AGENUS INC
Form 10-Q
May 06, 2011
**Table of Contents**

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 20549**

# Form 10-Q

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

**For the Quarterly Period Ended March 31, 2011**

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

**For the transition period from to**

**Commission File No. 000-29089**

# Agenus Inc.

**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware** | **06-1562417** |
|---|---|
| **(State of Incorporation)** | **(I.R.S. Employer Identification Number)** |

**3 Forbes Road, Lexington, MA 02421**

**(Address of Principal Executive Offices, including Zip Code)**

**(781) 674-4400**

**(Registrant s Telephone Number, including Area Code)**

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

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

Number of shares outstanding of the registrant s Common Stock as of May 3, 2011: 113,360,884 shares.

Table of Contents

**Agenus Inc.**

**Quarterly Period Ended March 31, 2011**

**Table of Contents**


| | | Page |
|---|---|---|
| | **PART I FINANCIAL INFORMATION** | |
| Item 1. | Financial Statements: | |
| | Condensed Consolidated Balance Sheets as of March 31, 2011 and December 31, 2010 (Unaudited) | 2 |
| | Condensed Consolidated Statements of Operations for the quarters ended March 31, 2011 and 2010 (Unaudited) | 3 |
| | Condensed Consolidated Statements of Cash Flows for the quarters ended March 31, 2011 and 2010 (Unaudited) | 4 |
| | Notes to Unaudited Condensed Consolidated Financial Statements | 5 |
| Item 2. | Management s Discussion and Analysis of Financial Condition and Results of Operations | 11 |
| Item 3. | Quantitative and Qualitative Disclosures About Market Risk | 17 |
| Item 4. | Controls and Procedures | 18 |
| | **PART II OTHER INFORMATION** | |
| Item 1. | Legal Proceedings | 19 |
| Item 1A. | Risk Factors | 19 |
| Item 6. | Exhibits | 33 |
| Signatures | | 34 |

Table of Contents

## PART I FINANCIAL INFORMATION

**Item 1** ***Financial Statements***

### AGENUS INC. AND SUBSIDIARIES

### CONDENSED CONSOLIDATED BALANCE SHEETS

**(Unaudited)**

| | March 31, 2011 | December 31, 2010 |
|---|---|---|
| **ASSETS** | | |
| Cash and cash equivalents | $ 10,630,571 | $ 19,781,976 |
| Short-term investments | 4,998,799 | |
| Accounts receivable | | 35,000 |
| Inventories | 26,432 | 26,432 |
| Prepaid expenses | 864,870 | 704,744 |
| Other current assets | 393,598 | 306,008 |
| Total current assets | 16,914,270 | 20,854,160 |
| Plant and equipment, net of accumulated amortization and depreciation of $25,144,541 and $24,993,225 at March 31, 2011 and December 31, 2010, respectively | 5,663,516 | 6,194,465 |
| Goodwill | 2,572,203 | 2,572,203 |
| Other long-term assets | 1,277,131 | 1,285,831 |
| Total assets | $ 26,427,120 | $ 30,906,659 |
| **LIABILITIES AND STOCKHOLDERS DEFICIT** | | |
| Current portion, long-term debt | $ 146,061 | $ 146,061 |
| Current portion, deferred revenue | 1,540,385 | 1,540,385 |
| Accounts payable | 450,458 | 698,554 |
| Accrued liabilities | 2,783,355 | 2,684,609 |
| Other current liabilities | 659,206 | 346,314 |
| Total current liabilities | 5,579,465 | 5,415,923 |
| Convertible senior notes | 28,722,005 | 34,050,033 |
| Deferred revenue | 3,227,060 | 3,612,156 |
| Derivative liability (Note G) | | 755,000 |
| Other long-term liabilities | 1,355,714 | 1,780,759 |
| Commitments and contingencies (Note E) | | |
| Stockholders deficit: | | |
| 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 March 31, 2011 and December 31, 2010; liquidation value of $31,817,625 at March 31, 2011 | 316 | 316 |
| Series B2 convertible preferred stock; 3,105 shares designated, issued, and outstanding at March 31, 2011 and December 31, 2010 | 31 | 31 |
| Common stock, par value $0.01 per share; 250,000,000 shares authorized; 113,574,657 and 111,885,759 shares issued at March 31, 2011 and December 31, 2010, respectively | 1,135,747 | 1,118,858 |
| Additional paid-in capital | 577,113,759 | 568,916,796 |
| Treasury stock, at cost; 260,944 shares of common stock at March 31, 2011 and December 31, 2010 | (324,792) | (324,792) |
| Accumulated deficit | (590,382,185) | (584,418,421) |

| | | |
|---|---|---|
| Total stockholders deficit | (12,457,124) | (14,707,212) |
| Total liabilities and stockholders deficit | $ 26,427,120 | $ 30,906,659 |

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

**AGENUS INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

**(Unaudited)**

| | Quarter Ended March 31, | |
|---|---|---|
| | **2011** | **2010** |
| Revenue | $ 671,881 | $ 936,428 |
| Operating expenses: | | |
| Research and development | (2,815,376) | (4,631,284) |
| General and administrative | (2,878,939) | (3,566,097) |
| Operating loss | (5,022,434) | (7,260,953) |
| Other income (expense): | | |
| Non-operating income (expense) | 6,867 | (317,858) |
| Interest expense | (955,517) | (1,240,327) |
| Interest income | 7,320 | 8,098 |
| Net loss | (5,963,764) | (8,811,040) |
| Dividends on series A convertible preferred stock | (197,625) | (197,625) |
| Net loss attributable to common stockholders | $ (6,161,389) | $ (9,008,665) |
| Per common share data, basic and diluted: | | |
| Net loss attributable to common stockholders | $ (0.05) | $ (0.10) |
| Weighted average number of common shares outstanding, basic and diluted | 112,868,940 | 90,981,912 |

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

**AGENUS INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(Unaudited)**

| | Quarter Ended March 31, | |
|---|---|---|
| | **2011** | **2010** |
| Cash flows from operating activities: | | |
| Net loss | $ (5,963,764) | $ (8,811,040) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 567,103 | 1,004,030 |
| Intangible asset impairment | | 629,382 |
| Change in fair value of derivative liability | | 328,070 |
| Share-based compensation | 642,280 | 1,559,584 |
| Non-cash interest expense | 252,096 | 302,684 |
| Gain on sale of property and equipment | 6,003 | 1,501 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 35,000 | (306,839) |
| Inventories | | 238,741 |
| Prepaid expenses | (160,126) | (344,445) |
| Accounts payable | (248,096) | (464,264) |
| Deferred revenue | (385,096) | 72,239 |
| Accrued liabilities and other current liabilities | 779,950 | 482,626 |
| Other operating assets and liabilities | (170,086) | (582,421) |
| Net cash used in operating activities | (4,644,736) | (5,890,152) |
| Cash flows from investing activities: | | |
| Proceeds from maturities of available-for-sale securities | | 10,000,000 |
| Proceeds from sale of property and equipment | 10,000 | 24,108 |
| Purchases of available-for-sale securities | (4,998,799) | (9,997,346) |
| Purchases of plant and equipment | (43,458) | (47,186) |
| Net cash used in investing activities | (5,032,257) | (20,424) |
| Cash flows from financing activities: | | |
| Deferred equity issuance costs | | (46,491) |
| Net proceeds from sales of equity | 680,621 | |
| Proceeds from employee stock purchases | 42,592 | 27,938 |
| Payment of series A convertible preferred stock dividends | (197,625) | (197,625) |
| Net cash provided by (used in) financing activities | 525,588 | (216,178) |
| Net decrease in cash and cash equivalents | (9,151,405) | (6,126,754) |
| Cash and cash equivalents, beginning of period | 19,781,976 | 20,066,817 |
| Cash and cash equivalents, end of period | $ 10,630,571 | $ 13,940,063 |

