

AGENUS INC  
Form 10-Q  
May 06, 2011  
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**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)

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**Delaware**  
(State of Incorporation)

**06-1562417**  
(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 ☒ 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 ☒

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 ☒

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

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**Agenus Inc.**

**Quarterly Period Ended March 31, 2011**

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**Table of Contents****PART I FINANCIAL INFORMATION****Item 1 Financial Statements****AGENUS INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****(Unaudited)**

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
<b>ASSETS</b>		
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
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
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)

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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.

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**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)**

	<b>Quarter Ended</b>	
	<b>March 31, 2011</b>	<b>2010</b>
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:

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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.	



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**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 biotechnology 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.

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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



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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:

	<b>Nonvested Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
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.

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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**

Agenu, 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. Agenu 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.



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### **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.

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

Description	March 31, 2011		December 31, 2010	
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Unobservable Inputs (Level 3)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Short-term investments	\$ 5,000	\$	\$	\$
<b>Liabilities:</b>				
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)
<b>Balance, March 31, 2011</b>	<b>\$</b>

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 & Vlask 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.





**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



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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 expression in 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.



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*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					
	Product	March 31, 2011	Year Ended December 31,			Prior to 2008	Total
		2010	2009	2008			
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*

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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.

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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



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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 & Vlcek 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

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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.



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**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.

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### **PART II OTHER INFORMATION**

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

Agenuus, 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. Agenuus 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.

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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: