,	Quarter Ended, September 30,	December 31,
	(In thousands, except per share data)			
<b>2010</b>				
Revenue	\$ 936	\$ 806	\$ 624	\$ 994
Net loss	(8,811)	(4,972)	(5,707)	(2,416)
Net loss attributable to common stockholders	(9,009)	(5,170)	(5,905)	(2,613)
Per common share, basic and diluted:				
Net loss attributable to common stockholders	\$ (0.60)	\$ (0.30)	\$ (0.36)	\$ (0.16)
Net loss attributable to common stockholders per share is calculated independently for each of the quarters presented. Therefore, the sum of the quarterly net loss per share amounts will not necessarily equal the total for the full fiscal year.				

**(19) Subsequent Events**

Subsequent to December 31, 2011, we issued approximately 952,000 shares of our common stock in at the market offerings through our sales agents, McNicoll, Lewis & Vlask LLC and Wm Smith & Co. and raised net proceeds of approximately \$2.8 million after deducting offering costs of approximately \$87,000. These offerings were made under effective shelf registration statements and proceeds from the offerings will be used for general corporate purposes. On March 2, 2012 we issued a notice of termination of this related At the Market Sales Agreement which, in accordance with the terms of the agreement, will be effective on March 12, 2012. In addition, on March 2, 2012 we entered into an At Market Issuance Sales Agreement with MLV & Co. LLC under which we may sell from time to time up to 5,000,000 shares of our common stock.

Also on March 2, 2012, we entered into an First Right to Negotiate and Amendment agreement with GSK whereby we agreed to grant GSK the first right to negotiate for the purchase of Agenus or certain of our assets. The first right to negotiate will expire after five years. Under the terms of the agreement, GSK will pay us a non-refundable payment of \$9 million, of which \$2.5 million is creditable against future manufacturing technology transfer royalty payments. The agreement also includes royalty payments for an undisclosed indication upon commercialization of a vaccine product.

We also received \$6.3 million through an amended license of non-core technologies.

## **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 Chief 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 Chief 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 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 Chief 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* 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, 2011.

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 2011 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, 2011, based on criteria established in *Internal Control - Integrated Framework* 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 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, 2011, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Agenus Inc. and subsidiaries as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity (deficit) and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2011, and our report dated March 6, 2012 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Boston, Massachusetts

March 6, 2012

**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 Director, Our Corporate Governance, and Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement relating to our 2012 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our 2011 fiscal year (the 2012 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 2012 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 2012 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 2012 Proxy Statement.

**Item 14. *Principal Accountant 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 Ratify the Appointment of KPMG LLP as our Independent Registered Public Accounting Firm for the Fiscal Year Ending December 31, 2012 in our 2012 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**

<b>Exhibit No.</b>	<b>Description</b>
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 Agenesis 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 Agenesis 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.
3.2	Fifth Amended and Restated By-laws of Agenesis 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 Agenesis 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 Agenesis 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.
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	Indenture, dated January 25, 2005, between the Registrant and HSBC Bank USA, National Association. Filed as Exhibit 4.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 25, 2005 and incorporated herein by reference.

## **Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
4.3	Registration Rights Agreement, dated January 25, 2005, between the Registrant and the initial purchasers. Filed as Exhibit 4.2 to our Current Report on Form 8-K (File No. 0-29089) filed on January 25, 2005 and incorporated herein by reference.
4.4	Form of Amended and Restated Note under the Securities Purchase Agreement dated as of October 30, 2006 (as amended), by and among Agenus Inc. 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.
4.5	Form of Amended and Restated PIK Note under the Securities Purchase Agreement dated as of October 30, 2006 (as amended), by and among Agenus Inc. Inc., a Delaware corporation and the investors listed on the Schedule of Buyers thereto. Filed as Exhibit 4.5 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.
4.6	Pledge of Security Agreement dated as of October 30, 2006 by and among Agenus Inc. Inc., a Delaware corporation and the investors listed on the Schedule of Buyers thereto. Filed as Exhibit 4.3 to our Current Report on Form 8-K (File No. 0-29089) filed on October 31, 2006 and incorporated herein by reference.
4.7	Guaranty dated as of October 30, 2006 by and between Agenus Inc. Inc., a Massachusetts corporation and Ingalls & Snyder LLC, as Collateral Agent for the Buyers. Filed as Exhibit 4.4 to our Current Report on Form 8-K (File No. 0-29089) filed on October 31, 2006 and incorporated herein by reference.
4.8	Guaranty dated as of October 30, 2006 by and between Aronex Pharmaceuticals, Inc. and Ingalls & Snyder LLC, as Collateral Agent for the Buyers. Filed as Exhibit 4.5 to our Current Report on Form 8-K (File No. 0-29089) filed on October 31, 2006 and incorporated herein by reference.
4.9	Securities Purchase Agreement dated as of October 30, 2006 by and among Agenus Inc. Inc., a Delaware corporation and the investors listed on the Schedule of Buyers thereto. Filed as Exhibit 4.6 to our Current Report on Form 8-K (File No. 0-29089) filed on October 31, 2006 and incorporated herein by reference.
4.10	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.
4.11	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.
4.12	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.
4.13	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.
4.14	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.
4.15	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.

## **Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
4.16	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.
4.17	Ninth Amendment of Rights with respect to Events of Default and Issuance of Other Securities by and between Agenus Inc. and Ingalls & Snyder Value Partners L.P. dated February 23, 2011. Filed as Exhibit 4.17 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.
10.1*	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*	1999 Employee Stock Purchase Plan, as amended. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 11, 2007 and incorporated herein by reference.
10.3	Founding Scientist s Agreement between Agenus Inc. and Pramod K. Srivastava, Ph.D. dated March 28, 1995. Filed as Exhibit 10.3 to our registration statement on Form S-1 (File No. 333-91747) and incorporated herein by reference.
10.3.1(1)	Amendment to Founding Scientist s Agreement dated January 1, 2003. Filed as Exhibit 10.29 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2002 and incorporated herein by reference.
10.4	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.
10.4.1	Current schedule indentifying 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 as Exhibit 10.4.1 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.
10.5(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.
10.6(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.
10.7	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.

## **Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.7.1	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.
10.7.2	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.
10.7.3	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.
10.7.4	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.
10.7.5	Fifth Amendment to Lease dated April 11, 2011 between TBCI, LLC, as successor to BHX, LLC, as Trustee of 3 Forbes Road Realty Trust, and Agenus Inc. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2011 and incorporated herein by reference.
10.8*	Agenus Inc. Directors' Deferred Compensation Plan, as amended. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 11, 2007 and incorporated herein by reference.
10.8.1*	Third Amendment to Directors' Deferred Compensation Plan. Filed as Appendix E to our Definitive Proxy Statement on Schedule 14A filed on April 27, 2009 and incorporated herein by reference.
10.8.2*	Fourth Amendment to Directors' Deferred Compensation Plan. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on December 14, 2010 and incorporated herein by reference.
10.9 <sup>(1)</sup>	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.
10.9.1(1)	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.
10.9.2(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.
10.10*	Employment Agreement dated February 20, 2007 between Agenus Inc. and Shalini Sharp. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on February 26, 2007 and incorporated herein by reference.
10.10.1*	First Amendment to Employment Agreement dated July 2, 2009 between Agenus Inc. and Shalini Sharp. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended September 30, 2009 and incorporated herein by reference.



## **Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.10.2*	Second Amendment to Employment Agreement dated December 15, 2010 between Agenesis Inc. and Shalini Sharp. Filed as Exhibit 10.10.2 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 February 20, 2007 between Agenesis 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.
10.11.1*	First Amendment to Employment Agreement dated July 2, 2009 between Agenesis 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.
10.11.2*	Second Amendment to Employment Agreement dated December 15, 2010 between Agenesis 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.
10.12*	Employment Agreement dated December 1, 2005 between Agenesis 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.
10.12.1*	First Amendment to Employment Agreement dated July 2, 2009 between Agenesis 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.
10.12.2*	Second Amendment to Employment Agreement dated December 15, 2010 between Agenesis 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.
10.13*	Amended and Restated Executive Change-in-Control Plan. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on November 3, 2010 and incorporated herein by reference.
10.14*	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.
10.15*	Consulting Agreement dated March 28, 2006 between Agenesis Inc. and Pramod Srivastava. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on March 28, 2006 and incorporated herein by reference.
10.16(1)	License Agreement by and between Agenesis 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.
10.17	Standard Form of Loft Lease effective October 24, 2006 between 162 Fifth Avenue Associates LLC and Agenesis Inc. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q  (File No. 0-29089) for the quarter ended September 30, 2006 and incorporated herein by reference.
10.18	Form of the Johns Hopkins University Uniform Provisions for Board Service. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 15, 2006 and incorporated herein by reference.
10.19	At Market Issuance Sales Agreement between Agenesis Inc. and McNicoll, Lewis & Vlak LLC and Wm Smith & Co., dated February 26, 2010. Filed as Exhibit 1.1 to our Current Report on Form 8-K (File No. 0-29089) filed on March 1, 2010 and incorporated herein by reference.
10.20*	Employment Agreement dated September 16, 2008 between Agenesis 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.

## **Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.20.1*	First Amendment to Employment Agreement dated July 2, 2009 between Agenesis 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.
10.20.2*	Second Amendment to Employment Agreement dated December 15, 2010 between Agenesis 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.
10.21(1)	Amended and Restated License Agreement by and between Antigenics Inc., a Massachusetts corporation and wholly owned subsidiary of Agenesis 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.
10.22	Notice of Assignment of Amended and Restated License Agreement by and between Antigenics Inc., a Massachusetts corporation and wholly owned subsidiary of Agenesis Inc., Elan Pharma International Limited, and Elan Pharmaceuticals, Inc. dated September 17, 2009. Filed as Exhibit 10.6 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended September 30, 2009 and incorporated herein by reference.
10.23(1)	Supply Agreement by and between Agenesis Inc. and ISSI-Strategy LLC dated July 9, 2009. Filed as Exhibit 10.7 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended September 30, 2009 and incorporated herein by reference.
10.24	Securities Purchase Agreement dated as of July 30, 2009 by and among Agenesis 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.
10.25	Securities Purchase Agreement dated as of August 3, 2009 by and among Agenesis 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.
10.26(1)	Amended and Restated Manufacturing Technology Transfer and Supply Agreement by and between Agenesis Inc. and GlaxoSmithKline Biologicals SA dated January 19, 2009. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2009 and incorporated herein by reference.
10.27*	Summary of oral agreement between Garo H. Armen, PhD and Agenesis Inc. Agenesis Inc. modifying the base salary of Dr. Armen. Filed as Exhibit 10.3 to our Quarterly Report on  Form 10-Q (File No. 0-29089) for the quarter ended March 31, 2009 and incorporated herein by reference.
10.28	Securities Exchange Agreement by and between Agenesis Inc. and Tang Capital Partners, LP dated June 3, 2009. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2009 and incorporated herein by reference.
10.29	Securities Exchange Agreement by and between Agenesis Inc. and The Conus Fund L.P., The Conus Fund Offshore Master Fund Ltd., and The Conus Fund (QP) L.P. dated June 4, 2009. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2009 and incorporated herein by reference.
10.30	Securities Exchange Agreement by and between Agenesis Inc. and The Wolverine Convertible Arbitrage Fund Trading Limited dated June 4, 2009. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2009 and incorporated herein by reference.

