

AGENUS INC  
Form 10-Q  
November 04, 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 September 30, 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 No.)

**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, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.:

Large accelerated filer  Accelerated filer

Non-accelerated filer  (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 issuer's Common Stock as of November 2, 2011: 21,455,205 shares.

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**Agenus Inc.**

**Quarterly Period Ended September 30, 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>September 30, 2011</b>	<b>December 31, 2010</b>
<b>ASSETS</b>		
Cash and cash equivalents	\$ 14,731,726	\$ 19,781,976
Accounts receivable		35,000
Inventories	26,432	26,432
Prepaid expenses	771,591	704,744
Other current assets	455,372	306,008
<b>Total current assets</b>	<b>15,985,121</b>	<b>20,854,160</b>
Plant and equipment, net of accumulated amortization and depreciation of \$25,940,639 and \$24,993,225 at September 30, 2011 and December 31, 2010, respectively	4,713,760	6,194,465
Goodwill	2,572,203	2,572,203
Other long-term assets	1,097,706	1,285,831
<b>Total assets</b>	<b>\$ 24,368,790</b>	<b>\$ 30,906,659</b>
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current portion, long-term debt	\$ 196,198	\$ 146,061
Current portion, deferred revenue	1,550,520	1,540,385
Accounts payable	504,141	698,554
Accrued liabilities	3,082,025	2,684,609
Other current liabilities	532,505	346,314
<b>Total current liabilities</b>	<b>5,865,389</b>	<b>5,415,923</b>
Convertible senior notes	30,820,134	34,050,033
Other long-term debt	100,747	
Deferred revenue	2,460,622	3,612,156
Derivative liability (Note G)		755,000
Other long-term liabilities	1,192,507	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 September 30, 2011 and December 31, 2010; liquidation value of \$31,817,625 at September 30, 2011	316	316
Series B2 convertible preferred stock; 3,105 shares designated, issued, and outstanding at September 30, 2011 and December 31, 2010	31	31
Common stock, par value \$0.01 per share; 250,000,000 shares authorized; 21,380,280 and 18,647,626 shares issued at September 30, 2011 and December 31, 2010, respectively (Note A)	213,803	186,476
Additional paid-in capital (Note A)	585,714,203	569,849,178

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Treasury stock, at cost; 43,490 shares of common stock at September 30, 2011 and December 31, 2010 (Note A)	(324,792)	(324,792)
Accumulated deficit	(601,674,170)	(584,418,421)
Total stockholders' deficit	(16,070,609)	(14,707,212)
Total liabilities and stockholders' deficit	\$ 24,368,790	\$ 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)**

	<b>Quarters Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
<b>Revenue:</b>				
Product revenue	\$	\$ 17,500	\$	\$ 52,500
Research and development revenue	653,681	606,947	2,111,994	2,313,547
<b>Total revenues</b>	<b>653,681</b>	<b>624,447</b>	<b>2,111,994</b>	<b>2,366,047</b>
<b>Operating expenses:</b>				
Cost of goods sold		65,048		122,946
Research and development	2,527,668	2,822,229	8,166,670	10,082,409
General and administrative	2,566,914	2,624,099	8,110,176	8,957,550
<b>Operating loss</b>	<b>(4,440,901)</b>	<b>(4,886,929)</b>	<b>(14,164,852)</b>	<b>(16,796,858)</b>
<b>Other income (expense):</b>				
Non-operating income (expense)	(298)	404,611	(1,114)	967,744
Interest expense, net	(1,093,201)	(1,225,090)	(3,089,783)	(3,661,096)
<b>Net loss</b>	<b>(5,534,400)</b>	<b>(5,707,408)</b>	<b>(17,255,749)</b>	<b>(19,490,210)</b>
Dividends on series A convertible preferred stock	(197,625)	(197,625)	(592,875)	(592,875)
<b>Net loss attributable to common stockholders</b>	<b>\$ (5,732,025)</b>	<b>\$ (5,905,033)</b>	<b>\$ (17,848,624)</b>	<b>\$ (20,083,085)</b>
<b>Per common share data, basic and diluted:</b>				
Net loss attributable to common stockholders	\$ (0.28)	\$ (0.36)	\$ (0.92)	\$ (1.26)
<b>Weighted average number of common shares outstanding, basic and diluted</b>	<b>20,225,034</b>	<b>16,516,102</b>	<b>19,352,035</b>	<b>15,884,573</b>

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents****AGENUS INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (17,255,749)	\$ (19,490,210)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	1,696,358	2,744,898
Intangible asset impairment		629,382
Change in fair value of derivative liability		105,832
Share-based compensation	1,647,627	2,571,551
Non-cash interest expense	2,350,225	2,217,739
Net gain on extinguishment of debt		(1,063,746)
Loss on sale of property and equipment	14,420	26,696
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	35,000	(35,000)
Inventories		297,603
Prepaid expenses	(66,847)	92,598
Accounts payable	(215,169)	(615,006)
Deferred revenue	(1,141,399)	(690,796)
Accrued liabilities and other current liabilities	1,101,734	84,378
Other operating assets and liabilities	(234,781)	(188,851)
<b>Net cash used in operating activities</b>	<b>(12,068,581)</b>	<b>(13,312,932)</b>
<b>Cash flows from investing activities:</b>		
Proceeds from maturities of available-for-sale securities	5,000,000	30,000,000
Proceeds from sale of property and equipment	22,749	43,535
Purchases of available-for-sale securities	(4,998,799)	(29,989,763)
Purchases of plant and equipment	(54,547)	(115,120)
<b>Net cash used in investing activities</b>	<b>(30,597)</b>	<b>(61,348)</b>
<b>Cash flows from financing activities:</b>		
Net proceeds from sales of equity	7,559,267	8,259,321
Proceeds from employee stock purchases	82,536	48,603
Payment of series A convertible preferred stock dividends	(592,875)	(592,875)
<b>Net cash provided by financing activities</b>	<b>7,048,928</b>	<b>7,715,049</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(5,050,250)</b>	<b>(5,659,231)</b>
Cash and cash equivalents, beginning of period	19,781,976	20,066,817
<b>Cash and cash equivalents, end of period</b>	<b>\$ 14,731,726</b>	<b>\$ 14,407,586</b>
<b>Non-cash investing and financing activities:</b>		
Convertible Note adjustment to equity for conversion option	\$ 5,580,124	

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Reclassification of derivative liability into equity	\$	755,000	
Issuance of senior secured convertible notes as payment in-kind for interest	\$	1,386,817	\$ 1,282,190
Note payable for purchase of plant and equipment	\$	171,640	
Issuance of common stock, \$0.01 par value, as payment of long-term debt including accrued and unpaid interest			\$ 1,125,918

See accompanying notes to unaudited condensed consolidated financial statements.



