

AGENUS INC  
Form 10-Q  
November 08, 2013  
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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Form 10-Q

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

For the quarterly period ended September 30, 2013

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 000-29089

Agenus Inc.

(exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of

incorporation or organization)

3 Forbes Road, Lexington, Massachusetts 02421

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code:

(781) 674-4400

06-1562417

(I.R.S. Employer

Identification No.)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulations S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Number of shares outstanding of the issuer's Common Stock as of November 4, 2013: 35,472,835 shares

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## PART I - FINANCIAL INFORMATION

## Item 1. Financial Statements

## AGENUS INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30, 2013	December 31, 2012
<b>ASSETS</b>		
Cash and cash equivalents	\$ 30,204,928	\$ 21,468,269
Inventories	3,273	16,022
Accounts receivable	1,127	552,334
Prepaid expenses	655,239	545,907
Other current assets	11,829	32,156
Total current assets	30,876,396	22,614,688
Plant and equipment, net of accumulated amortization and depreciation of \$27,534,821 and \$27,404,751 at September 30, 2013 and December 31, 2012, respectively	2,887,322	2,606,428
Goodwill	2,572,203	2,572,203
Other long-term assets	1,334,049	1,299,304
Total assets	\$ 37,669,970	\$ 29,092,623
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current portion, long-term debt	\$ 3,259,235	\$ 204,088
Current portion, deferred revenue	1,510,679	1,527,883
Accounts payable	365,350	634,752
Accrued liabilities	4,439,315	2,168,338
Other current liabilities	78,300	277,927
Total current liabilities	9,652,879	4,812,988
Convertible notes	—	35,679,232
Other long-term debt	6,066,858	34,427
Deferred revenue	3,571,479	4,800,776
Contingent royalty consideration	19,603,048	—
Other long-term liabilities	1,652,656	1,365,357
Commitments and contingencies		
<b>STOCKHOLDERS' DEFICIT</b>		
Preferred stock, par value \$0.01 per share; 5,000,000 shares authorized at September 30, 2013 and December 31, 2012:		
Series A-1 convertible preferred stock; 31,620 and 0 shares designated, issued, and outstanding at September 30, 2013 and December 31, 2012, respectively; liquidation value of \$32,218,658 at September 30, 2013	316	—
Series A convertible preferred stock; 0 and 31,620 shares designated, issued, and outstanding at September 30, 2013 and December 31, 2012, respectively	—	316
Series B2 convertible preferred stock; 3,105 shares designated, issued, and outstanding at September 30, 2013 and December 31, 2012	31	31
Common stock, par value \$0.01 per share; 70,000,000 shares authorized; 35,271,902 and 24,645,112 shares issued at September 30, 2013 and December 31, 2012, respectively	352,719	246,451
Additional paid-in capital	640,409,483	595,917,080
Treasury stock, at cost; 43,490 shares of common stock at September 30, 2013 and December 31, 2012	(324,792	) (324,792 )

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Accumulated deficit	(643,314,707	) (619,019,367	)
Noncontrolling interest	—	5,580,124	)
Total stockholders' deficit	(2,876,950	) (17,600,157	)
Total liabilities and stockholders' deficit	\$37,669,970	\$29,092,623	)

See accompanying notes to unaudited condensed consolidated financial statements.

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AGENUS INC. AND SUBSIDIARIES  
 CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
 (Unaudited)

	Quarters Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenue:				
Service revenue	\$357,196	\$486,833	\$1,402,957	\$781,591
Research and development revenue	378,796	381,971	1,249,673	14,088,925
Total revenues	735,992	868,804	2,652,630	14,870,516
Operating expenses:				
Cost of service revenue	(80,067 )	(217,186 )	(529,524 )	(369,339 )
Research and development	(3,892,929 )	(2,605,917 )	(9,763,813 )	(8,193,847 )
General and administrative	(3,577,778 )	(2,586,866 )	(11,111,558 )	(8,819,319 )
Operating loss	(6,814,782 )	(4,541,165 )	(18,752,265 )	(2,511,989 )
Other income (expense):				
Non-operating (loss) income	(156,890 )	2,880	(3,476,667 )	110,472
Interest expense, net	(347,021 )	(1,191,076 )	(2,066,408 )	(3,483,204 )
Net loss	(7,318,693 )	(5,729,361 )	(24,295,340 )	(5,884,721 )
Dividends on Series A and A-1 convertible preferred stock	(50,865 )	(197,625 )	(3,108,836 )	(592,875 )
Net loss attributable to common stockholders	\$(7,369,558 )	\$(5,926,986 )	\$(27,404,176 )	\$(6,477,596 )
Per common share data:				
Basic and diluted net loss attributable to common stockholders	\$(0.24 )	\$(0.24 )	\$(0.99 )	\$(0.28 )
Weighted average number of common shares outstanding:				
Basic and diluted	30,345,439	24,529,089	27,773,594	23,275,267

See accompanying notes to unaudited condensed consolidated financial statements.