## **Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
10.31*	Agenus Inc. 2009 Equity Incentive Plan. Filed as Appendix A to our Definitive Proxy Statement on Schedule 14A filed on April 27, 2009 and incorporated herein by reference.
10.31.1*	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.
10.31.2*	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.
10.32*	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.
10.33	Landlord, Sublessor and Sublessee Agreement dated August 4, 2010 between Agenus Inc., Cubist Pharmaceuticals, Inc., and TBCI, LLC, as Trustee of 3 Forbes Road Realty Trust. Filed as  Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2010 and incorporated herein by reference.
10.34	Sublease Agreement by and between Agenus Inc. and Cubist Pharmaceuticals, Inc. dated July 30, 2010. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2010 and incorporated herein by reference.
10.35	Form of Subscription Agreement. Filed as Exhibit 10.1 to our Current Report on Form 8-K  (File No. 0-29089) filed on December 14, 2010 and incorporated herein by reference.
10.36	Securities Exchange Agreement by and between Agenus Inc. and Invus Public Equities L.P. dated April 22, 2010. Filed as Exhibit 10.37 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.
10.37	Securities Exchange Agreement by and between Agenus Inc. and Bruce Fund Inc. dated November 18, 2010. Filed as Exhibit 10.38 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.
10.38	Securities Exchange Agreement by and between Agenus Inc. and Professional Life and Casualty dated November 18, 2010. Filed as Exhibit 10.39 to our Annual Report on Form 10-K  (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.
10.39	Securities Repurchase Agreement by and between Agenus Inc. and Ingalls & Snyder Value Partners L.P. dated December 7, 2010. Filed as Exhibit 10.40 to our Annual Report on Form 10-K (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.
10.40	Securities Exchange Agreement by and between Agenus Inc. and Ingalls & Snyder Value Partners L.P. dated December 28, 2010. Filed as Exhibit 10.41 to our Annual Report on Form 10-K  (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.
10.41	Underwriting Agreement by and between Agenus Inc. and William Blair & Company, LLC dated August 10, 2011. Filed as Exhibit 1.1 to our Current Report on Form 8-K (File No. 0-29089) filed on August 11, 2011 and incorporated herein by reference.
10.42	License Agreement by and between Agenus Inc. and NewVac LLC dated December 19, 2011. Filed herewith.
21	Subsidiaries of Agenus Inc. Filed as Exhibit 21 to our Annual Report on Form 10-K  (File No. 0-29089) for the year ended December 31, 2010 and incorporated herein by reference.
23	Consent of KPMG LLP, independent registered public accounting firm. Filed herewith.



---

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
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 Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith.
32.1(2)	Certification of Chief Executive Officer and Chief 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.
- (1) Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act or Rule 24b-2 of the Securities Exchange Act.
- (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.  
**Gar H. Armen, Ph.D.**  
*Chief Executive Officer and  
Chairman of the Board*

Dated: March 6, 2012

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 in the capacities indicated as of March 6, 2012.

Signature	Title
/s/ GARO H. ARMEN, PH.D.  <b>Gar H. Armen, Ph.D.</b>	Chief Executive Officer and Chairman of the Board of Directors  (Principal Executive Officer)
/s/ SHALINI SHARP  <b>Shalini Sharp</b>	Vice President and Chief Financial Officer  (Principal Financial Officer)
/s/ CHRISTINE M. KLASKIN  <b>Christine M. Klaskin</b>	Vice President, Finance  (Principal Accounting Officer)
/s/ BRIAN CORVESE  <b>Brian Corvese</b>	Director
/s/ TOM DECHAENE  <b>Tom Dechaene</b>	Director
/s/ WADIH JORDAN  <b>Wadih Jordan</b>	Director
/s/ TIMOTHY R. WRIGHT  <b>Timothy R. Wright</b>	Director

---

**Table of Contents**

**Exhibit 10.42**

**LICENSE AND DEVELOPMENT AND MANUFACTURING TECHNOLOGY TRANSFER AGREEMENT**

This Exclusive License and Development and Manufacturing Technology Transfer Agreement (this Agreement ), effective as of the date of the last signature hereto (the Effective Date ), is made by and between Agenesis Inc., a Delaware corporation having offices at 3 Forbes Road, Lexington, MA 02421 ( Agenesis ), and NewVac Ltd., a limited liability company established under Russian laws, with offices at 2a-1, Rabochaya St., Khimki, Moscow 141400 Russia ( Licensee ). Agenesis and Licensee are each referred to herein as a Party and collectively, as the Parties .

**RECITALS**

WHEREAS, Agenesis is in the business of developing novel products for the prevention and treatment of cancers and infectious diseases, and has proprietary rights in a product approved in the Russia Federation for the prevention of the recurrence of adjuvant renal cell carcinoma;

WHEREAS, Licensee is in the business of developing, manufacturing and commercializing novel products in the Russian Federation and is interested in collaborating with Agenesis for the further development and commercialization of the Agenesis product.

NOW THEREFORE, in consideration of the foregoing premises, the following mutual promises and covenants and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

**ARTICLE I**

**Definitions**

When used in this Agreement, each of the following terms shall have the meanings as set forth in this Article I.

1.1 Agenesis Product means HSPPC-96 vaccine, also known as vitespen, and also known as Oncophage<sup>®</sup> vaccine for the adjuvant treatment of renal cell carcinoma, as defined in the Registration Certificate attached in the Exhibit B.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

1.2 Agenus Product Requirements means the amount of Agenus Product which Licensee and its Sublicensees require pursuant to the provisions hereof for commercialization of Agenus Product pursuant to this Agreement and the research and development of the Combination Product pursuant to this Agreement.

1.3 Affiliate means any corporation or other entity that controls, is controlled by, or is under common control with, a Party. For purposes of this Section 1.3, an entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than 50% of the voting securities or other ownership interest of the other corporation or entity.

1.4 Biomaterial means a tumor tissue specimen collected for use in manufacturing Agenus Product.

1.5 cGMPs means the applicable current Good Manufacturing Practices for Finished Pharmaceuticals pursuant to 21 C.F.R. 210 et seq., as amended from time to time, or its equivalent in the Russian Federation or such other equivalent in the applicable territory within the Territory.

1.6 CMO means a contract manufacturing organization.

1.7 Development Indication shall mean the Licensed Indication, or such other indication(s) as may be agreed to in writing between the Parties.

1.8 Development Plan has the meaning set forth in Section 4.1(b).

1.9 Combination Product means Agenus Product combined with Licensee Product whether administered together or via different routes of administration and/or at different sites or times.

1.10 Commercialization Plan has the meaning set forth in Section 4.1(b)

1.11 Control or Controlled means with respect to any material, item of information or intellectual property right, the possession, whether by ownership, license or otherwise, of the right to grant a license, sublicense or other right with respect thereto.

1.12 Developments has the meaning set forth in Section 11.1(b).

1.13 First Commercial Sale means on a country-by-country basis the date of first commercial sale of such product in such country pursuant to this Agreement.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.



---

**Table of Contents**

1.14 Gross Sales means the amount billed or invoiced on arms-length sales by Licensee, its Sublicensees or distributors to Third Parties.

1.15 Licensed Indication means the adjuvant treatment of renal cell carcinoma in patients at intermediate risk of recurrence.

1.16 Licensed Know-how means (a) the Manufacturing Technology, and (b) any other materials, data, results, formulae, designs, specifications, methods, processes, improvements, techniques, ideas, discoveries, technical information, process information, clinical information and any other information, whether or not any of the foregoing is patentable, which is known to, and is Confidential Information and proprietary to, Agenus and Controlled by Agenus, to the extent that any of the foregoing (i) is necessary or reasonably useful to make, have made, use or sell the Agenus Product in the Licensed Indication in accordance with this Agreement, or (ii) is otherwise necessary or reasonably useful for the use of Agenus Product in connection with the research, development, manufacture or use of the Combination Product in the Development Indication in accordance with this Agreement.

1.17 Licensed Patent Rights means any and all patent applications and patents (including inventor's certificates and utility models) throughout the world, including any substitutions, extensions, reissues, reexaminations, renewals, divisions, continuations and continuations-in-part of the foregoing, Controlled by Agenus (regardless of any royalty or other payments to a Third Party required of Agenus), necessary or reasonably useful for the development, manufacture, use, sale offer for sale or importation of the Agenus Product or the Combination Product. The Licensed Patent Rights existing as of the Effective Date are listed on Exhibit A attached and incorporated into this Agreement.

1.18 Licensee Product means Istradefyllin as a co-adjuvant.

1.19 Manufacturing Capacity means the capacity of the Agenus manufacturing facility in Lexington, MA USA to make Agenus Product for Licensee hereunder, taking into account Agenus' other manufacturing & on-going compliance requirements, financial resources, staffing and capital equipment considerations, as of January 31, 2012, or such other capacity as may be agreed to between the Parties from time to time.

1.20 Manufacturing Technology means materials, data, results, formulae, designs, specifications, methods, processes, improvements, techniques, ideas, discoveries, technical information, process information, clinical information and any other information, whether or not any of the foregoing is patentable, which is known to and is Confidential Information and proprietary to Agenus and is Controlled by Agenus, solely to the extent that any of the foregoing is necessary or reasonably useful for the manufacture of the Agenus Product for the Licensed Indication and Development Indication in accordance with the Specifications and Agenus standard operating procedures as of the Effective Date, as further defined in the Technology Transfer Plan.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

---

**Table of Contents**

1.21 Net Sales means with respect to the Agenesis Product, or the Combination Product, as the case may be, the Gross Sales of such Agenesis Product or Combination Product minus the following items to the extent such items are incurred, taken or borne by the seller thereof and do not exceed reasonable and customary amounts in the market in which such sale occurred: (a) trade, cash or quantity discounts; (b) credits or allowances given or made for rejection or approved return of goods; (c) taxes or government charges, duties or tariffs (other than an income tax) levied on the sale, transportation or delivery of such Agenesis Product or Combination Product. Sales between Licensee and its Sublicensees or its distributors shall be excluded from the computation of Net Sales except where such Sublicensees are the end users, but Net Sales shall include the subsequent final sales to Third Parties by such Sublicensees, or distributors.

1.22 Pre-existing Intellectual Property shall have the meaning set forth in Section 11.1(a).

1.23 Price shall have the meaning set forth in Section 3.2.

1.24 Production Milestone has the meaning set forth in Section 12.2(a).

1.25 Production Milestone Deadline has the meaning set forth in Section 12.2(b).

1.26 Registration Certificate has the meaning set forth in Section 6.1(a).

1.27 Regulatory Approval means any approval of any applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical product in any country or regulatory jurisdiction in the Territory, including, if applicable, any separate pricing or reimbursement approvals that may be required in any country or regulatory jurisdiction in the Territory.

1.28 Regulatory Authority means any federal, national, multi-national, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing or sale of pharmaceutical products.

1.29 Regulatory Materials means regulatory applications, submissions, notifications, registrations, Regulatory Approvals, including the Registration Certificate, and/or other filings made to or with a Regulatory Authority that are necessary or reasonably desirable in order to research, develop, manufacture, receive Regulatory Approval or market and distribute the a pharmaceutical product in a particular country or regulatory jurisdiction.

1.30 Specifications shall mean the product release specifications for the Agenesis Product, whether sold as Agenesis Product or as part of the Combination Product, as defined in Exhibit C.

1.31 Sublicensee(s) means a party granted a sublicense of the licenses granted pursuant to Section 2.1 of this Agreement, whether such party is an Affiliate or Third Party.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

---

**Table of Contents**

1.32 Supply Opt Out has the meaning set forth in Section 12.3.

1.33 Supply Period has the meaning set forth in Section 12.3.

1.34 Technology Transfer Plan has the meaning set forth in Section 12.1.

1.35 Term is defined in Section 10.1.

1.36 Territory means the countries listed on Exhibit D.

1.37 Third Party means any party other than a Party, their respective Affiliates or a Sublicensee.

1.38 Valid Claim means a claim in an issued, unexpired patent, or a claim of a pending patent application, in the Licensed Patent Rights, which has not been held invalid, unpatentable or unenforceable in an unappealed or unappealable decision of a court or other governmental body of competent jurisdiction, which has not been rendered unenforceable through disclaimer or otherwise, and which has not been lost through an interference or other proceeding, provided that if any pending patent application is pending for more than [\*\*] years, it shall cease to be within the definition of Valid Claim unless and until it issues.