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**AGENUS INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 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 core technology portfolio consists of our Heat Shock Protein ( HSP ) Platform (based on our HSP based technologies) and our Saponin Platform (based on our saponin adjuvant based technologies). From our HSP Platform we are developing our Prophage Series vaccines. We have tested product candidates from our Prophage Series in Phase 3 clinical trials for the treatment of renal cell carcinoma ( RCC ), the most common type of kidney cancer, and for metastatic melanoma, as well as in Phase 1 and Phase 2 clinical trials in a range of indications. Prophage Series vaccine R-100 is registered for use in Russia in RCC as Oncophage® vaccine (vitespen). Product candidates from our Prophage G-Series are currently in Phase 2 clinical trials in glioma, a type of brain cancer. Within our HSP Platform we are also developing recombinant HSP based technologies (the Recombinant Series). HerpV, a therapeutic vaccine candidate from the Recombinant Series has been tested in a Phase 1 clinical trial for the treatment of genital herpes. Within our Saponin Platform is QS-21 Stimulon® adjuvant, or QS-21, which is used by our licensees in numerous vaccines under development in trials, some as advanced as Phase 3, for a variety of diseases, including human immunodeficiency virus, cancer, Alzheimer's disease, malaria, shingles, and tuberculosis. 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 September 30, 2011, we had an accumulated deficit of \$601.7 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 September 30, 2011, 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. 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, 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 September 30, 2011, we had debt outstanding of \$36.5 million in principal, including \$36.1 million in principal of our 8% senior secured convertible notes due August 2014 (the 2006 Notes ). We expect to attempt to raise additional funds in advance of depleting our current funds to repay existing obligations and for working capital purposes. We may attempt to raise additional funds by: (1) out-licensing technologies or products to one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities. Satisfying long-term liquidity needs may require the successful commercialization and/or one or more partnering arrangements for (1) our product, Oncophage and/or our Prophage Series vaccines, (2) vaccines containing QS-21 under development by our licensees and/or (3) potentially other product candidates, each of which will require additional capital. If we incur operating losses for longer than we expect and/or we are unable to raise additional capital, we may become insolvent and be unable to continue our operations.

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



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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 nine months ended September 30, 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.

Effective October 3, 2011, our certificate of incorporation was amended to effect a reverse stock split of our common stock on the basis of one post-split share for every six pre-split shares to, in part, regain compliance with the Nasdaq Marketplace Rule 5550(a)(2) (the "Bid Price Requirement"). All references in this Quarterly Report on Form 10-Q to shares and earnings per share have been retroactively restated to reflect the reverse stock split.

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 reported a net loss attributable to common stockholders for all periods presented, diluted loss per common share is the same as basic loss per common share, as the effect of utilizing the fully diluted share count would have reduced the net loss per common share. Therefore, the following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as of September 30, 2011 and 2010, as they would be anti-dilutive:

	<b>At September 30,</b>	
	<b>2011</b>	<b>2010</b>
Warrants	3,309,378	3,309,378
Stock options	1,827,458	1,228,105
Nonvested shares	143,321	97,655
Convertible preferred stock	333,333	333,333
Convertible notes		2,126,036

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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 nine months ended September 30, 2011 is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2010	1,212,095	\$ 13.43		
Granted	747,911	4.63		
Forfeited	(46,011)	9.32		
Expired	(86,218)	45.88		
Exercised	(319)	4.50		
Outstanding at September 30, 2011	1,827,458	\$ 8.40	7.9	\$ 2,351
Vested or expected to vest at September 30, 2011	1,721,443	\$ 8.63	7.8	\$ 2,276
Exercisable at September 30, 2011	974,010	\$ 11.60	6.6	\$ 2,210

The weighted average grant-date fair values of options granted during the nine months ended September 30, 2011, and 2010, were \$3.52, and \$3.54, respectively.

During the first nine 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 September 30, 2011, approximately \$2.3 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 2.5 years.

As of September 30, 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 approximately \$28,000. 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 nine months ended September 30, 2011 is presented below:

Nonvested Shares	Weighted Average Grant Date Fair Value
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Outstanding at December 31, 2010	85,564	\$	4.62
Granted	224,618		3.51
Vested	(157,489)		5.23
Forfeited	(9,372)		3.69
Outstanding at September 30, 2011	143,321	\$	2.27

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As of September 30, 2011, there was approximately \$231,000 of unrecognized share-based compensation expense related to these nonvested shares. This cost is expected to be recognized over a weighted average period of 1.7 years. The total intrinsic value of shares vested during the nine months ended September 30, 2011 was approximately \$861,000.

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 nine months ended September 30, 2011, approximately 21,000 shares were issued under the 2009 ESPP, and approximately 158,000 shares were issued as a result of the vesting of nonvested stock. In addition, during the nine months ended September 30, 2011, approximately 23,000 shares were issued to our CEO in lieu of cash salary.