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AGENUS INC. AND SUBSIDIARIES  
 CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
 (Unaudited)

	Nine months Ended September	
	30,	
	2013	2012
Cash flows from operating activities:		
Net loss	\$(24,295,340 )	\$(5,884,721 )
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	448,157	1,487,324
Share-based compensation	3,292,624	3,580,914
Noncash interest expense	1,676,427	2,708,718
Gain on sale of investment	(355,500 )	—
Loss on disposal of assets	17,944	703
Change in fair value of contingent royalty obligation	512,390	—
Loss on extinguishment of debt	3,322,657	—
Changes in operating assets and liabilities:		
Accounts receivable	551,207	(369,059 )
Inventories	12,749	4,050
Prepaid expenses	(109,332 )	(95,573 )
Accounts payable	(269,402 )	(340,094 )
Deferred revenue	(1,246,501 )	1,339,584
Accrued liabilities and other current liabilities	2,145,553	1,346,219
Other operating assets and liabilities	307,627	511,894
Net cash (used in) provided by operating activities	(13,988,740 )	4,289,959
Cash flows from investing activities:		
Proceeds from sale of investment	450,000	—
Purchases of plant and equipment	(746,995 )	(101,051 )
Net cash used in investing activities	(296,995 )	(101,051 )
Cash flows from financing activities:		
Net proceeds from sales of equity	23,131,020	10,464,203
Proceeds from employee stock purchases	104,010	76,662
Financing of property and equipment	(34,834 )	(26,982 )
Payments of series A convertible preferred stock dividends	—	(592,875 )
Debt issuance costs	(177,802 )	—
Proceeds from issuance of long-term debt	10,000,000	—
Payments of convertible notes	(10,000,000 )	(100,000 )
Net cash provided by financing activities	23,022,394	9,821,008
Net increase in cash and cash equivalents	8,736,659	14,009,916
Cash and cash equivalents, beginning of period	21,468,269	10,747,951
Cash and cash equivalents, end of period	\$30,204,928	\$24,757,867
Supplemental cash flow information:		
Cash paid for interest	\$367,277	\$14,055
Non-cash financing activity:		
Deemed dividend on Series A convertible preferred stock	\$2,906,664	\$—
Issuance of senior secured convertible notes as payment in-kind for interest	\$—	\$1,499,981
	\$11,275,000	\$—

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Issuance of common stock, \$0.01 par value, as payment of long-term debt including accrued and unpaid interest

Contingent royalty consideration	\$ 19,090,658	\$—
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Elimination of noncontrolling interest	\$ 5,580,124	\$—
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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, 2013

Note A - Business, Liquidity and Basis of Presentation

Agenus Inc. (including its subsidiaries, also referred to as “Agenus,” the “Company,” “we,” “us,” and “our”) is a biotechnology company working to develop treatments for cancers and infectious diseases. We are focused on immunotherapeutic products based on our core platform technologies with multiple product candidates advancing through the clinic, including several product candidates that have advanced into late-stage clinical trials through corporate partners. Our core technology portfolio consists of our Saponin Platform (based on our saponin adjuvant based technologies) and our Heat Shock Protein (“HSP”) Platform (based on our HSP based technologies). Within our Saponin Platform is QS-21 Stimulon® adjuvant, or QS-21 Stimulon, which is used by our licensees in numerous vaccines under development in trials, some as advanced as Phase 3, for a variety of diseases, including cancer, shingles, malaria, Alzheimer's disease, human immunodeficiency virus, and tuberculosis. Data from two trials being conducted by our licensees using QS-21 Stimulon have been reported during 2013. Within our HSP Platform we are developing our Recombinant Series and our Prophage Series vaccines. HerpV, a therapeutic vaccine candidate from the Recombinant Series which includes QS-21 Stimulon, has been tested in a Phase 1 clinical trial for the treatment of genital herpes and is currently in a Phase 2 trial. In our Prophage Series we have tested product candidates in Phase 3 clinical trials for the treatment of renal cell carcinoma (“RCC”), the most common type of kidney cancer, and for metastatic melanoma, as well as in Phase 1 and Phase 2 clinical trials in a range of indications. Prophage Series vaccine R-100 is registered for use in Russia for the treatment of RCC in patients at intermediate risk of recurrence as Oncophage® vaccine. There are also investigator-sponsored Phase 2 trials fully enrolled in the United States testing the Prophage Series vaccine candidates G-100 and G-200 in newly diagnosed and recurrent glioma, respectively. In addition, in May 2013 the Cancer Therapy Evaluation Program of the National Cancer Institute (NCI) opened patient enrollment in a randomized Phase 2 trial of Prophage Series vaccine G-200 in combination with Avastin® (bevacizumab) in patients with surgically resectable recurrent glioma.