Non-cash financing activity:

| | | |
|---|---|---|
| Convertible Note adjustment to equity for conversion option | $ | 5,580,124 |
| Reclassification of derivative liability into equity | $ | 755,000 |

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

**AGENUS INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2011**

**Note A Business, Liquidity and Basis of Presentation**

Agenus Inc., formerly Antigenics Inc., (including its subsidiaries, also referred to as Agenus, the Company, we, us, and our ) is a biotechnolo company developing and commercializing technologies to treat cancers and infectious diseases, primarily based on immunological approaches. Our most advanced product, Oncophage® (vitespen), is a patient-specific therapeutic cancer vaccine registered for use in Russia. As resources allow, we explore potential opportunities to seek product approval in other jurisdictions. Our Prophage Series of cancer vaccines has been tested in Phase 3 clinical trials for the treatment of renal cell carcinoma, the most common type of kidney cancer, as Oncophage, and for metastatic melanoma, and it has also been tested in Phase 1 and Phase 2 clinical trials in a range of indications. It is currently in Phase 2 clinical trials in glioma, a type of brain cancer, and adjuvant renal cell carcinoma, validating immune response. Our product candidate portfolio includes (1) 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, and tuberculosis, and (2) HerpV, a therapeutic vaccine program tested in a Phase 1 clinical trial for the treatment of genital herpes. Further clinical development of HerpV will be pursued if a development partnership can be successfully established. 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 March 31, 2011, we had an accumulated deficit of $590.4 million. Since our inception, we have financed our operations primarily through the sale of equity and convertible notes, interest income earned on cash, cash equivalents, and short-term investment balances, and debt provided through secured lines of credit. We believe that, based on our current plans and activities, our working capital resources as of March 31, 2011, anticipated revenues, and the estimated proceeds from our license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements into 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.

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 March 31, 2011, we had debt outstanding of $34.9 million in principal, including $34.7 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 subject to redemption at the option of the holders or us beginning February 1, 2012. We expect to attempt to raise additional funds in advance of depleting our current funds. We may attempt to raise additional funds by: (1) licensing technologies or products to one or more collaborative partners, (2) renegotiating third party agreements, (3) completing an outright sale of assets, (4) securing additional debt financing, and/or (5) selling additional 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 Prophage Series of cancer 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.

Table of Contents

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ( GAAP ) for interim financial information and with the instructions to Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete annual consolidated financial statements. In the opinion of management, the condensed consolidated financial statements include all normal and recurring adjustments considered necessary for a fair presentation of our financial position and operating results. All significant intercompany transactions and accounts have been eliminated in consolidation. Operating results for the three months ended March 31, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. For further information, refer to our consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the Securities and Exchange Commission.

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management 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. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

**Note B 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 have 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, shares underlying the warrants outstanding or issuable to acquire 19,856,302 shares, the outstanding stock options to acquire 8,740,144 shares, the 1,022,057 nonvested shares, the 2,000,000 common shares underlying the 31,620 outstanding shares of series A convertible preferred stock, and the impact of conversion of our 2005 Notes are not included in the calculation of diluted net loss per common share.

**Note C Share-Based Compensation**

We use the Black-Scholes option pricing model to value options for employees and non-employees as well as options granted to members of our Board of Directors. All stock option grants have a 10-year term and generally vest ratably over a three or four-year period. The non-cash charge to operations for non-employee options with vesting or other performance criteria is affected each reporting period, until the non-employee options are exercised or expire, by changes in the fair value of our common stock. A summary of option activity for the three months ended March 31, 2011 is presented below:

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2010 | 7,272,850 | $ 2.24 | | |
| Granted | 1,643,416 | 1.05 | | |
| Forfeited | (112,456) | 0.86 | | |
| Expired | (63,666) | 2.30 | | |
| Outstanding at March 31, 2011 | 8,740,144 | 2.03 | 7.3 | $ 263,217 |
| Vested or expected to vest at March 31, 2011 | 8,346,147 | 2.08 | 7.2 | $ 238,619 |
| Exercisable at March 31, 2011 | 4,963,561 | 2.67 | 6.3 | $ 101,556 |

**Table of Contents**

The weighted average grant-date fair values of options granted during the three months ended March 31, 2011, and 2010, were $0.83, and $0.57, respectively.

During the first three months of 2011, all options were granted with exercise prices equal to the fair market value of the underlying shares of common stock on the grant date. As of March 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 March 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 $101,000. 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 the Company s common stock on the date of grant.

A summary of nonvested stock activity for the three months ended March 31, 2011 is presented below:

| | Nonvested Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Outstanding at December 31, 2010 | 513,449 | $ 0.77 |
| Granted | 1,347,882 | 1.03 |
| Vested | (793,749) | 1.00 |
| Forfeited | (45,525) | 0.92 |
| Outstanding at March 31, 2011 | 1,022,057 | 0.93 |

As of March 31, 2011, there was $513,000 of unrecognized share-based compensation expense related to these nonvested shares. This cost is expected to be recognized over a weighted average period of 1.6 years. The total intrinsic value of shares vested during the three months ended March 31, 2011 was $751,000.

We issue new shares upon option exercises, purchases under the 2009 Employee Stock Purchase Plan (the 2009 ESPP ), vesting of nonvested stock, under the Directors Deferred Compensation Plan and in lieu of 34% of the base salary of our Chief Executive Officer ( CEO ). During the three months ended March 31, 2011, 65,075 shares were issued under the 2009 ESPP, and 793,749 shares were issued as a result of the vesting of nonvested stock. In addition, during the three months ended March 31, 2011, 38,988 shares were issued to our CEO in lieu of cash salary.