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 September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Research and development	\$ 126	\$ 185	\$ 395	\$ 925
General and administrative	317	334	1,253	1,647
<b>Total share-based compensation expense</b>	<b>\$ 443</b>	<b>\$ 519</b>	<b>\$ 1,648</b>	<b>\$ 2,572</b>

**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 \$42.00 for a 30-day period.

Our 2006 Notes are secured by the equity of our wholly-owned subsidiary that holds the rights or patents to QS-21 Stimulon<sup>®</sup> adjuvant and HerpV. At the option of the holders, our 2006 Notes can be converted in whole or in part into an equity interest in this subsidiary, subject to our ability to preempt the conversion by redeeming the 2006 Notes to be so converted at a price equal to the conversion amount of such notes plus an amount that, when taken together with any cash interest payments previously made with respect to such 2006 Notes, would generate a 30% annual internal rate of return to the holders. If converted into an equity interest of this subsidiary, the ownership interest in the subsidiary will be determined by multiplying (x) the quotient of the conversion amount divided by \$25.0 million, by (y) 30%. In addition, our 2006 Notes grant holders a right of first refusal in any future equity issuance in this subsidiary so that holders of our 2006 Notes may purchase up to 50% of any newly issued equity in this subsidiary. 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 September 30, 2011, the outstanding principal balance of the 2006 Notes was \$36.1 million.

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 notes has been included in additional paid-in capital on our condensed consolidated balance sheet and, accordingly, the carrying value of the 2006 Notes was reduced by approximately \$5.6 million.



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**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 September 30, 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.

**Note F Recent Accounting Pronouncements**

In December 2010, the Financial Accounting Standards Board ( FASB ) issued additional guidance on when to perform Step 2 of the goodwill impairment test for reporting units with zero or negative carrying amounts. The criteria for evaluating Step 1 of the goodwill impairment test and proceeding to Step 2 was amended for reporting units with zero or negative carrying amounts and requires performing Step 2 if qualitative factors indicate that it is more likely than not that a goodwill impairment exists. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Upon 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.

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

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



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

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

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

Description	September 30, 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)

**Liabilities:**

Derivative liability			\$	755
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The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3), as of September 30, 2011 (amounts in thousands):

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

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Balance, September 30, 2011	\$
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As of September 30, 2011, and December 31, 2010, \$36.1 million and \$34.7 million in principal of the 2006 Notes are outstanding respectively. The fair value of the debt portion of the 2006 Notes exclusive of the conversion option at September 30, 2011, and December 31, 2010, is \$29.6 million and \$30.8 million, respectively, based on a present value methodology. The fair value of the embedded conversion option at September 30, 2011, is \$1.9 million.

### **Note H Equity**

During August 2011, we issued and sold approximately 2.3 million shares of our common stock in an underwritten offering. Net proceeds after deducting offering expenses were approximately \$6.3 million. These shares were issued pursuant to a shelf registration statement on Form S-3 filed with the SEC on January 22, 2010. During the nine months ended September 30, 2011, we issued and sold approximately 134,000 shares of our common stock in at the market offerings through our sales agents, McNicoll, Lewis & Vlax LLC and Wm Smith & Co. and raised net proceeds of approximately \$810,000 after deducting offering costs. We also issued and sold 88,000 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 were not in compliance with the Bid Price Requirement because the bid price for our common

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stock had closed below the minimum \$1.00 per share requirement for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided 180 calendar days, or until August 30, 2011, to regain compliance with the Bid Price Requirement. On August 31, 2011, the Staff notified us that we had not timely regained compliance with the Bid Price Requirement by August 30, 2011. The Staff further indicated that, based upon our non-compliance with the Bid Price Requirement, our common stock was subject to delisting unless we requested a hearing before a Nasdaq Listing Qualifications Panel (the Panel). Such a hearing was held on October 6, 2011. On October 17, 2011, we received notice from the Panel that we had regained compliance with the Bid Price Requirement and otherwise satisfied all requirements for continued listing on Nasdaq.

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### **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. Our core technology portfolio consists of our Heat Shock Protein ( HSP ) Platform (based on our HSP based technologies) and our Saponin Platform (based on our saponin adjuvant based technologies). Some of our key candidates from these technology platforms are highlighted below:

**The Prophage Series vaccines:** The Prophage Series vaccines are a patient specific application of our HSP Platform. We believe that the collective results from our clinical trials to date with product candidates from the Prophage Series indicate a favorable safety profile and signals of efficacy in multiple cancer types. 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 and received Prophage Series vaccine R-100 demonstrated an approximately 46 percent lower risk of death compared with those in the control arm (n = 362;  $P < 0.05$ ; hazard ratio = 0.54). R-100 is approved for sale in this indication in Russia as Oncophage<sup>®</sup> vaccine (vitespen). Phase 2 trials are underway testing the Prophage Series vaccine candidates 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 using combinations of potentially synergistic therapies, as well as in pediatric neurological tumors.

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

**QS-21 Stimulon<sup>®</sup> adjuvant ( QS-21 ):** QS-21, from our Saponin Platform, is a substance added to a vaccine or other immunotherapy that is intended to enhance immune response. The key licensees of QS-21 are GlaxoSmithKline ( GSK ) and JANSSEN Alzheimer Immunotherapy ( JANSSEN AI ). There are approximately 15 vaccines containing QS-21 in clinical development by our licensees, including four in Phase 3 testing for malaria, melanoma, non-small cell lung cancer and shingles. Results of a Phase 3 trial testing for malaria demonstrated that the vaccine provided young African children with significant protection against clinical and severe malaria, reducing risk by 56% and 47%, respectively, for the 12-month period following vaccination. There is no guarantee that these products will obtain regulatory approval or, if so approved, will generate significant royalties, if any, or that we will be able to collect royalties in the future. Assuming they gain regulatory approval, the first products containing QS-21 could potentially be launched in the 2013-2014 timeframe, and we are entitled to royalties for at least 10 years post-launch. 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. QA-21, a veterinary grade of QS-21, is also within the Saponin Platform. QA-21 is in a commercial feline leukemia vaccine product of one of our licensees, and is under development for other veterinary applications.