Our business activities have included product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development activities, and support of our collaborations. Our product candidates require clinical trials and approvals from regulatory agencies, as well as acceptance in the marketplace. In addition to our internal development, we continue to pursue partnering opportunities and we are seeking partners for select products in our portfolio, which include QS-21 Stimulon, HerpV, and the Prophage G-Series vaccines, G-100 and G-200. We are also exploring in-licensing, acquisitions and sponsored research opportunities.

We have incurred significant losses since our inception. As of September 30, 2013, we had an accumulated deficit of \$643.3 million. Since our inception, we have financed our operations primarily through the sale of equity, issuance of debt, and interest income earned on cash, cash equivalents, and short-term investment balances. We believe that, based on our current plans and activities, our cash balance of \$30.2 million as of September 30, 2013, plus anticipated proceeds from equity offerings and potential proceeds from license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements through 2014. We continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be feasible, restrict capital expenditures and/or reduce the scale of our operations.

We expect to attempt to raise additional funds in advance of depleting our current funds. We may attempt to raise funds by: (1) out-licensing technologies or products to one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing, and/or (5) selling equity securities. Satisfying long-term liquidity needs may require the successful commercialization and/or one or more partnering arrangements for (1) HerpV, and the Prophage Series vaccines, (2) vaccines containing QS-21 Stimulon under development by our licensees and/or (3) potential other product candidates, each of which will require additional capital. If we incur



operating losses for longer than we expect and/or we are unable to raise additional capital, we may become insolvent and be unable to continue our operations.

Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions, and our review of the status of each program. Our product candidates are in various stages of development and significant additional expenditures will be required if we start new clinical 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, number of patients, and trial sponsorship. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because HerpV is in a Phase 2 clinical trial and the further development of our Prophage Series vaccines is subject to evaluation and uncertainty, we

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are unable to reliably estimate the cost of completing our research and development programs, the timing for bringing such programs to various markets, and, therefore, 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. Programs involving QS-21 Stimulon, other than our HerpV program, depend on our collaborative partners or licensees successfully completing clinical trials, successfully manufacturing QS-21 Stimulon to meet demand, obtaining regulatory approvals and successfully commercializing product candidates containing QS-21 Stimulon.

As of September 30, 2013, we had debt outstanding of \$10.2 million in principal (payments of approximately \$278,000 are due monthly beginning November 2013 and ending April 2015 with an additional \$5.0 million due in April 2015). In April 2013, we exchanged our \$39.0 million 8% senior secured convertible notes due August 2014 (the "2006 Notes") including accrued and unpaid interest, for \$10 million in cash, 2,500,000 shares of our common stock, and a revenue interest in certain QS-21 Stimulon partnered programs and HerpV. The cash portion of this exchange was financed through the issuance of new debt (see Note H for further detail). This exchange resulted in the elimination of \$5.6 million of non-controlling interest and a loss on extinguishment of \$3.3 million.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and with the instructions to Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete annual consolidated financial statements. In the opinion of our 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, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. 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, 2012 filed with the Securities and Exchange Commission.

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

**Note B - Net Loss Per Share**

Basic loss and income 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, or "DDCP"). 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 DDCP) plus the dilutive effect of outstanding instruments such as warrants, stock options, nonvested shares, and convertible preferred stock. 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 they would be anti-dilutive:

	September 30,	
	2013	2012
Warrants	3,642,712	3,309,378
Stock options	4,164,965	2,769,311
Nonvested shares	147,413	257,415
Convertible preferred stock	333,333	333,333

**Note C - Share-based Compensation Plans**

We use the Black-Scholes option pricing model to value stock options granted to employees and non-employees, as well as stock options granted to members of our Board of Directors. All stock options have 10-year terms and generally vest ratably

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over a 3 or 4-year period. A non-cash charge to operations for the stock options granted to non-employees that have vesting or other performance criteria is affected each reporting period, until the non-employee options vest, by changes in the fair value of our common stock. A summary of option activity for the nine months ended September 30, 2013 is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2012	2,748,883	\$7.07		
Granted	1,459,900	3.41		
Exercised	(4,503)	) 3.36		
Forfeited	(17,188)	) 4.82		
Expired	(22,127)	) 18.17		
Outstanding at September 30, 2013	4,164,965	\$5.74	7.9	\$23,279
Vested or expected to vest at September 30, 2013	3,935,396	\$5.87	7.9	\$18,408
Exercisable at September 30, 2013	2,023,191	\$7.58	6.5	\$2,069

The weighted average grant-date fair values of options granted during the nine months ended September 30, 2013 and 2012, were \$2.49 and \$3.94, respectively.

During the nine months ended September 30, 2013, and 2012, all options were granted with exercise prices equal to the market value of the underlying shares of common stock on the grant date. As of September 30, 2013, \$5.5 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 2.0 years.

As of September 30, 2013, unrecognized expense for options granted to outside advisors for which vesting has not yet occurred but the exercise price of the option is known is \$86,000. 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 options have vested.

Certain employees and consultants have been granted nonvested stock. The fair value of nonvested stock is calculated based on the closing sale price of our common stock on the date of issuance.

A summary of nonvested stock activity for the nine months ended September 30, 2013 is presented below:

	Nonvested Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2012	249,968	\$5.38
Granted	237,552	3.80
Vested	(339,800)	) 4.76
Forfeited	(307)	) 6.30
Outstanding at September 30, 2013	147,413	4.27

As of September 30, 2013, there was \$421,000 of unrecognized share-based compensation expense related to these nonvested shares awarded to employees expected to be recognized over a weighted average period of 2.9 years. As of September 30, 2013, unrecognized expenses for nonvested shares awarded to outside advisors is \$73,000. The total intrinsic value of shares vested during the nine months ended September 30, 2013, was \$1.3 million.

We issue new shares upon option exercises, purchases under our 2009 Employee Stock Purchase Plan, (the "2009 ESPP"), vesting of nonvested stock, issuances under the DDCP, and in lieu of approximately 33% of the base salary of our Chief Executive Officer ("CEO"). During the nine months ended September 30, 2013, 26,758 shares were

issued under the 2009 ESPP, 339,800 shares were issued as a result of the vesting of nonvested stock, 4,503 shares were issued as a result of option exercises, and 29,282 shares were issued to our CEO in lieu of cash salary. The impact on our results of operations from share-based compensation for the quarters and nine months ended September 30, 2013, and 2012, was as follows (in thousands):

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	Quarter Ended September		Nine Months Ended	
	30, 2013	2012	September 30, 2013	2012
Research and development	\$241	\$255	\$899	\$901
General and administrative	526	558	2,394	2,680
Total share-based compensation expense	\$767	\$813	\$3,293	\$3,581

## Note D - License Agreements

In March 2012, we entered into a First Right to Negotiate and Amendment Agreement with GlaxoSmithKline (“GSK”) whereby we granted GSK the first right to negotiate for the purchase of Agenus or certain of our assets and further amended certain existing agreements to clarify certain provisions and grant GSK an additional license and rights thereunder. The first right to negotiate will expire March 2017. Under the terms of the agreement, GSK paid us a nonrefundable payment of \$9.0 million, of which \$2.5 million is creditable against future manufacturing technology transfer royalty payments. The agreement provides GSK with an additional license to use QS-21 Stimulon in an undisclosed indication and also provides for additional royalty payments for this indication upon commercialization of a vaccine product. Also during March 2012, we received \$6.25 million through an amended license of non-core technologies with an existing licensee. This amendment converted the license grant from non-exclusive to exclusive and enabled the licensee to buy-out the current royalty stream structure. As we have no future service obligation under these agreements, we recognized \$12.8 million in revenue related to these amendments during the nine months ended September 30, 2012 and included \$2.5 million in deferred revenue in our condensed consolidated financial statements.