Table of Contents

The impact on our results of operations from the granting of stock options and nonvested shares and issuing shares for services was as follows (in thousands).

| | Quarter Ended March 31, | |
|---|---|---|
| | 2011 | 2010 |
| Research and development | $ 455 | $ 587 |
| General and administrative | 187 | 973 |
| Total share-based compensation expense | $ 642 | $ 1,560 |

**Note D Convertible Debt**

On February 23, 2011, we entered into a Ninth Amendment of Rights Agreement (the Amendment ) to the 2006 Notes. The Amendment extended the maturity date of the 2006 Notes to August 31, 2014, and waived the rights of the note holders to convert the 2006 Notes into our common stock. The Amendment also removed substantially all restrictions on us incurring indebtedness subordinate to the 2006 Notes and substantially all restrictions to issue our common stock. We also agreed to waive our right to prepay these notes in the event that our shares trade at a weighted average price over $7.00 for a 30-day period.

Prior to the Amendment, based on the guidance in Accounting Standards Codification ( ASC ) 815, *Derivatives and Hedging Contracts in Entity s Own Equity,* the conversion feature embedded in the 2006 Notes was treated as a derivative 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. 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 $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 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 note has been included in additional paid-in capital on our condensed consolidated balance sheet and, accordingly, the carrying value of the 2006 Note was reduced by approximately $5.6 million.

**Note E Commitments and 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 alleges 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 alleges 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. The parties have reached a global settlement of the litigation. Under the settlement, the insurers will pay the full amount of settlement share allocated to the defendants, and the defendants will bear no financial liability. Agenus and the other defendants will receive complete dismissals from the case. In October 2009, the Court entered an order granting final approval of the settlement, and subsequently judgment was entered. Various objectors have filed appeals. If for any reason the settlement does not become effective, we believe we have meritorious defenses to the claims and intend to defend the action vigorously. We are unable to predict the likelihood of an unfavorable outcome or estimate our potential liability, if any. No accrual has been recorded at March 31, 2011 for this action.

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

8

Table of Contents

**Note F Recent Accounting Pronouncements**

In December 2010, the 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 the 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.

**Note G 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 short-term investments and derivative liability at fair value. Our short-term investments are comprised of U.S. Treasury securities that are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized in Level 1. 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):

| | March 31, 2011 | | December 31, 2010 | |
|---|---|---|---|---|
| Description | 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) |
| Assets: | | | | |
| Short-term investments | $ 5,000 | $ | $ | $ |
| Liabilities: | | | | |
| Derivative liability | | | | 755 |

The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3), as of March 31, 2011 (amounts in thousands):

| | |
|---|---|
| Balance, December 31, 2010 | $ 755 |
| Decrease for reclassification as Equity (see Note D) | (755) |
| Balance, March 31, 2011 | $ |

As of March 31, 2011, $100,000 in principal of the 2005 Notes are outstanding with an estimated fair value of $87,000 based on the most recent market transactions. As of March 31, 2011, $34.7 million in principal of the 2006 Notes are outstanding. The fair value of the debt portion of the 2006 Notes exclusive of the conversion option is $28.5 million based on a present value methodology. The fair value of the embedded conversion option is $3.1 million.

**Note H Equity**

During the three months ended March 31, 2011, we issued approximately 185,000 shares of our common stock in at the market offerings through our sales agents, McNicoll, Lewis & Vlak LLC and Wm Smith & Co. and raised net proceeds of approximately $204,000 after deducting offering costs. We also issued and sold 530,000 shares based on the exercise of a purchase option under a subscription agreement dated December 13, 2010, and received net proceeds of $477,000.

On March 3, 2011, we were notified by the Listing Qualifications Staff of Nasdaq (the Staff ) that we are not in compliance with 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. In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), we have been provided 180 calendar days, or until August 30, 2011, to regain compliance with the Bid Price Requirement. After the initial 180 calendar day period, we could be eligible for an additional 180 day compliance period to regain compliance with the Bid Price Requirement, if we were to meet the Nasdaq Capital Market initial listing criteria set forth in Nasdaq Marketplace Rule 5505, excluding the Bid Price Requirement. To regain compliance with the minimum bid price continued listing requirement, the bid price of our common stock must close at $1.00 per share or more for a minimum of ten consecutive business days. The Staff may, in its discretion, require our common stock to maintain a bid price of at least $1.00 per share for a period in excess of ten consecutive business days before determining that we have demonstrated an ability to maintain long-term compliance.

**Note I Subsequent Event**

On April 11, 2011, we entered into a Fifth Amendment of Lease reducing the occupied space of our Lexington, Massachusetts location from approximately 162,000 square feet to approximately 83,000 square feet. This reduces our annual rental payments by approximately $1.1 million over the remaining lease term, commencing no later than November 1, 2011.

10

Table of Contents

**Item 2.** ***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. Some of our key assets are highlighted below:

The Prophage Series of cancer vaccines: The Prophage Series of cancer vaccines is based on our core heat shock protein technology. We believe that the collective results from our clinical trials to date indicate a favorable safety profile and signals of efficacy in multiple cancer types. In a registry following patients from a large randomized Phase 3 trial in non-metastatic renal cell carcinoma (RCC; kidney cancer), patients at intermediate risk of recurrence who were in the treatment arm 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). This product is approved for sale in this indication in Russia. Phase 2 trials are underway testing the Prophage Series vaccines G-100 and G-200 in newly diagnosed and recurrent glioma, respectively. 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. Additional trials are under evaluation in metastatic RCC and metastatic melanoma in combination with potentially synergistic therapies, as well as in pediatric neurological tumors.

QS-21 Stimulon® adjuvant ( QS-21 ): 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. There are approximately 15 vaccines containing QS-21 in clinical development by our licensees, including four in Phase 3 testing for malaria, melanoma, non-small cell lung cancer and shingles. The first products containing QS-21 are expected to be launched in the 2013-2014 timeframe, and we are entitled to royalties for at least 10 years post-launch. However, there is no guarantee that these products will generate significant royalties, if any, or 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 and are generally reimbursed for any related expenses by our licensees.

HerpV: HerpV is a therapeutic vaccine for the treatment of genital herpes, which is based on our HSP technology. 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 are currently seeking partners to advance HerpV and the platform technology into further development.

We have incurred significant losses since our inception. As of March 31, 2011, we had an accumulated deficit of $590.4 million. Since our inception, we have financed our operations primarily through the sale of equity and convertible notes, interest income earned on cash, cash equivalents, and short-term investment balances, and debt provided through secured lines of credit. We believe that, based on our current plans and activities, our working capital resources at March 31, 2011, anticipated revenues, and the estimated proceeds from our license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements into 2012. We expect to attempt to raise additional funds in advance of depleting our current funds. We may attempt to raise additional funds by: (1) licensing technologies or products to one or more collaborative partners, (2) renegotiating third party agreements, (3) completing an outright sale of assets, (4) securing additional debt financing, and/or (5) selling additional 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 of cancer 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.