We have incurred significant losses since our inception. As of September 30, 2011, we had an accumulated deficit of \$601.7 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 September 30, 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) out-licensing technologies or

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products to one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities. Satisfying long-term liquidity needs may require the successful commercialization and/or one or more partnering arrangements for (1) our product, Oncophage and/or our other Prophage Series 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*. In April 2009, we moved from The Nasdaq Global Market to The Nasdaq Capital Market as part of our plan to regain compliance with minimum market value requirements. On March 3, 2011, we were notified by the Listing Qualifications Staff of Nasdaq (the *Staff*) that we were not in compliance with Nasdaq Marketplace Rule 5550(a)(2) (the *Bid Price Requirement*) because the bid price for our common stock had closed below the minimum \$1.00 per share requirement for 30 consecutive business days. Effective October 3, 2011, our certificate of incorporation was amended to effect a reverse stock split of our common stock on the basis of one post-split share for every six pre-split shares to, in part, regain compliance with the Bid Price Requirement. On October 17, 2011, we received notice from the Nasdaq Listing Qualifications Panel (the *Panel*) that we had regained compliance with the Bid Price Requirement and otherwise satisfied all requirements for continued listing on Nasdaq.

## **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 (the *Exchange Act*). 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 expressions 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 statements 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.

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## **Historical Results of Operations**

### ***Quarter Ended September 30, 2011 Compared to the Quarter Ended September 30, 2010***

*Revenue:* We generated revenue of \$654,000 and \$624,000 during the quarters ended September 30, 2011 and 2010, respectively. Revenue includes license fees and royalties earned, and in 2010, product revenue. In each of the quarters ended September 30, 2011 and 2010, we recorded revenue of \$385,000, 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 expenses



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decreased 10% to \$2.5 million for the quarter ended September 30, 2011 from \$2.8 million for the quarter ended September 30, 2010. The decrease includes declines related to our general cost-containment efforts and to the status of our products under development.

*General and Administrative:* General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses held steady at \$2.6 million for the quarter ended September 30, 2011 from the same period ended September 30, 2010.

*Non-Operating Income (Expense):* Non-operating income of \$405,000 for the quarter ended September 30, 2010 consists of the change in the fair value of our derivative liability since June 30, 2010. No similar activity occurred in 2011.

*Interest Expense, net:* Interest expense, net decreased to \$1.1 million for the quarter ended September 30, 2011 from \$1.2 million for the quarter ended September 30, 2010. The increased interest expense on our 2006 Notes, due to the increased principal amount, was partially offset by the decrease in interest payable on our 5.25% convertible senior notes due February 2025 (the 2005 Notes ) due to the extinguishment of a portion of those notes.

***Nine Months Ended September 30, 2011 Compared to the Nine Months Ended September 30, 2010***

*Revenue:* We generated revenue of \$2.1 million and \$2.4 million during the nine months ended September 30, 2011 and 2010, respectively. This decreased revenue in 2011 is due primarily to fewer shipments of QS-21 to our QS-21 licensees in 2011 as compared to 2010. In each of the nine months ended September 30, 2011 and 2010, we recorded revenue of \$1.2 million 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 expenses decreased 19% to \$8.2 million for the nine months ended September 30, 2011 from \$10.1 million for the nine months ended September 30, 2010. The decrease resulted from declines in spending related to our general cost-containment efforts and to the status of our products under development.

*General and Administrative:* General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses decreased 9% to \$8.1 million for the nine months ended September 30, 2011 from \$9.0 million for the nine months ended September 30, 2010. This decrease is largely related to a reduction in our facility related expenses, reduction in our non-cash stock-based compensation expense and our general cost containment efforts.

*Non-Operating Income (Expense):* Non-operating income of \$968,000 for the nine months ended September 30, 2010 consists of the net gain of \$1.1 million on the extinguishment of a portion of our 2005 Notes partially offset by the increase in the fair value of our derivative liability of \$106,000. The change in our derivative liability is primarily due to an increase in our market value from December 31, 2009 to September 30, 2010. No similar activity occurred in 2011.

*Interest Expense, net:* Interest expense, net decreased 16% to \$3.1 million for the nine months ended September 30, 2011 from \$3.7 million for the nine months ended September 30, 2010. This decrease is primarily related to the repurchase of substantially all of our 2005 Notes. Interest on our 2006 Notes is payable semi-annually on December 30 and September 30 in cash or, at our option, in additional notes or a combination thereof. During the nine months ended September 30, 2011 and 2010, interest expense included \$1.4 million and \$1.3 million, respectively, which was paid in the form of issuing additional 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 September 30, 2011, these research and development programs consisted largely of our Prophage Series vaccines as indicated in the following table (in thousands).

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	Product	Nine Months Ended				Prior to 2008	Total
		September 30, 2011	Year Ended December 31, 2010	2009	2008		
<b>Research and Development Program</b>							
Heat Shock Proteins for Cancer	Prophage Series Vaccines	\$ 7,900	\$ 10,960	\$ 15,309	\$ 17,156	\$ 238,426	\$ 289,751
Heat Shock Proteins for Infectious Diseases	HerpV	213	644	262	1,377	16,071	18,567
Vaccine adjuvant *	QS-21	54	1,185	1,071	648	9,500	12,458
Other Research and Development Programs			89	261	1,482	31,695	33,527
<b>Total Research and Development Expenses</b>		<b>\$ 8,167</b>	<b>\$ 12,878</b>	<b>\$ 16,903</b>	<b>\$ 20,663</b>	<b>\$ 295,692</b>	<b>\$ 354,303</b>

\* 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 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.

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 with Oncophage 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. Using criteria defined by the Eastern Cooperative Oncology Group (ECOG), analysis of patients at intermediate-risk of disease recurrence (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 U.S. Food and Drug Administration (FDA) has indicated that, by itself, part I of our Phase 3 clinical trial in renal cell carcinoma is not sufficient to support a biologics license application (BLA) filing.

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. At the 2009 American Society of Clinical Oncology (ASCO) annual meeting, we announced results of an interim analysis from the 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 <



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0.05; hazard ratio = 0.54). Final analysis of this data has been completed.

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

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limited resources and minimal sales and marketing experience, we are not actively marketing Oncophage in Russia and are focusing our efforts in Russia on securing one or more partnering arrangements. 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, 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 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. Data presented at ASCO in June 2011 showed that 93% of the patients were alive at  $\geq 26$  weeks after surgery with a median overall survival of 11 months (47.6 weeks). In addition, measures of immune response post vaccination with Prophage Series G-200 demonstrated a significant tumor-specific CD8+ T-cell response as well as innate immune responses as marked by a significant increase in levels of circulating NK cells.