**ARTICLE II**

**Licenses**

2.1 Grant of License Rights to Licensee. Subject to the terms and conditions of this Agreement, Agenus hereby grants to Licensee an exclusive license within the Territory to use and practice the Licensed Know-how and Licensed Patent Rights: (a) to make, have made, use, sell, offer for sale, and import Agenus Product for the Licensed Indication in the Territory; and (b) to make, have made and use Agenus Product solely to research, develop, make, have made, use, sell, offer for sale and import Combination Products for the Development Indication in the Territory solely in accordance with the Development Plan. In no event shall Licensee, its Sublicensees, or any CMO acting at Licensee's or its Sublicensees' instruction, practice the Licensed Patent Rights or Licensed Know-how for purposes other than as set forth above. In no event shall Licensee have the right to manufacture or have manufactured the Agenus Product outside of the Specifications without the prior written consent of Agenus.

2.2 Sublicenses. Licensee shall have the right (a) to grant sublicenses of its rights under this Agreement with respect to Agenus Product and/or Combination Product, and/or (b) to engage a CMO approved pursuant to Section 12.2(d) for purposes of manufacturing the Agenus Product for use alone or in the Combination Product, in each case, solely with the prior written consent of Agenus. Licensee shall promptly notify Agenus of the execution of

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

each Sublicense or CMO arrangement and shall provide Agenus with a copy of the same. Licensee and each Sublicensee or CMO shall enter into a written sublicense agreement subject to, consistent with, and not to extend beyond the scope of Licensee's rights and obligations under, and the terms and conditions of, this Agreement, which written sublicense agreement shall require the Sublicensee to agree to be bound by and comply with provisions that are consistent with the provisions of this Agreement. Licensee shall remain responsible for compliance by any Sublicensee or CMO receiving any rights hereunder with all terms and conditions of this Agreement relevant to such Sublicensee or CMO.

### **ARTICLE III**

#### **Payments**

3.1 **Milestones.** As consideration for the rights and licenses granted to Licensee upon the achievement of [\*\*] of the Agenus Product (including as part of a Combination Product) of [\*\*] U.S. dollars (\$[\*\*] USD) (as measured on an Agreement year basis until the [\*\*] anniversary of the Effective Date, and as measured during any [\*\*] period thereafter), Licensee shall pay Agenus [\*\*] U.S. dollars (\$[\*\*] USD) within thirty days (30) of such achievement. Licensee shall promptly give Agenus notice of the occurrence of such milestone.

[\*\*] made in any currency other than United States dollars shall be converted to United States dollars for the purpose of assessing achievement of this milestone. Such conversion shall be done in accordance with the following formula:

$A/B$  = United States dollar sales amount for each month, where

A = foreign currency [\*\*] in the applicable month; and

B = foreign exchange conversion rate, expressed in local currency per United States dollar (using as the applicable foreign exchange conversion rate, the rate established by the Central Bank of the Russia Federation, or any other mutually agreed-upon source, for the last five (5) business days of each month).

#### 3.2 **Agenus Product Supply Pricing and Payment Terms.**

3.2.1 **Pricing.** For each patient batch of Agenus Product that may be supplied by Agenus pursuant to Section 12.3, Licensee shall purchase such Agenus Product at a transfer price (the Price) of \$[\*\*] USD per patient batch, subject to the remaining provisions of this Agreement. For Agenus Product so supplied by Agenus pursuant to Section 12.3 and to be used by Licensee for use in clinical trials under the Development Plan and for which Licensee

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

makes [\*\*] or receives any other form of [\*\*], Agenesis shall supply such Agenesis Product at [\*\*] (i.e., at a Price of \$[\*\*] USD per [\*\*]); provided, however, that is without in any way limiting Agenesis' other rights under this Agreement, in the event that Licensee has not met the [\*\*] (as defined in Section 12.2(a)) by the [\*\*] of the Effective Date and Agenesis agrees to [\*\*] the relevant milestone deadlines pursuant to the provisions of this Agreement, then Licensee shall pay Agenesis a Price of \$[\*\*] USD per patient batch for such Agenesis Product supplied by Agenesis pursuant to Section 12.3. The Price does not include, and Licensee shall be solely responsible for: (i) costs of transporting Biomaterials to Agenesis' facility in Lexington, MA, USA, including any additional licenses Agenesis would need to obtain to facilitate such activities, (ii) costs of shipping Agenesis Product to the Territory (CIP Moscow, customs border or such other country border within the Territory as may be agreed to between the Parties), including any additional licenses Agenesis would need to obtain to facilitate such activities, and (iii) all other costs and expenses related to the supply of the Agenesis Product by Agenesis, such as customs fees, VAT, etc. For the avoidance of doubt and notwithstanding any other provision of this Agreement, in the event that Licensee sells Agenesis Product to a Third Party for use in [\*\*] under the Development Plan, Licensee shall compensate Agenesis the applicable \$[\*\*] USD or \$[\*\*] USD Price for such Agenesis Product supplied by Agenesis pursuant to Section 12.3. In addition to the applicable Price set forth above, in the event that Licensee sells any Agenesis Product supplied by Agenesis pursuant to Section 12.3 at a Gross Sales price above \$[\*\*] USD per patient batch, then in addition to the Price for such Agenesis Product, Licensee shall also pay Agenesis a royalty of [\*\*]% on the difference in Net Sales for such Agenesis Product.

**3.2.2 Payment Terms.** Agenesis shall invoice Licensee for each Agenesis Product sold for which payment is owing pursuant to this Section 3.2. Invoices may be sent by Agenesis via email or in hard copy, such as with the Agenesis Product shipment. Licensee shall pay Agenesis the Price for each Agenesis Product and any royalty that may be owing under Section 3.2.1 above within the earlier of (i) five (5) Business Days of the receipt of payment to Licensee from the purchaser or (ii) sixty (60) days of delivery of Agenesis Product to the Russian customs border (or other applicable country within the Territory's customs border). Unless otherwise elected by Agenesis, Licensee shall make all payments required under this Agreement in United States Dollars by wire transfer to an account specified by Agenesis. Licensee shall be responsible for the banking charges associated with any wire transfers under this Agreement.

**3.3 Royalties.** Subject to other terms of this Agreement, and as consideration for the rights and licenses granted to Licensee hereunder, Licensee shall pay royalties to Agenesis on Net Sales of Agenesis Product not supplied by Agenesis pursuant to Section 12.3 as follows:

- (i) Licensee will pay to Agenesis a royalty of [\*\*] percent ([\*\*]%) of Net Sales of each Agenesis Product in the Territory.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

---

**Table of Contents**

- (ii) In the event of Regulatory Approval of the Combination Product in a given Territory, Licensee would pay to Agenesis a royalty of [\*\*] percent ([\*\*]%) of Net Sales of such Combination Product in such Territory. For the avoidance of doubt, Net Sales of Agenesis Product made prior to Regulatory Approval of the Combination Product would be subject to the royalty provisions of Section 3.3(i) above.

3.4 Royalty Term. Licensee will make royalty payments on a country-by-country basis during the Term, as may be extended pursuant to Section 10.2.

3.5 Royalty Payments, Reports and Records

- 3.5.1 Commercial Introduction. Licensee shall promptly give Agenesis notice of the occurrence of the First Commercial Sale of the Agenesis Product and the First Commercial Sale of the Combination Product, if applicable, in each country within the Territory hereunder. In no event shall the First Commercial Sale of any Agenesis Product occur prior to January 31, 2012 unless otherwise agreed in writing between the Parties.

3.5.2 Royalty Payments.

(a) Payments: Deduction of Taxes. A royalty report and payment under this Agreement on Net Sales of the Agenesis Product will be due and payable from Licensee to Agenesis within forty-five (45) days of the last calendar day of each month. Licensee will remit any such payment due to Agenesis under this Agreement by wire or check payable to Agenesis. Licensee shall make applicable withholding payments due on behalf of Agenesis and shall promptly provide Agenesis with written documentation of any such taxes withheld and paid by Licensee or its Sublicensees for the benefit of Agenesis. Notwithstanding the foregoing, if Agenesis is entitled under any applicable tax treaty to a reduction of the rate of, or the elimination of, applicable withholding tax, it may deliver to Licensee or the appropriate governmental authority (with the assistance of Licensee to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding tax or to relieve Licensee of its obligation to withhold tax, and Licensee shall apply the reduced rate of withholding tax, or dispense with withholding tax, as the case may be. If, in accordance with the foregoing, Licensee withholds any amount, it shall pay to Agenesis the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to Agenesis proof of such payment within thirty (30) days following that payment. In addition to, and notwithstanding any other provision of this Agreement, in the event that Licensee grants a sublicense or assigns its rights and obligations hereunder, and as a result of such sublicense or assignment, a deduction or withholding on any payment to Agenesis under this Agreement is required by any applicable

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## Table of Contents

law that would not have been required absent such sublicense or assignment, then Licensee (including its successors, transferees, and assigns) will pay (or authorize payment) to Agenesis such additional amount as is necessary to ensure that the net amount actually received by Agenesis (free and clear of any tax/withholding, including any tax/withholding imposed on or with respect to the additional amount, whether assessed against Licensee or Agenesis) will equal the full amount Agenesis would have received had no such deduction or withholding been required.

(b) Foreign Currency Conversion. For sales of any Licensed Product that occur in a currency other than United States dollars ( Foreign Currency Sales ), the monthly royalty payment will be calculated as follows:

$(A/B) \times C$  = United States dollars royalty payment on Foreign Currency Sales, where

A = foreign currency Net Sales per month; B = foreign exchange conversion rate, expressed in local currency per United States dollar (using as the applicable foreign exchange conversion rate, the rate established by the Central Bank of the Russia Federation, or any other mutually agreed-upon source, on the day of payment); and

C = the royalty rate applicable to such Net Sales under Section 3.3.

3.5.3 Royalty Reports. Licensee shall render to Agenesis, together with the royalty payment due under Section 3.5.2 for a given calendar month, within [\*\*] days of the end of such month, a written account for such calendar month showing (a) total Gross Sales and Net Sales for the Agenesis Product and the Combination Product in the Territory, separately, and (b) a calculation of the royalties payable under Section 3.3, or 3.2.2 if applicable, for the Agenesis Product (including, in the case of foreign currency sales, the total foreign currency Net Sales during such calendar month, the applicable foreign exchange conversion rate(s) and the total United States dollar royalty payment amount).

3.6 Delinquent Payments. Any delinquent payment amounts under this Agreement shall bear interest at a rate equal to [\*\*] percent ([\*\*]%) per month ([\*\*] percent ([\*\*]%) per [\*\*]) or, if lower, at the maximum rate allowed by applicable law. Agenesis reserves the right to withhold delivery of Agenesis Product during any period in which Licensee has any amounts outstanding and past due. Such withholding of delivery will not constitute a breach of Agenesis' obligations.

3.7 Licensee's Recordkeeping and Inspection. Licensee shall keep records of all sales of Agenesis Product and Combination Product in sufficient detail to permit Agenesis to confirm the accuracy of payments owing and made hereunder, for a period of at least [\*\*] years from the

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

date such payments would be owing hereunder. At the request of Agenesis no more frequently than once per year, upon at least ten (10) business days prior written notice to Licensee from Agenesis, and at the expense of Agenesis (except as otherwise provided below), Licensee shall permit a U.S. nationally recognized, independent certified public accountant selected by Agenesis and reasonably acceptable to Licensee to inspect, during regular business hours, any such Licensee records solely to the extent necessary to verify such calculations, provided that such accountant in advance has entered into a confidentiality agreement with Licensee (substantially similar to the confidentiality provisions of this Agreement) limiting the disclosure of such information to authorized representatives of the Parties. Results of any such inspection shall be made available to both Parties. If such inspection reveals a deficiency in the calculation of payments owed or owing resulting in an underpayment to Agenesis, Licensee shall promptly pay the difference owing, and in the event that the deficiency in the calculation of payments owed or owing results in an underpayment to Agenesis by five percent (5%) or more, Licensee shall promptly pay all reasonable costs and expenses of such inspection.