Our common stock is currently listed on the Nasdaq Capital Market under the symbol AGEN . On March 3, 2011, we were notified by the Listing Qualifications Staff of Nasdaq (the Staff ) that we are not in compliance with 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. In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), we have been provided 180 calendar days, or until August 30, 2011, to regain compliance with the Bid Price Requirement. If compliance is not demonstrated within the applicable compliance period, the Staff will notify us that our securities will be delisted from the Nasdaq Capital Market. However, we may appeal the Staff s determination to delist our

11

Table of Contents

securities to a Hearings Panel. During any appeal process, shares of our common stock would continue to trade on the Nasdaq Capital Market. There can be no assurance that we will meet the requirements for continued listing on the Nasdaq Capital Market or whether any appeal would be granted by the Hearings Panel.

**Forward-Looking Statements**

This Quarterly Report on Form 10-Q and other written and oral statements the Company makes from time to time contain certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. You can identify these forward-looking statements by the fact they use words such as could, expect, anticipate, estimate, target, may project, guidance, intend, plan, believe, will, potential, opportunity, future and other words and terms of similar meaning and exp connection with any discussion of future operating or financial performance. One 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, our commercialization efforts in Russia, 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.

Although the Company believes it has been prudent in its 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. The Company undertakes 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 that the Company believes could cause actual results to differ materially from any forward-looking statement in Part II-Item 1A Risk Factors of this Quarterly Report on Form 10-Q. 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.

**Historical Results of Operations**

***Quarter Ended March 31, 2011 Compared to the Quarter Ended March 31, 2010***

*Revenue:* We generated revenue of $672,000 and $936,000 during the quarters ended March 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. This higher revenue in 2010 is primarily due to the volume of shipments of QS-21 to our QS-21 licensees in the quarter ended March 31, 2010 as compared to the same quarter in 2011. In the quarters ended March 31, 2011 and 2010, we recorded revenue of $385,000 and $378,000, respectively, from the amortization of deferred revenue.

*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, administrative costs, and services provided by clinical research organizations. Research and development expense decreased 39% to $2.8 million for the quarter ended March 31, 2011 from $4.6 million for the quarter ended March 31, 2010. The decrease includes declines related to our general cost-containment efforts and to the status of our products under development as well as a decrease in our non-cash share-based compensation expense attributable to the level of awards during the first quarter of 2010.

*General and Administrative:* General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses decreased 19% to $2.9 million for the quarter ended March 31, 2011 from $3.6 million for the quarter ended March 31, 2010. This decrease is largely related to our general cost containment efforts and a decrease in our non-cash share-based compensation expense attributable to the level of awards during the first quarter of 2010.

12

Table of Contents

*Non-Operating Expense:* Non-operating expense of $318,000 for the quarter ended March 31, 2010 consists primarily of the change in the fair value of our derivative liability. As a result of the impact of the Ninth Amendment of Rights executed during the quarter ended March 31, 2011, we no longer record a derivative liability for the embedded conversion option contained in our 8% senior secured convertible notes maturing August 2014 (the 2006 Notes ). The resulting decrease in the derivative liability for the quarter ended March 31, 2011, is reflected as additional-paid-in capital.

*Interest Expense:* Interest expense decreased to $956,000 for the quarter ended March 31, 2011 from $1.2 million for the quarter ended March 31, 2010. This decrease is related to the repurchase of substantially all of our 5.25% convertible senior notes due February 2025 (the 2005 Notes ) during 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 quarters ended March 31, 2011 and 2010, interest expense included $693,000 and $641,000, respectively, related to the 2006 Notes.

**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 the quarter ended March 31, 2011, these research and development programs consisted largely of our Prophage Series vaccines as indicated in the following table (in thousands).

| | | Three Months Ended | Year Ended December 31, | | | Prior to | |
|---|---|---|---|---|---|---|---|
| | Product | March 31, 2011 | 2010 | 2009 | 2008 | 2008 | Total |
| **Research and Development Program** | | | | | | | |
| Heat Shock Proteins for Cancer | Prophage Series Vaccines | $ 2,785 | $ 10,960 | $ 15,309 | $ 17,156 | $ 238,426 | $ 284,636 |
| Heat Shock Proteins for Infectious Diseases | HerpV | 18 | 644 | 262 | 1,377 | 16,071 | 18,372 |
| Vaccine adjuvant * | QS-21 | 12 | 1,185 | 1,071 | 648 | 9,500 | 12,416 |
| Other Research and Development Programs | | | 89 | 261 | 1,482 | 31,695 | 33,527 |
| Total Research and Development Expenses | | $ 2,815 | $ 12,878 | $ 16,903 | $ 20,663 | $ 295,692 | $ 348,951 |

* 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 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 and generally on hold due to cost-containment efforts, 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***

*Prophage Series of Cancer 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, we have treated nearly 850 cancer patients in our 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 II-Item 1A. Risk Factors of this Quarterly Report on Form 10-Q.

Table of Contents

We believe that the collective results from our clinical trials thus far show that the Prophage Series vaccines have a favorable safety profile. We also believe that available results from clinical trials suggest that treatment with Prophage Series vaccines can generate immunological and anti-tumor responses.

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 showed a statistically significant difference in recurrence-free survival in favor of the Oncophage arm. In part because the intermediate-risk category was not prospectively delineated prior to the trial s initiation, the 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.

We opened a subsequent protocol that continued to follow patients from this trial in the format of a registry in order to collect overall survival information, as well as investigator reports of disease recurrence. The registry, which is expected to provide additional data on the effectiveness of the vaccine, followed patients until March 2010, an additional three years from closure of the initial trial, providing more than five years of data collection following the enrollment of the last patient in the trial. At the 2009 American Society of Clinical Oncology ( ASCO ) annual meeting, we announced results of an interim analysis from the ongoing global patient survival registry, which showed that patients with kidney cancer at intermediate risk of disease recurrence demonstrated an approximately 46 percent lower risk of death in the treatment arm compared with the control arm (n = 362; $P < 0.05$; hazard ratio = 0.54). Final analysis of this data has been completed and is under consideration for publication. There is no guarantee that the final data will uphold the results of our interim analysis.

In addition to the patient registry, we commenced a small study in non-metastatic RCC to assess immune response in the intermediate-risk patient population. Patient enrollment has been closed. Any results of the final survival registry analysis and the RCC immunology trial will not meet the requirements of the FDA or other regulatory authorities for submission and approval of a marketing application or similar applications for product approval outside the United States.

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. Since this approval we have been focusing our efforts in Russia on securing one or more distribution and/or partnering arrangements and related commercialization activities. The amount of any future revenue generated from the sale of Oncophage in Russia will depend on our ability to successfully execute on these efforts and identify and obtain adequate reimbursement, as well as on decisions of physicians and patients, among other factors. Furthermore, we may experience significant delays in the receipt of payment for Oncophage, or an inability to collect payments at all.

In October 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 of the EMA formally adopted a negative opinion on this MAA. Subsequently we withdrew our application and while we continue to explore paths forward in Europe, at this time there are no active partnership discussions ongoing. We continue to seek partnership discussions for our other Prophage Series vaccines.