UCSF also initiated an additional Phase 2 clinical trial in newly diagnosed glioma testing Prophage Series vaccine G-100 in combination with Temodar® (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 AI. 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. Results of a Phase 3 trial testing for malaria demonstrated that the vaccine provided young African children with significant protection against clinical and severe malaria reducing risk by 56% and 47%, respectively, for the 12-month period following vaccination. Assuming regulatory approval, the first products containing QS-21 are expected to be commercially 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, supply 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.

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. In addition to its ongoing Phase 3 trial in malaria, GSK has ongoing Phase 3 studies evaluating its

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investigational MAGE-A3 Antigen-Specific Cancer Immunotherapeutic containing QS-21 in non-small cell lung cancer and melanoma, and a Phase 3 trial in shingles. Revenues recognized with respect to this agreement were \$995,000 for each of the nine months ended September 30, 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 an Alzheimer's disease vaccine that contains QS-21 ( Licensed Product ). In 2007, Elan initiated a Phase 2 study with the Licensed Product. 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 AI. Under the terms of the Amended License Agreement assigned to JANSSEN AI, they have the right to develop, make, have made, use, sell, offer for sale, import, and have sold, the Licensed Product. In addition, pursuant to the terms of the Amended License Agreement, JANSSEN AI has the right to manufacture all of its requirements of QS-21 for use in the Licensed Product and we have no further supply obligations. 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 and commercial sales of the Licensed Product. Revenues recognized with respect to this agreement were \$128,000 and \$117,000 for the nine months ended September 30, 2011 and 2010, respectively.

**Liquidity and Capital Resources**

We have incurred annual operating losses since inception, and we had an accumulated deficit of \$601.7 million as of September 30, 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 September 30, 2011, we have raised aggregate net proceeds of \$514.0 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 & Vlax LLC and Wm Smith & Co (the Sales Agents ) under which we may sell an aggregate of up to approximately 3.3 million shares of our common stock from time to time through the Sales Agents. To date we have issued approximately 1.4 million shares of our common stock in at the market offerings through the Sales Agents and raised net proceeds of approximately \$9.8 million after deducting offering costs of approximately \$304,000. As of September 30, 2011, we had debt outstanding of \$36.5 million in principal, including \$36.1 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 September 30, 2011 were \$14.7 million, a decrease of \$5.1 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 September 30, 2011, 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) out-licensing technologies or products to one or more third parties, (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.

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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 September 30, 2011, we have expensed \$47.0 million as research and development expenses and \$46.7 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 previously 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 September 30, 2011. We may enter into additional sponsored research agreements in the future, 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 QS-21 Stimulon® adjuvant in numerous vaccines. These agreements grant exclusive worldwide rights in some fields of use and co-exclusive or non-exclusive rights in others. These agreements generally 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 nine months ended September 30, 2011 and 2010 was \$12.1 million and \$13.3 million, respectively. We continue to support and develop our QS-21 partnering collaborations, with the anticipation of earning royalties on QS-21 beginning 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 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.

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

In June 2011, the FASB issued Accounting Standard Update No. 2011-05, Comprehensive Income ( ASU 2011-05 ) which increases the prominence of other comprehensive income in financial statements. Under this standard, the components of net income and other comprehensive income must be presented in either one or two consecutive financial



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statements. The standard eliminates the option to present other comprehensive income in the statement of changes in equity. ASU 2011-05 is effective for fiscal years beginning after December 15, 2011 and interim and annual periods thereafter. The standard should be applied retrospectively and early adoption is permitted. Adoption of this standard will impact only the presentation of our financial information.

**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 and cash equivalents at September 30, 2011 of \$14.7 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 September 30, 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.

**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 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 September 30, 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 Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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**Table of Contents****PART II OTHER INFORMATION****Item 1. Legal Proceedings**

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.

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 September 30, 2011, we have incurred net losses totaling \$601.7 million. Our net losses for the nine months ended September 30, 2011 and the years ended December 31, 2010, 2009, and 2008, were \$17.3 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 development and commercialization of our Prophage Series vaccines and our other product candidates. If we incur operating losses for longer than we expect and/or we are unable to raise additional capital, we may become insolvent and be unable to continue our operations.

On September 30, 2011, we had \$14.7 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 September 30, 2011, 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 nine months ended September 30, 2011, our average monthly cash used in operating activities was \$1.3 million. We do not anticipate significant capital expenditures during the remainder of 2011.

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. 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,



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reduce, or eliminate some or all of our development, commercialization and clinical trial programs. We also may be forced to license or sell technologies to others under agreements that allocate to third parties substantial portions of the potential value of these technologies. We may also be unable to continue our operations, or we may become insolvent.

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

***We have significant debt, and we may not be able to make interest or principal payments when due.***

As of September 30, 2011, we had debt outstanding of \$36.5 million in principal, including \$36.1 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 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 nine months ended September 30, 2011 and for the years ended December 31, 2010, 2009, and 2008, net cash used in operating activities was \$12.1 million, \$14.8 million, \$24.2 million, and \$28.9 million, respectively.

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

Our 2006 Notes are secured by the equity of our wholly-owned subsidiary that holds the rights or patents to QS-21 and HerpV. At the option of the holders, our 2006 Notes can be converted in whole or in part into an equity interest in this subsidiary, subject to our ability to preempt the conversion by redeeming the 2006 Notes to be so converted at a price equal to the conversion amount of such notes plus an amount that, when taken together with any cash interest payments previously made with respect to such 2006 Notes, would generate a 30% annual internal rate of return to the holders. If converted into an equity interest of this subsidiary, the ownership interest in the subsidiary will be determined by multiplying (x) the quotient of the conversion amount divided by \$25.0 million, by (y) 30%. In addition, our 2006 Notes grant holders a right of first refusal in any future equity issuance in this subsidiary so that holders of our 2006 Notes may purchase up to 50% of any newly issued equity in this subsidiary. In addition, our 2006 Notes contain a number of restrictions and covenants, including, but not limited to, restrictions and covenants that limit our ability, and the ability of our subsidiary mentioned above, to:

incur certain additional indebtedness;

make certain investments;

enter into certain affiliated party transactions;

create certain liens;

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

change our line of business.