3.8 **Acknowledgement.** The Parties acknowledge and agree that (i) the compensation terms set forth in this Agreement were agreed to after careful evaluation of various alternatives to reasonably compensate Agenesis for its substantial investment over time in developing the Agenesis Product, Licensed Patent Rights and Licensed Know-how, including without limitation potential up-front payments, refunds for past investments by Agenesis, milestone payments, royalties, and maintenance fees, and (ii) the current payment terms as set forth herein were agreed to by Agenesis and Licensee each, for the convenience of the Parties, including to enable Licensee to defer payment obligations.

## **ARTICLE IV**

### **Joint Steering Committee and Specific Responsibilities of the Parties**

#### **4.1 Joint Steering Committee.**

(a) Within thirty (30) days after the Effective Date, Agenesis and Licensee will establish a joint steering committee (the "JSC") to oversee the activities to be undertaken pursuant to this Agreement. The JSC will facilitate communication between the Parties and provide a forum to review any matters relating to manufacturing technology transfer, supply, the Commercialization Plan and the Development Plan. The JSC shall consist of an equal number of individuals appointed by each Party (up to three (3) per Party), or such other number of representatives the Parties may mutually agree upon, and may also include additional representatives from the Parties, as mutually agreed, on an ad-hoc basis. The JSC shall be co-chaired by one appointee of each of Agenesis and Licensee. The co-chairs will coordinate agendas and minute-taking for meetings of the JSC. Each Party may replace its JSC representatives at any time upon written notice to the other Party provided that, the Party intending to change its representative(s) will first notify the other Party and will take the other

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.



## **Table of Contents**

Party's reasonable objection to any such replacement into consideration. Meetings of the JSC shall be effective only if at least one representative of each Party is present and participating. The JSC may establish certain ad hoc sub-committees which consider certain matters, including without limitation, one or more sub-committees (consisting of at least one (1) individual from each Party). Each Party shall be responsible for its own expenses for participating in the JSC.

(b) The JSC shall meet (in person, or by teleconference or videoconference as agreed by the Parties) at least once quarterly (or more frequently as the Parties mutually agree is appropriate, or on such dates and at such times as the Parties shall agree). The JSC (itself or through one or more sub-committees) will, among other things: (i) develop and oversee the commercialization activities relating to the Agenus Product in the Licensed Indication in the Territory, in accordance with the commercialization plan and budget (the Commercialization Plan), and (ii) develop and oversee the development activities relating to the Combination Product in the Development Indication, in accordance with the 3 year development and regulatory strategy, implementation plan and budget for the Combination Product in the Development Indication in the Territory (the Development Plan), as may be amended from time to time by the JSC, (iii) discuss and review the conceptual design of Licensee's or CMO's manufacturing facility for Agenus Product and discuss and review validation plans for manufacturing, QC testing and facilities; and (iv) address such other matters as may be agreed to between the Parties, including open matters that may exist at the level of the sub-committees. The initial Development Plan and Commercialization Plan shall be consistent with the provisions of Exhibit E-1 and E-2 respectively and shall be agreed to between the Parties within forty-five (45) days of the Effective Date, and may thereafter be amended from time to time by the JSC.

(c) Decisions of the JSC will be made by unanimous consent of the co-chairs. In the event that the co-chairs of the JSC cannot come to consensus within thirty (30) days with respect to any matter over which the JSC has authority and responsibility, the JSC shall submit the matter to dispute resolution in accordance with Section 13.4.

(d) The JSC shall continue to exist until the first to occur of: (a) the Parties mutually agreeing to disband the committee; or (b) Agenus providing to Licensee written notice of its intention to disband and no longer participate in the JSC.

(e) Should the JSC disband per subsection (d), above, and not as part of the termination of this Agreement, the Parties agree to each nominate a single point of contact within their respective companies, to facilitate the continuation of the activities and projects contemplated by this Agreement.

**4.2 Certain Responsibilities of the Parties.** The Parties acknowledge and agree that, subject to the provisions of this Agreement: (i) Licensee shall be primarily responsible for conducting the development activities under the Development Plan and all commercialization

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

activities under the Commercialization Plan, unless otherwise expressly set forth in this Agreement, at its sole cost and expense, (ii) Agenus shall reasonably cooperate with Licensee in connection therewith by providing reasonable access to (a) Licensed Know-How necessary to conduct the Development Plan and Commercialization Plan activities, and (b) personnel necessary to carry out the Commercialization Plan or Development Plan, at Agenus' sole cost and expense up to a maximum of \$[\*\*] USD during the Term (including FTEs at an annual FTE rate of \$[\*\*] USD), and Licensee shall reimburse Agenus all costs and expenses of Agenus, in excess of such \$[\*\*] cap, and in each case provided that such cooperation does not unreasonably interfere with the business operations of Agenus, (iii) Agenus shall provide available and approved tumor procurement/shipping kits for the Biomaterials and the Agenus Product during the Supply Period; and (iv) Licensee shall provide Licensee Product for use in the Development Plan activities during the Term at its sole cost and expense. In addition, and for the avoidance of doubt, Licensee shall have the following responsibilities: (a) use its best commercially reasonable efforts to commercialize the Agenus Product in the Territory in accordance with the provisions of the Agreement, the Commercialization Plan, and all applicable laws; (b) conduct a limited physician post marketing (observation or registry) study (PhIV) in the Licensed Indication during the initial Term; (c) conduct all marketing and sales activities for the Agenus Product in the Territory in the Licensed Indication (and Development Indication, if applicable) in accordance with a Commercialization Plan; (d) manage all tumor procurement and logistical activities; (e) manage all regulatory and pharmacovigilance activities for the Agenus Product in the Territory in the Licensed Indication and the Combination Product in the Development Indication in accordance with Article VI; (f) expeditiously obtain and maintain Biomaterial export and Agenus Product import licenses during the Supply Period, if applicable; (g) act as importer for tumor procurement/shipping kits during the Supply Period, if applicable; and (h) manufacture all Agenus Product for the Territory and Approved Indication and Development Indication in accordance with the Technology Transfer Plan and applicable laws, rules and regulations, other than any Agenus Product that may be supplied by Agenus pursuant to Section 12.3. Licensee acknowledges and agrees to the following obligations: (i) Licensee shall conduct all activities in the Territory with respect to the Agenus Product and Combination Product and its activities hereunder in accordance with this Agreement, the Specifications, and all applicable laws, rules, regulations and guidelines; and (ii) Licensee shall obtain and maintain all permits, licenses, filings, certifications or other authorizations required by Regulatory Authorities for the performance of its rights and obligations under this Agreement.

## **ARTICLE V**

### **Due Diligence**

5.1 **Maintenance of License.** In order to maintain the licenses granted pursuant to Section 2.1, Licensee shall use its best commercially reasonable efforts at its sole cost and expense to (i) complete the Manufacturing Diligence Milestones (as defined in Section 12.2) by the

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

**Table of Contents**

Manufacturing Milestone Deadlines (as defined in Section 12.2 and subject to Section 12.2(b)) and (ii) market and sell the Agenus Product in the Licensed Indication in the Territory and conduct the Development Plan activities, in each case in accordance with applicable laws, rules and regulations, and the provisions of this Agreement, including without limitation, meeting the following commercial milestones by the applicable milestone dates below (each a Commercial Milestone Deadline):

<b>MILESTONE</b>	<b>MILESTONE DATE</b>
\$[**] USD in [**] Gross Sales	By [**], provided that in the event that [**] the [**], then within first [**] months of the [**] date,
\$[**] USD in [**] Gross Sales	between [**] and [**], provided that in the event that [**] the [**], then between the [**] and [**] [**] of the [**] date
\$[**] USD in [**] Gross Sales	between [**] and [**], provided that in the event that [**] the [**], then between the [**] and the [**] [**] of the [**] date

In the event that any of the milestones above are not met by the respective milestone date, the Parties shall meet to discuss the reasons for failure. In the event that Licensee demonstrates to Agenus satisfaction that it used its best commercially reasonable efforts to meet such milestone, the Parties shall agree upon an appropriate extension for achievement of such milestone and Agenus shall not have the right to terminate the Agreement. In addition and notwithstanding the above, in the event that Licensee fails to demonstrate to Agenus satisfaction that it used its best commercially reasonable efforts to meet any of the above commercial milestones by the milestone dates (or any extension allowed for above), Agenus shall have a right to terminate the Agreement upon 60 days written notice to Licensee. Upon receipt of any termination notice under this Agreement, Licensee shall immediately cease taking new product orders with respect to Agenus Product and Combination Product (if applicable) unless otherwise agreed in writing between the Parties, and shall cause its Sublicensees and distributors to do the same.

Gross Sales made in any currency other than United States dollars shall be converted to United States dollars for the purpose of assessing achievement of this milestone. Such conversion shall be done in accordance with the following formula:

$A/B$  = United States dollar sales amount for each month, where

A = foreign currency Gross Sales in the applicable month; and

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

B = foreign exchange conversion rate, expressed in local currency per United States dollar (using as the applicable foreign exchange conversion rate, the rate established by the Central Bank of the Russia Federation, or any other mutually agreed-upon source, for the last five (5) business days of each month).

### **ARTICLE VI**

#### **Regulatory Matters**

##### **6.1 Regulatory Filings**

###### **(a) Agenus Product.**

(i) Agenus will maintain and transfer to Licensee the registration certificate for Regulatory Approval of the Agenus Product for the Licensed Indication in Russia (the Registration Certificate ) upon the later of (i) Licensee's achievement of the Production Milestone or (ii) the extension of the initial Registration Certificate (the Certificate Transfer Date ); provided that Licensee is in full compliance with the provisions of this Agreement. In furtherance thereof and subject to the foregoing, the Parties shall work together to begin the process of filing necessary amendments in a timely manner so as to mitigate the chances of a potential lag in the effectiveness of the Registration Certificate. Upon transfer of the Registration Certificate to Licensee hereunder, Licensee shall be responsible for the maintenance thereof in accordance with the remaining provisions of this Section 6.1 at its sole cost and expense.

(ii) Except as expressly set forth above and unless otherwise agreed in writing between the Parties, Licensee shall be responsible for preparing and filing all Regulatory Materials, including without limitation furnishing timely notice of all side effects, drug interactions and other adverse effects identified or suspected with respect to the Agenus Product, and seeking all Regulatory Approvals for the Licensed Indication in the Territory in the name of Licensee, and for all communications and other dealings with the Regulatory Authorities relating to the Agenus Product in the Territory. Notwithstanding the foregoing or any other provision of this Agreement, Agenus shall have the right to review and pre-approve and/or propose modifications of, all such materials, approvals and communications, as well as all marketing and/or education materials collectively referred to herein as Pre-Certificate Transfer Date Regulatory Materials ) relating to the Agenus Product prior to the Certificate Transfer Date. NewVac shall provide all such Pre-Certificate Transfer Date Regulatory Materials to Agenus in both the Russian and English languages in a timely manner, and Agenus will provide to NewVac a response (in English) approving or requesting modifications to such Pre-Certificate Transfer Date Regulatory Materials within 5 business days from receipt thereof.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

(iii) Upon the expiration or termination of this Agreement, Licensee shall promptly take all actions necessary to make Agenesis the legal and beneficial owner of all Regulatory Approvals and Regulatory Materials for the Agenesis Product in the Territory. In the event that any such Regulatory Approvals and/or Regulatory Materials are not transferable to Agenesis, then Licensee shall use its best efforts, at its own expense, to assist Agenesis in obtaining Regulatory Approvals and/or Regulatory Materials substantially similar to the non-transferable Regulatory Approvals and/or Regulatory Materials. Without in any way limiting the foregoing, upon the expiration or termination of the Agreement, the Registration Certificate would be re-transferred to Agenesis, and Licensee would take all legal actions necessary to facilitate such transfer or reissuance.