A Phase 1/2 clinical trial with Prophage Series vaccine G-200 vaccine in recurrent, high-grade glioma, designed to enroll approximately 50 patients, 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. Phase 1 results, presented at the Society for Neuro-Oncology Annual Meeting Conference in November 2008, showed that vaccination following brain cancer surgery increased overall median survival to approximately 10.5 months, with four patients surviving beyond 12 months and one patient surviving almost 2.5 years. The study also showed that all 12 treated patients demonstrated a significant immune

Table of Contents

response after vaccination with G-200 ( $P < 0.001$) and that patients with minimal residual disease at time of first vaccination (n = 7) were more likely to survive beyond nine months compared with patients with significant residual disease.

The Phase 2 portion of this study has expanded to include New York-Presbyterian Hospital/Columbia University Medical Center and University Hospitals/Case Western Reserve. Interim data was presented at the Society for Neuro-Oncology meeting in October 2009, which showed a median survival of 10.1 months in the first 20 patients treated with G-200, and that to date six patients (30 percent) had survived at or beyond 12 months. This early data shows an improvement in overall survival over the previous long-standing historical median survival of 6.5 months, and is also slightly favorable to the recently reported median survival of 9.2 months with Avastin® (bevacizumab) in patients with recurrent high-grade glioma. In May 2010, data presented at the International Conference on Brain Tumor Research and Therapy suggested that vaccination with this candidate may improve overall survival in patients with recurrent high-grade glioma. An overall median survival of 44 weeks after tumor resection was observed. Approximately 70% of the evaluable patients survived beyond 36 weeks, and 41% survived up to or longer than one year. Additional data from this trial will be reported at ASCO in June 2011. UCSF also initiated an additional Phase 2 clinical trial in newly diagnosed glioma testing Prophage Series vaccine G-100 in combination with Temodar® (temozolomide). This trial is currently enrolling, with a target of 50 patients. Based on promising trends to date, this trial is being expanded to include up to 10 clinical sites.

*QS-21*

QS-21 Stimulon® adjuvant 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 Alzheimer Immunotherapy. There are approximately 15 vaccines containing QS-21 in clinical development by our licensees, including four in Phase 3 testing for malaria, melanoma, non-small cell lung cancer and shingles. The first products containing QS-21 are expected 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 and is generally reimbursed for any related expenses by its licensees.

In return for rights to use QS-21, our licensees 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. From time to time our collaborators or licensees initiate and/or cease programs containing QS-21. For example, an undisclosed infectious disease Phase 3 program was discontinued during 2010 by one of our collaborators.

On January 16, 2009, we entered into an Amended and Restated Manufacturing Technology Transfer and 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. We understand that QS-21 is a key component included in several of GSK s proprietary adjuvant systems and that a number of GSK s vaccine candidates currently under development are formulated using adjuvant systems containing QS-21. GSK has initiated Phase 3 studies evaluating its investigational MAGE-A3 Antigen-Specific Cancer Immunotherapeutic containing QS-21 in non-small cell lung cancer and melanoma. GSK has also initiated a Phase 3 clinical trial in malaria and a Phase 3 clinical trial in shingles. Revenues recognized with respect to this agreement were $332,000 for each of the three months ended March 31, 2011 and 2010.

Elan Pharmaceuticals, Inc. and/or its affiliates ( Elan ) had a commercial license for the use of QS-21 in the research and commercialization of products. Effective September 14, 2009, we entered into an Amended and Restated License Agreement ( Amended License Agreement ) with Elan. On September 17, 2009, the Amended License Agreement was assigned to JANSSEN Alzheimer Immunotherapy. Under the terms of the Amended License Agreement assigned to JANSSEN Alzheimer Immunotherapy, they will have the right to develop, make, have made, use, sell, offer for sale, import, and have sold, the Alzheimer s disease vaccine that contains QS-21 ( Licensed Product ). In addition, pursuant to the terms of the Amended License Agreement, JANSSEN Alzheimer Immunotherapy 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. Under the terms of the Amended License Agreement, we are entitled to receive future milestone payments and product royalties in the event of the successful development of the Licensed Product. In 2007, Elan initiated a Phase 2 study of their vaccine. Revenues recognized with respect to this agreement were $43,000 and $32,000 for the three months ended March 31, 2011 and 2010, respectively.

Table of Contents

**Liquidity and Capital Resources**

We have incurred annual operating losses since inception, and we had an accumulated deficit of $590.4 million as of March 31, 2011. We expect to incur significant losses over the next several years as we continue our clinical trials, apply for regulatory approvals, prepare for commercialization, and continue development of our technologies. Since our inception, we have financed our operations primarily through the sale of equity and convertible notes, interest income earned on cash, cash equivalents, and short-term investment balances, and debt provided through secured lines of credit. From our inception through March 31, 2011, we have raised aggregate net proceeds of $506.6 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, and borrowed $20.5 million under two credit facilities. During February 2010, we entered into an At the Market Sales Agreement with McNicoll, Lewis & Vlak LLC and Wm Smith & Co (the Sales Agents ) under which we may sell an aggregate of up to 20 million shares of our common stock from time to time through the Sales Agents. To date we have issued approximately 7.0 million shares of our common stock in at the market offerings through the Sales Agents and raised net proceeds of approximately $8.8 million after deducting offering costs of approximately $331,000. As of March 31, 2011, we had debt outstanding of $34.9 million in principal, including $34.7 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 subject to redemption at the option of the holders or us beginning February 1, 2012.

Our cash, cash equivalents, and short-term investments at March 31, 2011 were $15.6 million, a decrease of $4.2 million from December 31, 2010. Based on our current activities we anticipate that our net cash burn (defined as cash used in operating activities plus capital expenditures and dividend payments) will be in the $16-$18 million range for the year ending December 31, 2011. In addition, we hope to generate royalties from our QS-21 product in the 2013-2014 timeframe.

We believe that, based on our current plans and activities, our working capital resources at March 31, 2011, anticipated revenues, and the estimated proceeds from our license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements into 2012. 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 funds. In order to fund our operations through 2011 and beyond, we will need to contain costs and raise additional funds. We may attempt to raise additional funds by: (1) licensing technologies or products to one or more collaborative partners, (2) renegotiating third party agreements, (3) completing an outright sale of selected 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 current 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. Please see the Forward-Looking Statements section and the risks highlighted under Part II-Item 1A. Risk Factors of this Quarterly Report on Form 10-Q.