If the holders elect not to convert into the subsidiary, then at the maturity of the 2006 Notes, we may elect to repay the then outstanding balance in cash or in common stock, subject to certain limitations. If we elect to repay the notes in common stock, we are limited to the number of shares we can issue, whereby the note holders cannot beneficially own in excess of 9.99% of our outstanding common stock at any given time. At September 30, 2011, the outstanding principal balance of the 2006 Notes was \$36.1 million.

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***We may not be able to successfully commercialize Oncophage in Russia or generate significant revenue from sales of Oncophage in Russia.***

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

Since approval, minimal sales have occurred in Russia and we have been seeking a partner to facilitate future sales. Conducting business in Russia is difficult without a local business presence. As long as we manufacture Oncophage in the U.S. for importation into Russia, complexities unique to the logistics of this product may delay shipments and limit our ability to move commercial product in an efficient manner without incident. If we are unable to partner this program, we do not anticipate successful commercialization.

In addition, to date we have not been able to secure government reimbursement and there appears to be a limited private-pay market in Russia. 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, and have not yet finalized a long-term, successful partnering arrangement, commercialization of Oncophage in Russia 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 health insurance coverage of our product candidates, and if coverage is obtained, it may be substantially delayed, or there may be significant restrictions on the circumstances in which the products would be reimbursed. We are unable to predict what impact any future regulation or third-party payer initiatives relating to reimbursement will have on our sales.

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

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

In 2008, we submitted a marketing authorization application ( MAA ), to the European Medicines Agency ( EMA ), requesting conditional authorization of Oncophage in earlier-stage, localized kidney cancer. After its review, the Committee for Medicinal Products for Human Use ( CHMP ) of the EMA adopted a negative opinion on our MAA 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 Prophage Series vaccine 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



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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 vaccines may experience high development costs and a long regulatory review process, either of which could delay or prevent commercialization efforts.

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

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

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

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

### ***Our competitors in the biotechnology and pharmaceutical industries may have superior products, manufacturing capability, selling and marketing expertise and/or financial and other resources.***

Our product candidates and the product candidates in development by our collaborative partners may fail because of intense competition from major pharmaceutical companies and specialized biotechnology companies that market products, or that are engaged in the development of product candidates, directed at cancer, infectious diseases and degenerative disorders.

Genentech markets Avastin and Eisai markets Gliadel, both for treatment of recurrent glioma. In addition, TVAX Biomedical is developing an immunotherapy candidate (TVI-Brain-1) for recurrent glioma. Schering Corporation, a subsidiary of Merck, markets Temodar for treatment of patients with newly diagnosed glioma. Other companies are developing vaccine candidates for the treatment of patients with newly diagnosed glioma, such as Innocell Corp (Immuncell-LC), ImmunoCellular Therapeutics (ICT-107), Northwest Biotherapeutics (DC-Vax) and Celldex (CDX-110). One or more of these companies may also develop product candidates for recurrent glioma.

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

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 Willex AG's Rencarex (WX-G250), sorafenib, sunitinib, temsirolimus, bevacizumab and pazopanib. As vaccines from our Prophage Series are

potentially developed in other indications, they

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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 the past, the Company has provided QS-21 to other entities under materials transfer arrangements. In at least one instance, it is possible that this material was used unlawfully to develop synthetic formulations and/or derivatives of QS-21. Companies such as Adjuvance Technologies, Inc. and CSL Limited, as well as academic institutions, are developing saponin adjuvants, including derivatives and synthetic formulations. It is possible that these compounds could be substituted for the Company's QS-21 in partnered programs.

Many of our competitors, including large pharmaceutical companies, have greater financial and human resources and more experience than we do. Our competitors may:

commercialize their product candidates sooner than we commercialize our own;

develop safer or more effective therapeutic drugs or preventive vaccines and other therapeutic products;

implement more effective approaches to sales and marketing and capture some of our potential market share;

establish superior intellectual property positions;

discover technologies that may result in medical insights or breakthroughs, which render our drugs or vaccines obsolete, possibly before they generate any revenue; or

adversely affect our ability to recruit patients for our clinical trials.

***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. While we believe we will be able to cover demand in the near term, there is no guarantee that we will be able to meet all future or unanticipated increases in demand, and a failure to do so could adversely affect our business. Such demand may also limit our ability to manufacture product in support of clinical trials, and this could cause a delay or failure in our Prophage Series vaccine development programs. Manufacturing of Prophage Series vaccines is complex, and various factors could cause delays or an inability to supply vaccine. Deviations in the processes controlling manufacture could result in production failures. Furthermore, we have limited manufacturing resources and there is no assurance that we will be able to obtain the necessary resources, timely or at all, to meet any increased demand.

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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.

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.



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We currently rely upon and expect to continue to rely upon third parties, potentially including our collaborators or licensees, to produce materials required to support our product candidates, preclinical studies, clinical trials, and commercial efforts. A number of factors could cause production interruptions at our manufacturing facility or at our contract manufacturers or suppliers, including equipment malfunctions, labor or employment retention problems, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers. Alternatively, there is the possibility we may have excess manufacturing capacity if product candidates do not progress as planned.

There are a limited number of contract manufacturers or suppliers that are capable of manufacturing our product candidates or the materials used in their manufacture. If we are unable to do so ourselves or to arrange for third-party manufacturing or supply of these product candidates or materials, or to do so on commercially reasonable terms, we may not be able to complete development of these product candidates or commercialize them ourselves or through our collaborative partners or licensees. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, and the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Manufacturing is also subject to extensive government regulation. Regulatory authorities must approve the facilities in which human health care products are produced. In addition, facilities are subject to ongoing inspections, and minor changes in manufacturing processes may require additional regulatory approvals, either of which could cause us to incur significant additional costs and lose revenue.

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

We currently rely upon and expect to continue to rely upon third party licensees, particularly GSK and JANSSEN AI, to develop, test, market and manufacture vaccines that utilize our QS-21 adjuvant. We expect that we will rely on similar relationships in the development of new adjuvants in our Saponin Platform.