(iv) Combination Product. Unless otherwise agreed in writing between the Parties, Licensee shall be responsible for preparing and filing all Regulatory Materials, including without limitation furnishing timely notice of all side effects, drug interactions and other adverse effects identified or suspected with respect to the Combination Product, and seeking all Regulatory Approvals in the Development Indication in the Territory. All Regulatory Materials for the Combination Product in the Territory shall be filed in the name of Licensee, and Licensee shall be responsible for all communications and other dealings with the Regulatory Authorities relating to the Combination Product in the Territory. Notwithstanding the foregoing or any other provision of this Agreement, Agenesis shall have the right to review and pre-approve and/or propose modifications of, all Pre-Certificate Transfer Date Regulatory Materials relating to the Combination Product prior to the Certificate Transfer Date. NewVac shall provide all such Pre-Certificate Transfer Date Regulatory Materials to Agenesis in both the Russian and English languages in a timely manner, and Agenesis will provide to NewVac a response (in English) approving or requesting modifications to such Pre-Certificate Transfer Date Regulatory Materials within a commercially reasonable time from receipt thereof. Licensee shall be the legal and beneficial owner of all Regulatory Approvals, to the extent applicable during the Term, and Regulatory Materials for the Combination Product in the Territory or in the event any such Regulatory Approvals and/or Regulatory Materials may not be owned by Licensee, they shall be held for the benefit of Licensee and shall be transferable as directed by Licensee, subject to Section 13.2.

6.2 Dealings with Regulatory Authorities. In addition and notwithstanding the foregoing, each Party shall promptly notify the other Party of all Regulatory Materials that it submits pursuant to this Agreement, and, at the other Party's request, shall promptly provide the other Party with a copy of such Regulatory Materials. Each Party will provide the other Party with reasonable advance notice of any scheduled meeting with any Regulatory Authority in the Territory relating to the Agenesis Product or Combination Product in the Licensed Indication or Development Indication (as applicable), and the other Party shall have the right to participate

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

---

**Table of Contents**

in any such meeting, to the extent permitted by law. Each Party shall promptly furnish the other Party with summaries (in English) of all material correspondence or material meetings with any Regulatory Authority relating to the Agenesis Product or Combination Product in the Licensed Indication or Development Indication (as applicable) in the Territory, and each Party shall, at the other Party's request, promptly furnish the other Party with copies of such correspondence or copies of minutes of such meetings in English.

6.3 Adverse Events. Licensee agrees, subject to regulatory guidelines and restrictions, to provide Agenesis with all safety information developed during the course of its studies in humans on the Agenesis Product or Combination Product. On an on-going basis during the Term and for the term during which Licensee has any safety reporting responsibilities for the Agenesis Product or Combination Product, Licensee agrees to provide Agenesis with any written information in its possession and Control which likely related to adverse effects in humans associated with the Agenesis Product or Combination Product, and all written information in its possession and Control of a reasonably material nature regarding the amelioration of such adverse events.

6.4 Product Withdrawals and Recalls. In the event that any Regulatory Authority (a) threatens or initiates any action to remove the Agenesis Product or Combination Product from the market in any country in the Territory or (b) requires Licensee or its Affiliates to distribute a Dear Doctor letter or its equivalent regarding use of the Agenesis Product or Combination Product in the Territory, Licensee shall notify Agenesis and the JSC of such event within one (1) business day after Licensee becomes aware of the action, threat, or requirement. The JSC shall immediately evaluate the request of such Regulatory Authority prior to initiating a recall or withdrawal of the Agenesis Product or Combination Product in the Territory. If the Parties do not reach an agreement within five (5) business days the final decision as to whether to recall or withdraw the Agenesis Product or Combination Product or take other remedial action in the Territory, such decision will be the responsibility of the party holding the Registration Certificate. Licensee will be responsible, at its sole expense, for conducting any recalls or taking such other necessary remedial action related to the Agenesis Product or Combination Product. Licensee shall maintain complete distribution records by purchaser, and by unique patient code and batch number for all Agenesis Product or Combination Product sold within the Territory in accordance with cGMPs. If either Party becomes aware of information about the Agenesis Product or Combination Product indicating that it may not conform to the Specifications for the Agenesis Product (including as part of a Combination Product), or that there are potential adulteration, misbranding and/or other issues regarding safety or effectiveness, it shall promptly so notify the other Party.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

**Table of Contents**

**ARTICLE VII**

**Representations and Warranties and Obligations of the Parties**

7.1 General Licensee Representations. Licensee represents and warrants and agrees as follows as of the Effective Date:

(a) Organization, Standing and Authority. Licensee is a company duly organized, validly existing and in good standing under the laws of Russia. Licensee has all requisite corporate power to own and operate its properties and assets and to carry on its business as presently being conducted and as proposed to be conducted. Licensee has, and will have on all relevant dates, all requisite legal and corporate power to execute and deliver this Agreement, and to carry out and perform its obligations under the terms of this Agreement.

(b) The execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate Licensee corporate action. The performance by Licensee of any of terms and conditions of this Agreement on its part to be performed does not and will not constitute a breach or violation of any other agreement or understanding, written or oral, to which it is a party.

7.2 General Agenesis Representations and Obligations. Agenesis represents and warrants and agrees as follows as of the Effective Date:

(a) Organization, Standing and Authority. Agenesis is a corporation duly organized, validly existing and in good standing under the laws of the state of Delaware. Agenesis has all requisite corporate power to own and operate its properties and assets and to carry on its business as presently being conducted and as proposed to be conducted. Agenesis has, and will have on all relevant dates, all requisite legal and corporate power to execute and deliver this Agreement.

(b) The execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate Agenesis corporate action. The performance by Agenesis of any of the terms and conditions of this Agreement on its part to be performed does not and will not constitute a breach or violation of any other agreement or understanding, written or oral, to which it is a party. Agenesis has the full right and legal capacity to provide in the Territory all rights to the Licensed Know-how and Licensed Patent Rights granted to Licensee hereunder.

(c) Agenesis shall maintain all permits, licenses, filings, certifications or other authorizations existing as of the Effective Date to the extent required by Regulatory

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

Authorities for the performance of its rights and obligations under this Agreement. In the event that Licensee seeks Regulatory Approval(s) for territories within the Territory other than the Russian Federation during the Supply Period, if applicable and subject to Supply Opt Out, Agenesis shall reasonably consider any request of Licensee to obtain any additional permits licenses, filings, certifications or other authorizations required by Regulatory Authorities for Agenesis to supply in such territories within the Territory, but shall not be obligated to do so.

7.3 Licensee Performance Representations. Licensee, represents, warrants, and covenants and agrees to Agenesis as follows:

- (a) the rights conferred hereunder are of significant importance and value to the business prospects of Licensee;
- (b) Licensee shall conduct all activities in the Territory with respect to the Agenesis Product and Combination Product and its activities hereunder in accordance with this Agreement, the Specifications, and all applicable laws, rules, regulations and guidelines;
- (c) Licensee shall obtain and maintain all permits, licenses, filings, certifications or other authorizations required by Regulatory Authorities for the performance of its rights and obligations under this Agreement.

7.4 U.S. Foreign Corrupt Practices Act Compliance.

(a) Licensee acknowledges that it understands that Agenesis is an issuer of securities in the United States and is subject to the provisions of the U. S. Foreign Corrupt Practices Act, 15 U.S.C. §§ 78m, 78dd-1 through 78dd-3 ( FCPA ). This law prohibits making, promising or offering to make corrupt payments to foreign officials, political parties or candidates, or making payments to other persons who will offer or make payments to any of the aforementioned parties in order to obtain business, retain business or gain an improper advantage. Licensee represents and warrants and confirms to Agenesis that it is familiar with and understands the FCPA.

(b) Licensee is obligated to ensure that throughout the Term, neither Licensee, nor any person performing activities on behalf of Licensee will engage in any activity that could cause a violation of any provision of the FCPA by Agenesis. Licensee represents and warrants and confirms that it has not made, promised to make, or arranged for any third party to make any payments or gifts to foreign officials in connection with Agenesis Product, Combination Product, the practice of any rights or licensed granted under this Agreement, or any activities contemplated by this Agreement. Further, Licensee represents and warrants and confirms to Agenesis that it has not violated any anti-corruption law, including any law applicable within the Territory, and further that Licensee is not involved in,

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.



## **Table of Contents**

or the subject of, any investigation involving bribery, corruption or improper payments to foreign government officials, as defined in the FCPA. Licensee agrees to update these foregoing statements on a periodic basis as required by Agenus in a format prescribed by Agenus.

(c) Licensee agrees to notify Agenus immediately in writing if Licensee or any person who is performing activities on behalf of Licensee is suspected of violating any anti-corruption law or becomes involved in, or a subject of, an investigation or law enforcement inquiry into possible improper payments to foreign officials or possible violations of anti-corruption laws. Licensee further agrees to provide such notification if Licensee or any person performing activities hereunder on behalf of Licensee becomes involved in any action, suit, claim, investigation or proceeding that is pending, or to the knowledge of Licensee threatened, relating to a potential violation of any anti-corruption laws, including the FCPA.

(d) It is agreed between Licensee and Agenus that this Section is deemed by the Parties to be a material provision of this Agreement.

## **ARTICLE VIII**

### **Indemnification and Liability**

#### **8.1 Indemnification.**

8.1.1 **Indemnification by Licensee**. During the Term and thereafter, Licensee shall indemnify and hold Agenus, its Affiliates and their respective officers, directors, employees, consultants and agents (each, an Agenus Indemnitee ) harmless against any liability, damages or loss from any Third Party claims, demands, suits, or other proceedings (each a Claim ) arising out of, based on or caused by Licensee's or its Sublicensees', distributors' or CMOs' activities with respect to the Agenus Product or Combination Product or the practice of the licenses granted hereunder, or otherwise resulting from any activities undertaken by or on behalf of Licensee, its Sublicensees, distributors or CMOs, except to the extent that such Claim is due to product liability arising from Agenus' negligence or willful misconduct.

8.1.2 **Indemnification by Agenus**. During the term of this Agreement and thereafter, Agenus will defend, indemnify and hold harmless Licensee, its Affiliates and their respective officers, directors, employees, consultants and agents (each, a Licensee Indemnitee ) against any and all third Party Claims arising out of, based on or caused by product liability issues arising from Agenus' negligence or the willful misconduct of Agenus.

8.1.3 **Indemnification Procedures**. Any Agenus Indemnitee or Licensee Indemnitee (each, an Indemnitee ) shall promptly notify the other Party (the Indemnitor ) of any loss, claim, damage, liability, or other action in respect of which the Indemnitee intends to claim such

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

---

**Table of Contents**

indemnification, setting forth the nature of the claim and the basis for indemnification hereunder, and the Indemnitor shall assume the defense thereof with counsel of its choice, subject to such counsel being reasonably acceptable to the other Party; provided, however, that the Indemnatee shall have the right to retain its own counsel, with the reasonable fees and expenses to be paid by the Indemnitor, only if representation of the Indemnatee by the counsel retained by the Indemnitor would be inappropriate due to actual or reasonably likely conflicts of interest between such Indemnatee and any party represented by such counsel in such proceedings. The Indemnatee shall cooperate fully with the Indemnitor in such defense and will permit the Indemnitor to conduct and control such defense and the disposition of such claim, suit, or action (including all decisions relative to litigation, appeal and settlement). The Indemnitor shall have no liability hereunder for amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected by the Indemnatee without the consent of the Indemnitor. The failure to deliver notice to the Indemnitor promptly after the commencement of any such action, to the extent prejudicial to its ability to defend such action, shall relieve the Indemnitor of any liability to the Indemnatee under this Agreement. The Indemnifying Party agrees not to enter into any settlement which would have a material adverse effect on the other Party without prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed.