Our future cash requirements include, but are not limited to, supporting our 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 $47.2 million over the term of the studies. Through March 31, 2011, we have expensed $46.6 million as research and development expenses and $46.5 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 March 31, 2011. We plan to enter into additional sponsored research agreements, and we anticipate significant additional expenditures will be required to advance our clinical trials, apply for regulatory approvals, continue development of our technologies, and bring our product candidates to market. Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing collaborative arrangements 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

Table of Contents

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 three months ended March 31, 2011 and 2010 was $4.6 million and $5.9 million, respectively. We continue to support and develop our QS-21 partnering collaborations, with the goal of generating 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 the Forward-Looking Statements section and the risks highlighted under Part II-Item 1A. Risk Factors of this Quarterly Report on Form 10-Q.

Effective July 30, 2010, we sublet part of our Lexington facility to Cubist Pharmaceuticals, Inc. whose lease expires in July 2012. On April 11, 2011, we executed an amendment to our Lexington facility lease reducing our occupied space effective no later than November 1, 2011. Our Lexington facility and New York office leases expire August 2013 and April 2012, respectively.

We are currently involved in certain legal proceedings as detailed in Note E of the notes to our unaudited condensed consolidated financial statements. 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.

***Recent Accounting Pronouncements***

In December 2010, the 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 was effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Upon the 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.

**Item 3.** ***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. There has been no material change with respect to our interest rate and foreign currency exposures or our approach toward those exposures, as described in our Annual Report on Form 10-K for the year ended December 31, 2010. However, we are exploring possible commercialization of Oncophage outside of the U.S., which could result in increased foreign currency exposure.

We had cash, cash equivalents, and short-term investments at March 31, 2011, of $15.6 million, which are exposed to the impact of interest rate changes, and our interest income fluctuates as interest rates change. Due to the short-term nature of our investments in money market funds, the carrying value approximates the fair value of these investments at March 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 liquidity to meet operating needs, and maximize yields. We review our investment policy annually and amend it as deemed necessary. Currently, our 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 derivatives or other financial instruments that would require disclosure under this item.

17

Table of Contents

**Item 4.** ***Controls and Procedures***

***Evaluation 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) and Rule 15d-15(e) promulgated under the Securities Exchange Act of 1934 (the Securities Exchange Act ). Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective and were designed to ensure that information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our Chief Executive Officer and Chief Financial Officer have each concluded that our disclosure controls and procedures as of the end of the period covered by this report are effective at a level that provides such reasonable assurances

***Changes in Internal Control Over Financial Reporting***

During the quarter ended March 31, 2011, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

## PART II OTHER INFORMATION

**Item 1.** ***Legal Proceedings***

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 alleges 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 alleges 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. The parties have reached a global settlement of the litigation. Under the settlement, the insurers will pay the full amount of settlement share allocated to the defendants, and the defendants will bear no financial liability. Agenus and the other defendants will receive complete dismissals from the case. In October 2009, the Court entered an order granting final approval of the settlement, and subsequently judgment was entered. Various objectors have filed appeals. If for any reason the settlement does not become effective, we believe we have meritorious defenses to the claims and intend to defend the action vigorously. We are unable to predict the likelihood of an unfavorable outcome or estimate our potential liability, if any.

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. 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 1A.** ***Risk Factors***

Our future operating results could differ materially from the results described in this Quarterly Report on Form 10-Q due to the risks and uncertainties described below. We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Please see the Forward-Looking Statements section of this Quarterly Report on Form 10-Q. 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 March 31, 2011, we have incurred net losses totaling $590.4 million. Our net losses for the three months ended March 31, 2011 and the years ended December 31, 2010, 2009, and 2008, were $6.0 million, $21.9 million, $30.3 million, and $30.8 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 commercialization of Oncophage and our various 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.

On March 31, 2011, we had $15.6 million in cash and cash equivalents, and short-term investments. We believe that, based on our current plans and activities, our working capital resources at March 31, 2011, combined with anticipated revenues, and the estimated proceeds from our license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements into 2012. We expect to attempt to raise additional funds in advance of depleting our funds although funds may not be available on favorable terms, or at all. For the three months ended March 31, 2011, our average monthly cash used in operating activities was $1.5 million. We do not anticipate significant capital expenditures during 2011.

We are required to maintain effective registration statements in connection with certain private placement agreements. If we are unable to keep the registration statements continuously effective in accordance with the terms of the private placement agreements, or do not maintain our listing on Nasdaq or any electronic bulletin board, we are subject to liquidated damages penalties of up to a maximum of 10% of the aggregate

purchase price paid by the original investors, or up to $3.8 million.

Table of Contents

Since our inception, we have financed our operations primarily through the sale of equity and convertible notes, interest income earned on cash, cash equivalents, and short-term investment balances, and debt provided through secured lines of credit. 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. During February 2010, we entered into an At the Market Sales Agreement with McNicoll, Lewis & Vlak LLC and Wm Smith & Co (the Sales Agents ) under which we may sell an aggregate of up to 20 million shares of our common stock from time to time through the Sales Agents. To date we have sold approximately 7.0 million shares of our common stock under this agreement for net proceeds, after expenses, of $8.8 million.

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.***

At the option of the holders, our 2006 Notes can be converted into an interest in one of our wholly-owned subsidiaries that holds the rights or patents to QS-21 and HerpV. If converted into an interest of this subsidiary, the ownership interest in the subsidiary will be determined by multiplying the quotient of the conversion amount divided by $25.0 million, by 30%. 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 March 31, 2011, the outstanding balance of the 2006 Notes was $34.7 million. These notes are secured by the equity of the subsidiary that holds the rights or patents to QS-21 and HerpV.

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 three months ended March 31, 2011 and for the years ended December 31, 2010, 2009, and 2008, net cash used in operating activities was $4.6 million, $14.8 million, $24.2 million, and $28.9 million, respectively.

***Several factors could prevent the successful commercialization of Oncophage in Russia. In addition, we do not expect to generate significant revenue from sales of Oncophage in Russia in the near term.***

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 and, in September 2008, the FDA granted the necessary permission to allow for the export of Oncophage from the United States to Russia. The Russian registration was our first product approval from

a regulatory authority.

Table of Contents

Since approval, modest sales have occurred in 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. We currently do not have a business presence outside of the United States and rely on third parties to conduct our Oncophage operations in Russia. If we are unable to obtain local distribution arrangements including favorable pricing and payment terms, and/or develop appropriate logistical processes for distribution of Oncophage, our commercialization efforts would be adversely affected.

To date we have not been able to secure government reimbursement and there appears to be a limited private-pay market in Russia. If we are unsuccessful in obtaining substantial reimbursement for Oncophage from national or regional funds, we will have to rely on private-pay for the foreseeable future, which may limit or prevent our sales efforts because the ability and willingness of patients to pay is unclear 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. Because we have limited resources and minimal sales and marketing experience, successful commercialization of Oncophage in Russia and elsewhere may not materialize. Furthermore, we may experience significant delays in the receipt of payment for Oncophage, or an inability to collect payments at all.

***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 collaborative partners 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 collaborative partners 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 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.