In return for rights to use QS-21, our licensees have generally agreed to pay us license fees, supply payments, milestone payments and royalties on product sales for a minimum of 10 years after commercial launch of a vaccine that utilizes QS-21. As each licensee controls its own product development process, we cannot control or predict our licensees' requirements for QS-21 in the future or to what extent, if any, they will develop vaccines that use QS-21 as an adjuvant. Our licensees may initiate or cease programs containing QS-21 at any time. In the event that our licensees develop vaccines using QS-21, there is no guarantee that these products will obtain regulatory approval or, if so approved, will generate significant royalties, if any, or that we will be able to collect royalties, in the future.

In addition, where we had previously supplied our licensees with all their requirements of commercial grade QS-21, we have amended our agreements so that our licensees are permitted to manufacture their own QS-21. We are unable to predict what amount of QS-21, if any, will be purchased from us by licensees in the future.

Our patent on QS-21 composition of matter has already expired in virtually all territories, and our patent rights are limited to protecting certain combinations of QS-21 with other adjuvants or formulations of QS-21 with other agents. Our licenses also rely on unpatented technology, trade secrets, and confidential information. We may not be able to collect expected revenue from our licensees. Any such inability would have a material adverse effect on our business, financial condition and results of operations.

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

Clinical development, including preclinical testing and the process of obtaining and maintaining regulatory approvals for new therapeutic products, is lengthy, expensive, and uncertain. It also can vary substantially based on the type, complexity, and novelty of the product. We must provide regulatory authorities with manufacturing, product characterization, and preclinical and clinical data demonstrating that our product candidates are safe and effective before they can be approved for commercial sale. It may take us many years to complete our testing, and failure can occur at any stage of testing. Interim results of preclinical studies or clinical trials do not necessarily predict their final results, and acceptable results in early studies might not be seen in later studies. Any preclinical or clinical test may fail to produce results satisfactory to regulatory authorities for many reasons, including but not limited to insufficient product characterization, poor study structure conduct or statistical analysis planning, failure to enroll a sufficient number of patients or failure to prospectively identify the most appropriate patient eligibility criteria, and collectability of data. Preclinical and clinical data can be interpreted in different ways, which could delay, limit, or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, adverse medical events during a clinical trial, or



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safety issues resulting from products of the same class of drug could require a preclinical study or clinical trial to be repeated or cause a program to be terminated, even if other studies or trials relating to the program are successful. We or the FDA, other regulatory agencies, or an institutional review board may suspend or terminate human clinical trials at any time on various grounds. As of September 30, 2011, we have spent approximately 17 years and \$289.8 million on our research and development program in heat shock proteins for cancer.

The timing and success of a clinical trial is dependent on enrolling sufficient patients in a timely manner, avoiding serious or significant adverse patient reactions, and demonstrating efficacy of the product candidate in order to support a favorable risk versus benefit profile, among other considerations. The timing and success of our clinical trials, in particular, are also dependent on clinical sites and regulatory authorities accepting each trial's protocol, statistical analysis plan, product characterization tests, and clinical data. In addition, regulatory authorities may request additional information or data that is not readily available. Delays in our ability to respond to such requests would delay, and failure to adequately address concerns would prevent, our commercialization efforts.

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

adversely affect the marketing of any products we or our licensees or collaborators develop;

impose significant additional costs on us or our licensees or collaborators;

diminish any competitive advantages that we or our licensees or collaborators may attain;

limit our ability to receive royalties and generate revenue and profits; and

adversely affect our business prospects and ability to obtain financing.

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

***Even if we receive marketing approval for our product candidates, such product approvals could be subject to restrictions, withdrawals, or other commercialization hurdles if we fail to comply with regulatory requirements, if these regulatory requirements change, or if we experience other unanticipated regulatory problems.***

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

Because we are a company operating in a highly regulated industry, regulatory authorities could take enforcement action against us in connection with our 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.



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From time to time, new legislation is passed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA and other foreign health authorities. Additionally, regulations and guidance are often revised or reinterpreted by health agencies in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted, or whether regulations, guidance, or interpretations will change, and what the impact of such changes, if any, may be.

***New data from our research and development activities, 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, substantial royalty rates or milestones. If we fail to enter into any such agreements, our efforts to develop and/or commercialize our products or product candidates may be undermined. In addition, if we do not raise funds through any such agreements, we will need to rely on other financing mechanisms, such as sales of debt or equity securities, to fund our operations. Such financing mechanisms, if available, may not be sufficient or timely enough to advance our programs forward in a meaningful way in the short-term.

While we have been pursuing these business development efforts for several years, we have not entered into a substantial agreement relating to the potential development or commercialization of Oncophage or any of the other Prophage Series vaccines. 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. Advancing clinical development of HerpV will require a partner or additional funding.

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

Part of our strategy is to develop and commercialize a majority of our product candidates by continuing 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,

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

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. As stated in our Quarterly Report on Form 10-Q as filed with the Securities and Exchange Commission for the period ended June 30, 2011, we have exclusive rights to 73 issued United States patents and 124 issued foreign patents. We also have exclusive rights to 4 pending United States patent applications and 24 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

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our patents if we attempt to enforce them, and they are challenged, is uncertain. In addition, the type and extent of patent claims that will be issued to us in the future is uncertain. Any patents that are issued may not contain claims that permit us to stop competitors from using similar technology.

Furthermore, the product development timeline for biotechnology products is lengthy and it is possible that our issued patents covering our product candidates in the United States and other jurisdictions may expire prior to commercial launch. In addition, because our patent on QS-21 composition of matter has already expired in virtually all territories, our patent rights are limited to protecting certain combinations of QS-21 with other adjuvants or formulations of QS-21 with other agents, e.g., excipients that improve performance of the compound. However, there is no guarantee that a third party would necessarily choose to use QS-21 in combination with such adjuvants or formulate it with the excipients covered by our patents. We are aware of at least one other party that makes a synthetic version of QS-21, claimed by such party to be equivalent in activity to natural QS-21, and has also developed derivatives of QS-21, which have shown biological activity.

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

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

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

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

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

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.