8.2 **LIMITATION OF LIABILITY.** EXCEPT A) WITH RESPECT TO LIABILITY RELATING TO THIRD PARTY CLAIMS UNDER SECTIONS 8.1; B) LIABILITY FOR BREACH OF ARTICLE IX; AND C) CLAIMS FOR MISUSE, MISAPPROPRIATION OR INFRINGEMENT OF INTELLECTUAL PROPERTY, IT IS AGREED BY THE PARTIES THAT NEITHER PARTY NOR ITS AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR ANY SPECIAL, CONSEQUENTIAL, INDIRECT, EXEMPLARY OR INCIDENTAL DAMAGES (INCLUDING LOST OR ANTICIPATED REVENUES (OTHER THAN REVENUES COMPRISING ROYALTIES OR OTHER PAYMENTS TO BE EARNED AND PAID TO A PARTY BY THE OTHER PARTY UNDER THIS AGREEMENT) OR PROFITS RELATING TO THE SAME), ARISING FROM ANY CLAIM RELATING TO THIS AGREEMENT, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, EVEN IF AN AUTHORIZED REPRESENTATIVE OF SUCH PARTY IS ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SAME.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

---

**Table of Contents**

**ARTICLE IX**

**Confidentiality**

9.1 **Confidential Information** shall mean any proprietary and valuable technical, scientific or business information, which the Disclosing Party (as defined below) has taken reasonable measures to protect, furnished by or on behalf of one Party or its Affiliates (the Disclosing Party ) to the other Party or its Affiliates (the Receiving Party ) in connection with this Agreement or the activities contemplated hereunder, regardless of whether such information is specifically designated as confidential and regardless of whether such information is in oral, written, electronic or other form. Notwithstanding the foregoing or any other provision of this Article IX, the Developments shall be considered the Confidential Information of both Parties, and the terms of this Agreement shall be considered Confidential Information of both Parties, in each case subject to the provisions of this Article IX and Section 13.6. Confidential Information shall not include information that: (a) is in the public domain or thereafter becomes available to the public through no act of the Receiving Party; or (b) was independently known to the Receiving Party prior to receipt thereof or was discovered independently outside the scope of this Agreement by an employee of the Receiving Party who had no access to the information supplied by or on behalf of the Disclosing Party; or (c) was made available to the Receiving Party as a matter of lawful right by a Third Party who had no obligations of confidentiality to the Disclosing Party.

9.2 **Obligations**. The Receiving Party agrees that it shall not, without the prior written consent of the Disclosing Party, directly or indirectly: (a) make any use of any portion of the Confidential Information of the Disclosing Party for purposes other than those set forth in this Agreement; or (b) disclose or transfer any portion of the Confidential Information to any person, except that the Receiving Party may disclose or permit the disclosure of Confidential Information to its Affiliates and sublicensees and subcontractors and partners and its and their respective directors, officers, employees, consultants, and advisors, and potential collaborative partners, and investors and potential investors in connection with a general financing transaction who are under obligations no less stringent than those included herein (contractual or otherwise) to maintain the confidential nature of such Confidential Information and who need to know such Confidential Information for the purposes set forth in this Agreement or for other legitimate business purposes. Notwithstanding the above, the Receiving Party may disclose Confidential Information of the Disclosing Party when required by applicable laws or government rules or regulations (including without limitation, applicable securities regulations), provided that, to the extent reasonably possible, the Receiving Party provides reasonable prior written notice of such disclosure to the Disclosing Party and takes reasonable and lawful efforts to avoid and/or minimize the extent of disclosure.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

9.3 Upon expiration or termination of this Agreement and upon request of the Disclosing Party, all copies of any Disclosing Party's Confidential Information shall be returned to the Disclosing Party or destroyed, such destruction being accompanied by an affidavit certifying the destruction, except that each Receiving Party may retain one (1) copy of the Confidential Information received hereunder, solely for monitoring its obligations under this Agreement.

9.4 No option, license, or conveyance of such rights, express or implied, is granted to the Receiving Party in connection with any Confidential Information disclosed by the Disclosing Party, except for the express licenses granted in Article II or the rights granted in Article XI. If any such rights are to be granted to the Receiving Party, such grant shall be expressly set forth in a separate written instrument.

## **ARTICLE X**

### **Term and Termination**

10.1 Term. This Agreement shall commence as of the Effective Date and, unless sooner terminated or extended as provided in this Article X, shall expire on the third (3<sup>rd</sup>) anniversary of the Effective Date, provided that in the event that Agenesis exercises the Supply Opt Out pursuant to Section 12.3, and Licensee meets the Production Milestone Deadline, then the Agreement shall expire thirty (30) days after the third (3<sup>rd</sup>) anniversary of the Production Milestone achievement date (the Term).

10.2 Term Extension. The Parties acknowledge that the initial Term is intended for the Parties to (A) assess the feasibility of Licensee establishing successful manufacturing and commercial operations in the Territory, and (B) generate data under the Development Plan to better formulate potential long term development plans of Licensee for the Combination Product in the Development Indication in the Territory. In addition, the Parties recognize the prior investment of Agenesis and the investments being made by both Parties during the initial Term, and mutual desire for a longer term commitment pending favorable outcomes. Accordingly, the Parties agree as follows:

(a) If: (1) (x) both Parties are in material compliance with this Agreement, and (y) Licensee has met the milestones set forth in Sections 5.1 and 12.2(a) by the respective deadlines, and (2) Licensee elects in writing to continue the manufacturing and commercialization of the Agenesis Product in the Licensed Indication in the Territory, such writing to be received by Agenesis by the Production Milestone achievement date, then the Parties shall amend this Agreement to extend the license granted under Section 2.1(a) of this Agreement for a period ending the later to occur of: (i) ten years from the Effective Date, or (ii) the expiration of the last Valid Claim of the Licensed Patent Rights, subject to the Parties agreement on a reasonable on-going Commercialization Plan and related sales milestones.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

(b) In the event that Licensee used its best commercially reasonable efforts but did not meet the milestones set forth in Sections 5.1 and 12.2(a) by the respective deadlines, Agenesis shall reasonably consider Licensee's request to amend this Agreement to extend the license granted under Section 2.1(a) of this Agreement for a period ending the later to occur of: (i) ten years from the Effective Date, or (ii) the expiration of the last Valid Claim of the Licensed Patent Rights, subject to the Parties' agreement on a reasonable on-going Commercialization Plan, related sales milestones and other terms and conditions; provided that Agenesis shall not be obligated to enter into any such amendment.

(c) In the event the Agreement is not extended beyond the initial Term, upon Agenesis' request, the Parties agree to negotiate in good faith provisions for the continuation of the manufacture by Licensee of Agenesis Product on behalf of Agenesis and/or its designees and to establish a supply agreement for Agenesis Product to be manufactured in Licensee's designated facility for Agenesis and/or its Affiliates, licensees and partners.

(d) Upon the recommendation of the JSC (or agreement of both Parties in the event the JSC is disbanded), and provided the Parties agree to extend the term of the license granted under Section 2.1(a) of this Agreement pursuant to clauses (i) or (ii) above, the Parties agree to negotiate in good faith an extension of the license granted in Section 2.1(b) of this Agreement and provisions for further development activities for the Combination Product, including an updated Development Plan.

10.3 **Material Breach**. Failure by either Party to comply with any of the material obligations contained in this Agreement shall entitle the other Party to give to the Party in default written notice specifying the nature of the default and requiring it to cure such default. If such default is not cured within sixty (60) days after the receipt of such notice, the notifying Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement and in addition to any other remedies available to it by law or in equity, to terminate this Agreement effective upon written notice to the other Party.

10.4 **Termination by Agenesis**. In addition and notwithstanding the foregoing, Agenesis shall have the right to terminate the Agreement upon no less than sixty (60) days written notice: (i) in the event that manufacturing operations are not maintained in accordance with the Specifications, cGMP and Agenesis' operating procedures, (ii) pursuant to Section 5.1, (iii) pursuant to Section 12.2(b) and (iv) pursuant to Section 13.7.

10.5 **Termination by Licensee**. Licensee may terminate this Agreement without cause by giving sixty (60) days written notice to Agenesis, provided that upon such termination all rights to Licensed Know-how and Licensed Patent Rights shall revert to Agenesis.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

### **10.6 Accrued Rights, Post-Termination Obligations, Sublicensees.**

(a) Upon receipt or delivery of any termination notice under this Agreement, Licensee shall immediately cease taking new product orders with respect to Agenesis Product and Combination Product (if applicable) unless otherwise agreed in writing hereunder, and shall cause its Sublicensees and distributors to do the same. Expiration or any termination of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such expiration or termination. Unless otherwise agreed in writing by Agenesis, expiration or termination of this Agreement shall automatically terminate any sublicense or CMO agreement.

(b) In the event of the termination or expiration this Agreement, Licensee shall immediately cease and shall instruct its Sublicensees, distributors, and CMOs to immediately: (i) cease any use of the Licensed Patent Rights and Licensed Know-how, and, coordinate the transfer or appropriate disposition of any Biomaterials or Agenesis Product in the possession of Licensee and/or its Sublicensees, CMO, distributors or legitimate third parties in cooperation with and as instructed by Agenesis, and (ii) decommission any portion of the manufacturing facility in the Territory dedicated to Agenesis Product manufacture or otherwise containing, incorporating, utilizing, or based on the Manufacturing Technology or other Licensed Know-how, and certify to Agenesis that the foregoing has been accomplished. Notwithstanding the foregoing however, in the event that Licensee believes that it will have any product orders in process at the time of expiration or termination, it shall promptly notify Agenesis thereof, and, at the election of Agenesis, fill such orders prior to ceasing operations. Should Agenesis elect to immediately take over all sales operations, both Parties agree that Licensee shall receive full credit and compensation for any product orders in process made by Licensee in accordance with the provisions of this Agreement, less] any royalties or other payments owing to Agenesis with respect thereto. Immediately after termination or expiration, Licensee shall provide all cooperation and assistance reasonably requested by Agenesis to enable Agenesis to assume and/or continue, with as little disruption as reasonably possible, the continued sale and distribution of Agenesis Product in the Territory, including, without limitation, (a) as directed by Agenesis, terminate all agreements between Licensee and any Third Parties relating to the distribution or sale of Agenesis Product, or assign them to Agenesis or a Third Party designated by Agenesis, (b) at the direction of Agenesis, remove from any literature or other media of Licensee any and all references to Agenesis and the Agenesis Product, (c) cease to use any Agenesis Trademarks and Tradenames (as defined in Section 11.4(b)) and assign to Agenesis all right, title and interest in any such trademarks or tradenames to the extent necessary, (d) transfer or assign to Agenesis all Regulatory Materials, Regulatory Approvals, licenses, permits, authorizations or similar documents for the Agenesis Product that Licensee holds as of the time of any such termination, (e) return to Agenesis all Confidential Information of Agenesis, (f) pay Agenesis any outstanding invoices and royalty amounts, and (h) provide Agenesis with a final marketing and distribution report containing data through the effective date of the termination or expiration of this Agreement, including without limitation, customer account information and market data and intelligence.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

---

**Table of Contents**

**ARTICLE XI**

**Intellectual Property**

**11.1 Inventions.**

(a) This Agreement does not affect the ownership of inventions (whether patentable or unpatentable), trade secrets, works of authorship, and other developments existing as of the Effective Date, and all patents, copyrights, trade secret rights and other intellectual property rights to such inventions, discoveries, trade secrets, works of authorship, and other developments, (collectively, Pre-existing Intellectual Property ). Neither Party shall have any rights to any Pre-existing Intellectual Property of the other Party, except as may be otherwise expressly provided in this Agreement.