***If we fail to comply with regulatory requirements in the countries in which we conduct our business, if these regulatory requirements change, or if we experience unanticipated regulatory problems, our commercial launch of our Prophage Series vaccines could be prevented or delayed, or our product candidates could be subjected to restrictions, or be withdrawn from the market, or some other action may be taken that may be adverse to our business.***

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 marketing 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, recall or seizure 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 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.

21

Table of Contents

***We may not be able to make the Prophage Series of cancer vaccines available in countries other than Russia or in indications other than 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 of 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 biologics license application ( 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 and subsequently we withdrew our application. We have stopped actively pursuing European approval, and while we continue to explore paths forward in Europe, at this time there are no active partnership discussions ongoing.

The FDA has indicated that our Phase 3 clinical trials of Oncophage and M-200 cannot, by themselves, support BLA filings in the studies indications (renal cell carcinoma and metastatic melanoma). The signals and trends observed in these Phase 3 trials are based on data analysis of subgroups of patients, some of which were not pre-specified. While the subgroup data might be suggestive of treatment effect, under current regulatory guidelines the results cannot be expected, alone, to support registration or approval in the United States, and our existing data may not support registration or approval in other territories outside of Russia, including in Europe. Due to our lack of resources, our ability to perform additional studies may be limited. Furthermore, studies may take years to complete and may fail to support regulatory filings for many reasons. In addition, 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 deriving from the Prophage Series of vaccines may experience high development costs and a long regulatory review process, either of which could delay or prevent our 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.

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 financial position, results of operations, and cash flows can be affected by fluctuations in foreign currency exchange rates, primarily for the euro and the ruble. Movement in foreign currency exchange rates could cause revenue or clinical trial costs to vary significantly in the future and may affect period-to-period comparisons of our operating results. Historically, we have not hedged our exposure to these fluctuations in exchange rates.

***Our commercial and international operations experience and resources are limited and 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

Table of Contents

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.

***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 products and the products in development by our collaborative partners may fail because of intense competition from major pharmaceutical companies and specialized biotechnology companies engaged in the development of product candidates directed at cancer, infectious diseases and degenerative disorders. Several of these companies have products that utilize technologies similar to our Prophage Series vaccines and/or patient-specific or other vaccine based techniques, such as Dendreon and Accentia, as well as Innocell Corp (Immuncell-LC), ImmunoCellular Therapeutics (ICT-107), Northwest Biotherapeutics (DC-Vax) and Celldex (CDX-110), all for treatment of patients with newly diagnosed glioma.

There is no guarantee that our products/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 Wilex AG s Rencarex (WX-G250), which is in Phase 3 clinical trials. Additionally, sorafenib and sunitinib, which are approved for advanced renal cell carcinoma, are being studied in non-metastatic renal cell carcinoma, and other products that have been developed for metastatic renal cell carcinoma, such as temsirolimus, bevacizumab and pazopanib, may also be developed for non-metastatic renal cell carcinoma. As our Prophage Series vaccines are potentially developed in other indications, they would 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.

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 addition, at least one company, CSL Limited, as well as academic institutions, are developing saponin adjuvants, including derivatives and synthetic formulations.

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.

***Manufacturing problems may cause product launch 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 and we intend to continue using this facility to satisfy all demands for product. While we believe we will be able to cover all demands 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

Table of Contents

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.

We can also manufacture other clinical products in our own manufacturing facility. Our manufacturing facility has support areas that it shares with the Prophage Series vaccine manufacturing areas. As we seek to make Prophage Series vaccines available in other territories, the applicable 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. We would then have to manufacture or have manufactured other product candidates in an appropriate alternative facility.

Currently, we do not manufacture QS-21 in our own manufacturing facility, and we have given two QS-21 licensees who have the most advanced QS-21 programs the right to manufacture QS-21 themselves or through third-party manufacturers. If these licensees are unable to successfully manufacture or have manufactured QS-21, the commercialization of the product candidates being developed by such licensees could be delayed or prevented, and we could lose important potential future revenue streams. We currently outsource the manufacture of QS-21 under an agreement that expires in 2012. If we are not able to renew this agreement we may have to identify an alternative manufacturing source or to invest substantial funds to develop our own manufacturing facility. 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.

***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. As of March 31, 2011, we have spent approximately 16 years and $284.6 million on our research and development program in heat shock proteins for cancer.

Table of Contents

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.

Our existing Oncophage data may not support registration or approval in territories outside of Russia, including in the U.S. or Europe. Furthermore, regulatory authorities, including the FDA and the EMA, may have varying opinions of our product characterization, preclinical and clinical trial data for our other product candidates, which could delay, limit, or prevent regulatory approval or clearance. 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 will not be able to commercialize them in the timeframe anticipated, and our business will suffer.

***New data from our research and development activities, in-licensing and/or acquisition 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.

***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 or substantial royalty rates. 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.

Table of Contents

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. 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 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. Further clinical development of HerpV will require a partner to support its advancement.

***Because we rely on collaborators and licensees for the development and commercialization of some 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 some of our product candidates by continuing our existing arrangements with academic and corporate collaborators and licensees and by entering into new collaborations. 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 University of California, San Francisco, 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 depend on the success of our collaborative partners or licensees, and the Company s relationships with these third parties. Such product candidates depend on the successful and adequate manufacture and/or supply of QS-21, and 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.

These 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. For example, an undisclosed infectious disease Phase 3 program was discontinued by one of our collaborators in 2010. Several of our agreements also require us to transfer important rights and regulatory compliance responsibilities to our collaborators and licensees. As a result of these collaborative agreements, we will not control the nature, timing, or cost of bringing these product candidates to market. Our collaborators and licensees could choose not to devote resources to these arrangements or, under certain circumstances, may terminate these arrangements early. They may cease pursuing product candidates or elect to collaborate with different companies. In addition, these collaborators and licensees, outside of their arrangements with us, may develop technologies or products that are competitive with those that we are developing. From time to time, we may also become involved in disputes with our collaborators or licensees. Such disputes could result in the incurrence of significant expense, or the termination of collaborations. We may be unable to fulfill all of our obligations to our collaborators, which may result in the termination of collaborations. As a result of these factors, our strategic collaborations may not yield revenue. Furthermore, we may be unable to enter into new collaborations or enter into new collaborations on favorable terms. Failure to generate significant revenue from collaborations would increase our need to fund our operations through sales of debt or equity securities and would negatively affect our business prospects.

***If we are unable to purify heat shock proteins we may have difficulty successfully initiating or completing our clinical trials, and, even if we do successfully complete our clinical trials, generating sizable market potential.***

Depending on the type and stage of cancer and the patient population, our ability to successfully develop and commercialize the Prophage Series vaccines for a particular cancer depends in part on our ability to purify heat shock proteins from that type of cancer. If we 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 90% of the tumors received for patients enrolled in our ongoing 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.