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

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

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

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

***If we fail to retain the services of our key employees and external consultants we may not be able to achieve our strategic and operational objectives.***

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

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

We also rely on a small staff of highly trained and experienced senior management and scientific, administrative and operations personnel and consultants to conduct our business. Reductions in our staffing levels have eliminated redundancies in key capabilities and skill sets among our full time staff and required us to 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.

***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, Dr. Garo H. Armen, 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.



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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 Occupational Safety and Health Administration, the Environmental Protection Agency, the Drug Enforcement Agency, the Department of Transportation, the Centers for Disease Control and Prevention, the National Institutes of Health, the International Air Transportation Association, and various state and local agencies. At any time, one or more of the aforementioned agencies could adopt regulations that may affect our operations. We are also subject to regulation under the Toxic Substances Control Act and the Resource Conservation Development programs.

Although we believe that our current procedures and programs for handling, storage, and disposal of these materials comply with federal, state, and local laws and regulations, we cannot eliminate the risk of accidents involving contamination from these materials. Although we have a

workers' compensation liability policy, we could be held liable for resulting damages in the event of an accident or accidental release, and such damages could be substantially in excess of any available insurance coverage and could substantially disrupt our business.

**Risks Related to our Common Stock**

*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 approximately 924,000 shares of our outstanding common stock and 31,620 shares of our series A convertible preferred stock. The shares of preferred stock are

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currently convertible at any time into approximately 333,000 shares of common stock at an initial conversion price of \$94.86, are non-voting, and carry a 2.5% annual dividend yield. If Mr. Kelley had converted all of the shares of preferred stock on September 30, 2011, he would have held approximately 6% of our outstanding common stock. We currently have a right of first refusal agreement with Mr. Kelley that provides us with limited rights to purchase certain of Mr. Kelley's shares if he proposes to sell them to a third party.

Collectively, Mr. Kelley and Dr. Armen, our Chief Executive Officer, control approximately 11% of our outstanding common stock as of September 30, 2011, providing the ability, if they vote in the same manner, to determine the outcome of matters submitted to a stockholder vote. If Mr. Kelley were to convert all of his preferred stock into common stock, the combined total would increase to 13%. Additional purchases of our common stock by Mr. Kelley also would increase both his percentage of outstanding voting rights and the percentage combined with our Chief Executive Officer. While Mr. Kelley's shares of preferred stock do not carry voting rights, the shares of common stock issuable upon conversion carry the same voting rights as other shares of common stock.

***Our stock may be delisted from The Nasdaq Capital Market, which could affect its market price and liquidity.***

Our common stock is currently listed on The Nasdaq Capital Market ( Nasdaq ) under the symbol AGEN. In the event that we fail to maintain compliance with the applicable listing requirements, our common stock could become subject to delisting from The Nasdaq Capital Market.

On March 3, 2011, we were notified by the Nasdaq Staff that we were not in compliance with the minimum bid price requirement set forth in Nasdaq Listing 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 for 30 consecutive business days.

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

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

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

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

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us without the consent of our Board of Directors. Our certificate of incorporation provides for a staggered board and removal of directors only for cause. Accordingly, stockholders may elect only a minority of our Board at any annual meeting, which may have the effect of delaying or preventing changes in management. In addition, under our certificate of incorporation, our Board of Directors may issue additional shares of preferred stock and determine the terms of those shares of stock without any further action by our stockholders. Our issuance of additional preferred stock could make it more

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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 September 30, 2011, and for the nine months ended September 30, 2011, as adjusted for our October 3, 2011 one for six reverse stock-split, the closing price of our common stock has fluctuated between \$1.80 and \$315.78 per share and \$2.82 and \$4.99 per share, respectively. The average daily trading volume for the nine months ended September 30, 2011 was approximately 58,000 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 September 30, 2011, as adjusted for our October 3, 2011 one-for-six reverse stock-split, we had approximately 21,337,000 shares of common stock outstanding. All of these shares are eligible for sale on The Nasdaq Capital Market, although certain of the shares are subject to sales volume and other limitations. We have filed registration statements to permit the sale of approximately 4,240,000 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 approximately 167,000 shares of common stock under our employee stock purchase plan, to permit the sale of 125,000 shares of common stock under our Directors' Deferred Compensation Plan, to permit the sale of approximately 8,274,000 shares of common stock pursuant to various private placement agreements. As of September 30, 2011, an aggregate of 5.5 million shares remain available for sale under these registration

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statements. The market price of our common stock may decrease based on the expectation of such sales.

As of September 30, 2011, options to purchase 1,827,458 shares of our common stock with a weighted average exercise price per share of \$8.40 were outstanding. These options are subject to vesting that occurs over a period of up to four years following the date of grant. As of September 30, 2011, we have 143,321 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 Securities and Exchange Commission and the Nasdaq have resulted in significant costs to us. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations regarding the required assessment of our internal control over financial reporting, and our

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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.

Our internal control over financial reporting (as defined in Rules 13a-15 of the Exchange Act) is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external purposes in accordance with U.S. GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect all deficiencies or weaknesses in our financial reporting. While our management has concluded that there were no material weaknesses in our internal control over financial reporting as of December 31, 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.

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**Item 6. Exhibits**

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

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**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: November 4, 2011

AGENUS INC.

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



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<b>Exhibit</b>	
<b>No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of Antigenics Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 10, 2002 and incorporated herein by reference.
3.1.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Antigenics Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 11, 2007 and incorporated herein by reference.
3.1.2	Certificate of Ownership and Merger changing the name of the corporation to Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 6, 2011 and incorporated herein by reference.
3.1.3	Certificate of Second Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 30, 2011 and incorporated herein by reference.
3.2	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.
10.1*	Agenus Inc. Board Compensation Election Policy. Previously described in our proxy statement dated May 3, 2011 in connection with our 2011 Annual Meeting of Stockholders. 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.
101.INS	XBRL Instance Document(2)
101.SCH	XBRL Taxonomy Extension Schema Document(2)
101.CAL	XBRL Calculation Linkbase Document(2)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document(2)
101.LAB	XBRL Label Linkbase Document(2)
101.PRE	XBRL Taxonomy Presentation Linkbase Document(2)

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

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

\* Indicates a management contract or compensatory plan.