(b) The Parties shall jointly own all data and inventions arising from Licensee's activities under the Commercialization Plan or Development Plan ( Developments ), and each Party shall fully cooperate with the other Party to vest title therein with both Parties, including executing any necessary documents of assignment. With respect to the Combination Product, the Parties acknowledge and agree that it is not feasible at this point in time to determine the long term development and commercialization plans for the Combination Product. Accordingly, the Parties acknowledge and agree that each Party has and shall have the right to license and otherwise exploit the Developments, subject to any freedom to operate restrictions, without any further accounting to the other Party, provided however, that neither Party is receiving hereunder any rights to the Pre-existing Intellectual Property or any other intellectual property of the other Party, including without limitation, the Licensed Patent Rights and Licensed Know-how of Agenus, in each case except as expressly set forth in the Agreement.

**11.2 Patent Prosecution Strategy.** Subject to the other terms of this Agreement, as mutually agreed by the Parties, one Party shall assume responsibility (the Controlling Party ) for the preparation, filing, prosecution, and maintenance of all U.S. and foreign patent applications and patents covering Developments ( Development Patent Rights ), using patent counsel reasonably acceptable to both Parties, and the non-Controlling Party shall reasonably cooperate with respect thereto. The Controlling Party shall (i) notify the non-controlling Party reasonably prior to the filing of any Development Patent Rights and permit review of such Development Patent Rights by the non-Controlling Party, (ii) provide the non-Controlling Party promptly with copies of all communications received by the Controlling Party with respect to Development Patent Rights, (iii) keep the non-Controlling Party reasonably informed of the status of such Development Patent Rights, and (iv) provide the non-Controlling Party notice at least thirty (30) days in advance of taking or failing to take any action that would affect the scope or validity of any such Development Patent Rights (including but not limited to substantially narrowing or canceling any claim, abandoning any

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## Table of Contents

such Development Patent Rights or not filing or perfecting the filing of any such Development Patent Rights in any country), with prior written notice of such proposed action or inaction so that the non-Controlling Party has a reasonable opportunity to review and make comments. Unless otherwise agreed, the Parties shall share equally the expenses of such preparation, filing, prosecution, and maintenance. Either Party may assign its rights to any jointly owned Development Patent Rights to the other Party, who will have the right in its discretion, to assume the prosecution and maintenance thereof at its sole expense and as the sole owner thereof.

11.3 Third Party Infringement. Either Party promptly shall notify the other Party in writing of any alleged infringement of the Licensed Patent Rights in the Territory, or the Development Patent Rights and of any available evidence thereof. The Parties shall consult as to a potential litigation strategy or strategies against any alleged infringer. If the Parties commence and prosecute a suit jointly, Licensee shall pay all associated attorney's fees and out-of-pocket litigation expenses. All monies recovered upon the final judgment or settlement of any such action shall be used (a) first, to reimburse the costs and expenses (including reasonable attorneys' fees and costs) of the Parties, (b) second (to the extent that damages are awarded for lost sales or lost profits from the sale of Agenesis Product or Combination Product), to Licensee with Agenesis receiving the royalties that would have been payable to Agenesis on the sale of such products, and (c) the remainder to be split equally between the Parties. If the Parties do not decide to jointly commence an action within thirty (30) days of the notice specified above, or otherwise terminate the alleged infringement, Agenesis shall have the right, at its expense, to bring suit against the allegedly infringing party.

### 11.4 Trademarks.

(a) The terms "Trademark" or "Tradename" shall include, without limitation, the name or names of any Agenesis Product or Combination Product, the design of the packaging of any Agenesis Product or Combination Product, and the appearance of dosage forms of any Agenesis Product or Combination Product.

(b) Unless otherwise agreed between the Parties in writing, Agenesis, at its expense, shall be responsible for the selection, registration and maintenance of all Trademarks and Tradenames employed in connection with the Agenesis Product (the Agenesis Trademarks and Tradenames). The Agenesis Trademarks and Tradenames in the Territory as of the Effective Date are set forth on Exhibit F. The Agenesis Trademarks and Tradenames, and any reputation and goodwill in them, are, and will remain, the exclusive property of Agenesis, and Licensee does not have and shall not have any right to use any Agenesis Trademarks and Tradenames other than in connection with the exercise of its rights under the terms and conditions of this Agreement. All use of the Agenesis Trademarks and Tradenames shall inure solely to the benefit of Agenesis.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.



## **Table of Contents**

(c) Subject to the foregoing and the remaining provisions of this Agreement, Agenesis hereby grants to Licensee a license to use the Agenesis Trademarks and Tradenames in the Territory during the Term solely in connection with the exercise of the licenses granted in Section 2.1, and in conformance with the standards established by Agenesis. Licensee shall not: (i) use any Agenesis Trademarks and Tradenames, or any word, symbol, or design confusingly similar to any Agenesis Trademarks and Tradenames as part of its corporate or legal name or in connection with any product sold by Licensee, its Sublicensees or distributors except as set forth herein; or (ii) do or cause to be done any act or thing which would in any way impair the rights of Agenesis in and to any Agenesis Trademarks and Tradenames. The use of Trademarks and Tradenames in connection with the sale of Combination Products shall be as agreed to between the Parties.

## **ARTICLE XII**

### **Manufacture and Supply**

12.1 **Manufacturing Technology Transfer.** The Parties shall use commercially reasonable efforts to complete the Manufacturing Technology transfer in accordance with the plan and timelines as set forth in this Article XII and the technology transfer plan governing the transfer of the Manufacturing Technology between the Parties (the Technology Transfer Plan ). The initial Technology Transfer Plan is attached to this Agreement as Exhibit G, and may be updated between the Parties upon mutual written agreement within thirty (30) days of the Effective Date. Agenesis will provide reasonable training to Licensee and assist Licensee in the Manufacturing Technology transfer process in accordance with the Technology Transfer Plan at its sole cost and expense up to \$[\*\*] USD (including FTEs at an annual FTE rate of \$[\*\*] USD). Licensee shall reimburse Agenesis all costs and expenses of Agenesis in excess of such \$[\*\*] cap. Due to the unique nature of the manufacturing process for the Agenesis Product which was perfected by Agenesis over time, it is critical that Licensee maintain the integrity and quality of the manufacturing process. Upon the written request of Licensee, the Parties shall enter into a quality agreement governing the manufacture of the Agenesis Product in the Territory during the Supply Period, which shall contain typical terms and conditions as agreed to between the Parties. In addition, the Parties shall agree upon appropriate, thorough, and meaningful safeguards for Agenesis, including the following (i) Licensee shall guarantee to hire the appropriate amount of qualified Licensee employees in Russia to the reasonable satisfaction of Agenesis to ensure a smooth transition, (ii) Agenesis will have the right to pre-approve the manufacturing facility, and (iii) Agenesis will have the right (but not the obligation) to have an employee or consultant in the manufacturing facility overseeing and approving manufacturing operations and release of Agenesis Product until the Production Milestone is achieved.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

### 12.2 Licensee Obligations to Establish Manufacturing Capability.

(a) Licensee shall use its best commercially reasonable efforts at its sole cost and expense to do the following activities, in each case in accordance with all applicable laws, rules and regulations, and the provisions of the Agreement: (i) manufacture, market and sell the Agenesis Product in the Licensed Indication in the Territory in accordance with the Specifications and the Commercialization Plan, (ii) carrying out the Development Plan, and (iii) establish manufacturing capability in the Territory, including without limitation, meeting the following milestones (each a Manufacturing Diligence Milestone ):

<b>MILESTONE:</b>	<b>DATE</b>
Identify [**] for [**]	[**] days from Effective Date
[**] of NewVac [**] (Agenesis sign off, requires [**] of [**] and [**] of [**])	[**] from Effective Date
[**] for [**] to [**] of [**] ( <u>[**] Milestone</u> )	[**] from Effective Date
Obtain [**] for [**] for [**] ( <u>[**] Milestone</u> )	[**] from [**] Milestone
Produce [**] of Agenesis Product manufactured in Russia at the manufacturing facility in accordance with the Specifications ( <u>Production Milestone</u> )	[**] after [**]

(b) In the event that any Manufacturing Diligence Milestone is not met by the respective milestone date (each date, the applicable Manufacturing Milestone Deadline ), the Parties shall meet to discuss the reasons for such delay. In the event that Licensee demonstrates to Agenesis satisfaction that it used its best commercially reasonable efforts to meet such Manufacturing Milestone Deadline, the Parties shall agree upon an appropriate extension for such Manufacturing Milestone Deadline (a Milestone Extension ) and Agenesis shall not have the right to terminate the Agreement for such failure, provided that in the event that Agenesis elects to exercise the Supply Opt Out pursuant to Section 12.3 below, then in no event shall the Production Milestone Manufacturing Milestone Deadline or any Milestone Extension thereof (the Production Milestone Deadline ) extend beyond the third anniversary of the Effective Date unless otherwise agreed by Agenesis in its sole discretion. In addition and notwithstanding the above, if Licensee fails to demonstrate to Agenesis satisfaction that it used its best

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

commercially reasonable efforts to meet the above Manufacturing Diligence Milestones by the Manufacturing Milestone Deadlines or any Milestone Extensions, or for the avoidance of doubt, in the event that Licensee fails to meet the Production Milestone Deadline, Agenus shall have a right to terminate the Agreement.

(c) Licensee shall not use any CMO to manufacture or produce the Agenus Product, alone or as part of the Combination Product, without the prior written consent of Agenus in its sole discretion.

### **12.3 Agenus Product Supply**

(a) Agenus Supply Opt Out. The Parties acknowledge and agree that Agenus shall have the right to opt out of its right and obligation to supply any Agenus Product under this Agreement (the Supply Opt Out ) at any time prior to January 31, 2012 upon written notice to Licensee.

(b) Supply Period Obligations. In the event that Agenus does not exercise the Supply Opt Out pursuant to Section 12.3 (a) above, then from January 31, 2012 (or such sooner period of time as may be elected in writing by Agenus) until the achievement of the Production Milestone (the Supply Period ), the following provisions shall apply. During the Supply Period, Licensee agrees to purchase solely from Agenus, and Agenus agrees to use its commercially reasonable efforts to supply Licensee and its Sublicensees with one hundred percent (100%) of their initial requirements of Agenus Product (subject to the Manufacturing Capacity) for use solely in accordance with the licenses granted pursuant to Section 2.1 of this Agreement. Following the Supply Period, Licensee shall have no further obligation to purchase Agenus Product from Agenus, and Agenus shall have no further obligation to supply Agenus Product. Subject to the terms and conditions contained in this Agreement, during the Supply Period Licensee shall purchase from Agenus and Agenus shall supply to Licensee, Agenus Product in the amounts and timelines and pursuant to the terms and conditions set forth in Section 3.2 and on Exhibit H.

12.4 Agenus Reservation of Rights. Agenus reserves the right to manufacture (or have manufactured) and supply Agenus Product for itself, Affiliates and/or any Third Parties outside the exclusive license grants to Licensee hereunder.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

**Table of Contents**

**ARTICLE XIII**

**Miscellaneous Provisions**

13.1 **No Partnership.** Nothing in this Agreement is intended or shall be deemed to constitute a partnership, distributorship, agency, employer-employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.

13.2 **Assignments.** Neither Party shall assign any of its right or obligations hereunder or this Agreement without the prior written consent of the other Party, except that Agenus may do so: (a) to a Third Party as incident to the merger, consolidation, reorganization or acquisition of stock or assets affecting all or substantially all of the assets of such Party relating to the subject matter of this Agreement ( Acquiring Party ); or (b) to an Affiliate. This Agreement shall be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any Party of its responsibility for the performance of any obligations that such Party has under this Agreement. Any assignment not in accordance with this Section 13.2 shall be void.