Table of Contents

We may encounter problems with other types of cancer or patients, such as pediatric 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 currently have exclusive rights to 73 issued United States patents and 123 issued foreign patents. We also have exclusive rights to 4 pending United States patent applications and 27 pending foreign patent applications. However, our patents may not protect us against our competitors. Our patent positions, and those of other pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific, and factual questions. The standards which the United States Patent and Trademark Office 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

Table of Contents

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.

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 and operations personnel and consultants to conduct our business. Reductions in our staffing levels have eliminated redundancies in key capabilities and skill sets among our full time staff and required us to rely more heavily on outside consultants. 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.

Table of Contents

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

Agenus, our Chairman and Chief Executive Officer, 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 alleges 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 alleges 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. The parties have reached a global settlement of the litigation. Under the settlement, the insurers will pay the full amount of settlement share allocated to the defendants, and the defendants will bear no financial liability. Agenus and the other defendants will receive complete dismissals from the case. In October 2009, the Court entered an order granting final approval of the settlement, and subsequently judgment was entered. Various objectors have filed appeals. If for any reason the settlement does not become effective, we believe we have meritorious defenses to the claims and intend to defend the action vigorously. We are unable to predict the likelihood of an unfavorable outcome or estimate our potential liability, if any.

In addition, we may currently be, or may become involved in additional litigation. Any such litigation could be expensive in terms of out-of-pocket costs and management time, and the outcome of any such litigation is uncertain.

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.***

We use or may use hazardous, infectious, and radioactive materials, and recombinant DNA in our operations, which have the potential of being harmful to human health and safety or the environment. We store these hazardous (flammable, corrosive, toxic), infectious, and radioactive materials, and various wastes resulting from their use, at our facilities pending use and ultimate disposal. We are subject to a variety of federal, state, and local laws and regulations governing use, generation, storage, handling, and disposal of these materials. We may incur significant costs complying with both current and future environmental health and safety laws and regulations. In particular, we are subject to regulation by the

Table of Contents

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 limited pollution liability coverage ($2.0 million) and 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**

***The unaffiliated holders of certain convertible securities have the right to convert such securities into a substantial percentage of our outstanding common stock.***

According to publicly filed documents, Mr. Brad M. Kelley beneficially owns 5,546,240 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 2,000,000 shares of common stock at an initial conversion price of $15.81, are non-voting, and carry a 2.5% annual dividend yield. If Mr. Kelley had converted all of the shares of preferred stock on March 31, 2011, he would have held approximately 7% 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.

Mr. Kelley s substantial ownership position provides him with the ability to substantially influence the outcome of matters submitted to our stockholders for approval. Furthermore, collectively, Mr. Kelley and Garo Armen, our CEO, control approximately 11% of our outstanding common stock as of March 31, 2011, providing 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 12%. 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 CEO. 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.

***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 under the symbol AGEN. In the event that we fail to satisfy any of the listing requirements, our common stock may be put under review or removed from the listing on the Nasdaq Capital Market.

On March 3, 2011, we were notified by the Staff that we are not in compliance with the Bid Price Requirement because the bid price for our common stock had closed below the minimum $1.00 per share requirement for 30 consecutive business days. In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), we have been provided 180 calendar days, or until August 30, 2011, to regain compliance with the Bid Price Requirement.

If compliance is not demonstrated within the applicable compliance period, the Staff will notify us that our securities will be delisted from the Nasdaq Capital Market. However, we may appeal the Staff s determination to delist our securities to a Hearings Panel. During any appeal process, shares of our common stock would continue to trade on the Nasdaq Capital Market. There can be no assurance that we will meet the requirements for continued listing on the Nasdaq Capital Market or whether any appeal would be granted by the Hearings Panel.

***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

30

Table of Contents

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

***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 March 31, 2011, and for the three months ended March 31, 2011, the closing price of our common stock has fluctuated between $0.30 and $52.63 per share and $0.93 and $1.11 per share, respectively. The average daily trading volume for the three months ended March 31, 2011 was approximately 401,000 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.

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

The sale by us or the resale by stockholders of a significant number of shares of our common stock could cause the market price of our common stock to decline. As of March 31, 2011, we had approximately 113,301,000 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 25,437,000 shares of common stock under our equity incentive plan and certain equity plans that we assumed in our acquisitions of Aquila Biopharmaceuticals, Inc. and Aronex Pharmaceuticals, Inc. We have also filed registration statements to permit the sale of 1,000,000 shares of common stock under our employee stock purchase plan, to permit the sale of 450,000 shares of common stock under our Directors Deferred Compensation Plan, to permit the sale of 49,643,966 shares of common stock pursuant to various private placement agreements. As of March 31, 2011, an aggregate of 38.3 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 March 31, 2011, options to purchase 8,740,144 shares of our common stock with a weighted average exercise price per share of $2.03 were outstanding. Many of these options are subject to vesting that generally occurs over a period of up to four years following the date of grant. As of March 31, 2011, we have 1,022,057 nonvested shares outstanding.

***Because we are a small public company we believe we have been disproportionately negatively impacted by the Sarbanes-Oxley Act of 2002 and related regulations which have increased our costs in the past and have required additional management resources.***

The Sarbanes-Oxley Act of 2002 and rules adopted by the SEC 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. Additionally, these laws and regulations could make it more difficult for us to attract and retain qualified members for our Board of Directors, particularly independent directors, or qualified executive officers.

Table of Contents

Our internal control over financial reporting (as defined in Rules 13a-15 of the Securities 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. generally accepted accounting principles. 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, 2010, 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.

Table of Contents

**Item 6.** ***Exhibits***

The Exhibits listed in the Exhibit Index are included in this Quarterly Report on Form 10-Q.

Table of Contents

**AGENUS INC.**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 6, 2011

AGENUS INC.

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

Table of Contents

**Exhibit Index**

| Exhibit No. | Description |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation of Antigenics Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 10, 2002 and incorporated herein by reference. |
| 3.1.1 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Antigenics Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 11, 2007 and incorporated herein by reference. |
| 3.1.2 | Certificate of Ownership and Merger changing the name of the corporation to Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 6, 2011 and incorporated herein by reference. |
| 3.2 | Fifth Amended and Restated By-laws of Agenus Inc. Filed as Exhibit 3.2 to our Current Report on Form 8-K (File No. 0-29089) filed on January 6, 2011 and incorporated herein by reference. |
| 3.3 | Certificate of Designation, Preferences and Rights of the Series A Convertible Preferred Stock of Agenus Inc. filed with the Secretary of State of the State of Delaware on September 24, 2003. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 25, 2003 and incorporated herein by reference. |
| 3.4 | Certificate of Designations, Preferences and Rights of the Class B Convertible Preferred Stock of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 5, 2007 and incorporated herein by reference. |
| 4.1 | 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. |
| 10.2 | 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. |
| 10.3 | 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 herewith. |
| 31.1 | Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith. |
| 31.2 | Certification of 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(1) | 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. |

(1) This certification accompanies the Quarterly Report on Form 10-Q and is not filed as part of it.