13.3 **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

13.4 **Dispute Resolutions.** Except for the right of any Party to apply for a temporary restraining order, a preliminary injunction or other preliminary equitable relief in any court or tribunal of appropriate jurisdiction to preserve the status quo or prevent irreparable harm, any dispute, other than disputes regarding the construction, validity or enforcement of patents, arising between the Parties relating to, arising out of or in any way connected with this Agreement or any term or condition hereof, or the performance by either Party of its obligations hereunder, whether before or after termination of this Agreement, shall be resolved exclusively as follows:

- (a) Any Party may trigger this provision by written notice to the other Party that reasonably describes the nature of the dispute;
- (b) If the dispute cannot be resolved by the Parties through their duly authorized representatives within thirty (30) days of such notice, the Chief Executive Officers of the Parties (or their respective designees) shall meet in person at a mutually acceptable time and location or by means of telephone or video conference within ten (10) business days of the matter being referred to them.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

(c) If the Chief Executive Officers of the Parties (or their respective designees) are unable to settle any dispute within thirty (30) days, then either Party may initiate mediation upon written notice to the other Party (the Notice Date), whereupon both Parties shall engage in a mediation proceeding under the then current International Institute for Conflict Prevention and Resolution Inc. (CPR) Mediation Procedure, except that specific provisions of this Section shall override any inconsistent provisions of the CPR Mediation Procedures. The mediator will be selected from the CPR Panel of Neutrals. If the Parties cannot agree upon a mediator within 15 business days of the Notice Date, one shall be appointed by the CPR. The Parties shall attempt to resolve the dispute through mediation until the first of the following to occur: (i) the Parties reach a written settlement, (ii) the mediators notify the Parties in writing that they have reached an impasse, (iii) the Parties agree in writing that they have reached an impasse, or (iv) the Parties have not reached a settlement within sixty (60) days after the Notice Date. Completion of the requirements of this provision is a condition precedent to proceeding to provision (d) unless one of the Parties refuses to cooperate in step (c).

(d) If the Parties fail to resolve the dispute through mediation, the Parties shall submit to final and binding arbitration administered by the International Institute for Conflict Prevention and Resolution Inc. pursuant to the International Institute for Conflict Prevention & Resolution Rules for Non-Administered Arbitration. The Parties agree that the Arbitrator(s) may provide any and all appropriate relief, including injunctive relief. Any such arbitration shall take place in the Commonwealth of Massachusetts.

13.5 No Name or Trademark Rights. Except as otherwise provided herein, no right, express or implied, is granted by this Agreement to use in any manner the names of the Parties or any version or contraction thereof or any other Tradename or Trademark of Agenus or Licensee in connection with the performance of this Agreement.

13.6 Public Announcements. The Parties have agreed on the pre-cleared content for public disclosure (as described in more detail on Exhibit I attached hereto) for release by either Party within a reasonable time after the Effective Date. Except for such content, neither Party shall issue any press releases or public disclosure relating to this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed, provided, however, that (i) a Party may, without the prior consent of the other Party, issue such press release or public disclosure as may be required by applicable laws, rules and regulations (including any applicable securities regulations) and (ii) once any press release or other public disclosure is approved for disclosure by the Parties, either Party hereto may make a subsequent public disclosure of the contents of such approved press release or other public disclosure. Notwithstanding the provisions of Section 13.11 below, for purposes of this Section 13.6, and notices may be sent via email, if to Agenus, to shalini.sharp@agenusbio.com with a copy to karen.valentine@agenusbio.com, and if to Licensee, to Sergey Bugrov: sb@newvac.ru with a copy to Ron Demuth: rdemuth@torreypinesinv.com.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

## **Table of Contents**

13.7 Force Majeure. If any default or delay occurs which prevents or materially impairs a Party's performance and is due to a cause beyond the Party's reasonable control, including but not limited to any act of any god, flood, fire, explosion, earthquake, casualty, accident, war, terrorism, revolution, civil commotion, blockade or embargo, injunction, law, proclamation, order, regulation or governmental demand, the affected Party promptly shall notify the other Party in writing of such cause and shall exercise diligent efforts to resume performance under this Agreement as soon as possible. Neither Party shall be liable to the other Party for any loss or damage due to such cause. Neither Party may terminate this Agreement because of such default or delay, unless such event continues unabated for a period of [\*\*] months, in which case the Party disadvantaged by such default or delay may, at its option, terminate this Agreement upon written notice to the other Party.

13.8 Entire Agreement of the Parties. Amendments. This Agreement, including the exhibits attached hereto which are incorporated herein, constitutes and contains the entire understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether verbal or written, between the Parties respecting the subject matter hereof. No waiver, modification or amendment or any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each of the Parties.

13.9 Severability. In the event that any of the provisions of this Agreement shall for any reason be held by any court or authority of competent jurisdiction to be invalid, illegal or unenforceable, such provision or provisions shall be validly reformed to as nearly as possible approximate the intent of the Parties and, if unenforceable, shall be divisible and deleted in such jurisdiction; elsewhere, this Agreement shall not be affected so long as the Parties are still able to realize the principal benefits bargained for in this Agreement.

13.10 Applicable Law. This Agreement shall be governed by and interpreted in accordance with the laws of the Commonwealth of Massachusetts, USA applicable to agreements made and performed wholly within such state without regard to its principles of conflicts of laws, provided that questions affecting the construction and effect of any patent shall be determined by the laws of the country in which the patent shall have been granted. The Parties agree that the 1980 United Nations Convention on Contracts for the International Sale of Goods shall not apply to or affect any term of this Agreement.

13.11 Notices and Deliveries. Any notice, requests, delivery, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by facsimile (with written confirmation to follow via an internationally recognized courier) or three (3) days after being sent by internationally recognized courier to the Party to whom it is directed at its address shown below or such other address as such Party shall have last given by written notice to the other Party in accordance with this Section.

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

**Table of Contents**

If to Agenesis, addressed to:

Agenesis Inc.

3 Forbes Road

Lexington, MA 02421

Attn: Chief Financial Officer

*With a copy to:*

Agenesis Inc.

3 Forbes Road

Lexington, MA 02421

Attn: Legal Department

If to Licensee, addressed to:

NewVac LLC

Rabochaya St. 2-a, Bldg. 1

Khimki, Moscow

141400, Russia

Phone: +7 (495) 995-4944

Fax: +7 (495) 926 9970

Attn: Sergey Bugrov, PhD, CEO

*With a copy to:*

De Novo Legal PC

2244 Faraday Ave. Suite 103

Carlsbad, CA 92008

Attn: Maria Johnson

13.12 **Governing Language.** The Parties acknowledge and agree that the English language shall govern this Agreement and all communications required or anticipated pursuant to this Agreement. All written materials to be provided by Licensee to Agenesis pursuant to this Agreement shall be written in the English language, and all oral communications between the Parties shall be with fluent English speaking representatives of the Parties.

13.13 **Counterparts.** This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Execution and delivery of this Agreement by

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.



## **Table of Contents**

facsimile or electronic copies bearing the facsimile signatures of the Parties shall constitute a valid and binding execution and delivery of this Agreement by the signing Party, and such facsimile and/or electronic copies shall constitute original documents.

13.14 **Compliance with Laws**. Licensee and Agenus each shall comply with all applicable laws in connection with its own performance under this Agreement. Without limiting the generality of the foregoing, Licensee shall be responsible for compliance with all applicable product safety, product testing, product labeling, package marking, and product advertising laws and regulations, except with respect to efforts performed by Agenus in which case Agenus shall be responsible for its activities as governed by such laws and regulations.

13.15 **Survival**. Unless otherwise expressly noted herein, the following provisions shall survive expiration or termination of this Agreement: Articles III (with respect to payment obligations owing or that have accrued prior to the effective date of expiration or termination, or sales made prior to the effective date of expiration or termination or in accordance with Section 10.6(b)), Article VIII, and IX, and Sections 6.1(iii), 6.3, 7.3, 7.4, 10.6, 11.1, 11.2, 11.3, 13.4, 13.5, 13.10, 13.12, 13.13, and this Section 13.15.

13.16 **Construction**. Except where the context requires otherwise, the use of any gender is applicable to all genders and the term "including" or "includes" means including, without limiting the generality of any description preceding such term. The wording of this Agreement shall be deemed to be the wording mutually chosen by the parties and no rule of strict construction shall be applied. All monetary amounts are in United States dollars unless otherwise explicitly provided. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be signed by their respective corporate officers, duly authorized as of the dates written below.

### **Agenus**

**By:** /s/ Garo H. Armen

**Name:** Garo H. Armen

**Title:** Chairman and CEO

**Date:** December 16, 2011

### **Licensee**

/s/ Nikolay Savchuk

Nikolay Savchuk

Chairman of the Board

December 16, 2011

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

**Table of Contents**

For valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and in consideration of Agenesis executing and delivering this Agreement, Chemrar Group Companies hereby unconditionally guaranties to Agenesis, its successors and assigns, full and prompt payment and performance of all of the obligations of Licensee in connection with this Agreement. This guaranty shall operate as continuing, absolute, and irrevocable. The liability of Chemrar Group Companies hereunder should be primary, and Chemrar Group Companies hereby waives all suretyship defenses.

**Chemrar Group Companies**

**By:** /s/ Nikolay Savchuk

**Name:** Nikolay Savchuk

**Title:** Board Member

**Date:** December 16, 2011

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unpredicted version of this exhibit has been filed separately with the Commission.

**Table of Contents**

**Exhibit 23**

**Consent of Independent Registered Public Accounting Firm**

The Board of Directors

Agenus Inc.:

We consent to the incorporation by reference in the registration statements on Form S-8 (Nos. 333-40440, 333-40442, 333-50434, 333-69580, 333-106072, 333-115984, 333-143807, 333-143808, 333-151745, 333-160084, 333-160087, 333-160088 and 333-176609), on Form S-3 (Nos. 333-149116, 333-150326, 333-151244, 333-161277, 333-163221 and 333-164481), and on Form S-1 (No. 333-156556) of Agenus Inc. and subsidiaries of our reports dated March [ ], 2012, with respect to the consolidated balance sheets of Agenus Inc. and subsidiaries as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity (deficit) and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2011, and the effectiveness of internal control over financial reporting as of December 31, 2011, which reports appear in the December 31, 2011 annual report on Form 10-K of Agenus Inc. and subsidiaries.

/s/ KPMG LLP

Boston, Massachusetts

March 6, 2012

**Table of Contents**

**Exhibit 31.1**

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

I, Garo H. Armen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Agenesis Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles;
  - c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent function):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial

Edgar Filing: AGENUS INC - Form 424B3

information; and

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

Date: March 6, 2012

/s/ GARO H. ARMEN, Ph.D.  
**Garro H. Armen, Ph.D.**  
**Chief Executive Officer**

**Table of Contents**

**Exhibit 31.2**

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

I, Shalini Sharp, certify that:

1. I have reviewed this Annual Report on Form 10-K of Agenesis Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles;
  - c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent function):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial

Edgar Filing: AGENUS INC - Form 424B3

information; and

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

Date: March 6, 2012

/s/ SHALINI SHARP  
**Shalini Sharp**  
**Chief Financial Officer**

---

**Table of Contents**

**Exhibit 32.1**

**Certification**

Pursuant to 18 U.S.C. Section 1350,

As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 10-K of Agenesis Inc. (the "Company") for the year ended December 31, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned to his/her knowledge hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (i) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (ii) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ GARO H. ARMEN, PH.D.  
**Garro H. Armen, Ph.d.**  
**Chief Executive Officer**

/s/ SHALINI SHARP  
**Shalini Sharp**  
**Chief Financial Officer**

Date: March 6, 2012

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

The foregoing certification is being furnished to the Securities and Exchange Commission as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 2011 and should not be considered filed as part of the Annual Report on Form 10-K.