## Note E - Accrued Liabilities

Accrued liabilities consist of the following as of September 30, 2013 and December 31, 2012 (in thousands):

	September 30, 2013	December 31, 2012
Professional fees	\$1,120	\$919
Payroll	1,470	592
Clinical trials	1,380	291
Other	469	366
	\$4,439	\$2,168

## Note F - Equity

In February 2013, we entered into a Securities Exchange Agreement (the “Exchange Agreement”) with the holder of our Series A Preferred Stock pursuant to which the holder exchanged all 31,620 of the outstanding shares of our Series A Preferred Stock for an equivalent number of shares of our Series A-1 Preferred Stock. The terms of the Series A-1 Preferred Stock are substantially identical to the Series A Preferred Stock, except that the Series A-1 Preferred Stock accrues a 0.6325% annual dividend, as compared to a 2.5% annual dividend for the Series A Preferred Stock. In exchange for this reduction in dividend obligations, we issued to the holder 666,666 shares of our common stock. The issuance of these shares resulted in a deemed dividend of \$2.9 million to the holder, which is reflected in the statement of operations as an adjustment from net loss to net loss attributable to common stockholders. After giving effect to the transactions contemplated by the Exchange Agreement, no shares of Series A Preferred Stock remain outstanding. In April 2013, we issued 2,500,000 shares of our common stock to the holders of our 2006 Notes. See Note H for further detail.

During the nine months ended September 30, 2013, we sold an aggregate of approximately 3,726,000 shares of our common stock and received net proceeds of approximately \$13.6 million in at the market offerings under our Amended and Restated At Market Sales Issuance Agreement.

During September 2013, we sold approximately 3,333,000 shares of our common stock and warrants to purchase 1,000,000 shares of our common stock in a registered direct public offering raising net proceeds of approximately \$9.5 million, after deducting offering expenses. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase 0.3 of a share of common stock. Subject to certain ownership limitations, the warrants will be exercisable beginning six months following issuance and will expire five

years from the date they become exercisable, at an exercise price of \$3.75 per share. The number of shares issuable upon exercise of the warrants and the exercise price of

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the warrants are adjustable in the event of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

#### Note G - Recent Accounting Pronouncements

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

In July 2013, the FASB issued Accounting Standards Update No. 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists, ("ASU 2013-11"). ASU 2013-11 amends Accounting Standards Codification 740, Income Taxes, by providing guidance on the financial statement presentation of an unrecognized benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists ("ASC 740"). ASU 2013-11 does not affect the recognition or measurement of uncertain tax positions under ASC 740. ASU 2013-11 will be effective for interim and annual periods beginning after December 15, 2013, with early adoption permitted. We do not expect the adoption of ASU 2013-11 to have any impact on our consolidated financial statements.

#### Note H - Debt

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

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

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



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

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indebtedness with an aggregate principal balance of \$5 million or more if such default has the effect of accelerating the maturity of such indebtedness, or become subject to a legal judgment or similar order for the payment of money in an amount greater than \$5 million if such amount will not be covered by third-party insurance. The debt discount, and issuance costs of approximately \$178,000, are being amortized using the effective interest method over two years, the expected life of the SVB Loan and the Subordinated Notes.

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## Note I - Fair Value Measurements

We measure our contingent royalty consideration at fair value. The fair value of our contingent royalty consideration, \$19.6 million, is based on significant inputs not observable in the market, which require it to be reported as a Level 3 liability within the fair value hierarchy. The valuation uses assumptions we believe would be made by a market participant. In particular, the valuation analysis used the Income Approach based on the sum of the economic income that an asset is anticipated to produce in the future. In this case that asset is the potential royalty income to be paid to us as a result of certain license agreements for QS-21 Stimulon and the potential net sales generated from HerpV. The fair value of the contingent royalty consideration is estimated by applying a risk adjusted discount rate (11.5%) to the probability adjusted royalty revenue stream based on expected approval dates. These fair value estimates are most sensitive to changes in the probability of regulatory approvals. The Discounted Cash Flow method of the Income Approach was chosen as the method best suited to valuing the contingent royalty consideration.

The following table presents our liability measured at fair value using significant unobservable inputs (Level 3) , as of September 30, 2013 (amounts in thousands):

Balance, December 31, 2012	\$—
Contingent royalty consideration	19,091
Increase in fair value during the quarter ended September 30, 2013	512
Balance, September 30, 2013	\$19,603

The increase in fair value of the contingent royalty consideration liability is included in non-operating (loss) income in our condensed consolidated statement of operations for the quarter and nine-months ended September 30, 2013. There were no changes in the valuation techniques during the period and there were no transfers into or out of Levels 1 and 2.

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

The fair value of the SVB Note and the Subordinated Notes at September 30, 2013, was \$10.2 million combined and the fair value of the debt portion of the 2006 Notes as of December 31, 2012, was \$32.1 million, both based on the level 2 valuation hierarchy of the fair value measurements standard using a present value methodology.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

## Forward Looking Statements

This Quarterly Report on Form 10-Q and other written and oral statements we make 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," "potential," "opportunity," "future" and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to relate to, among other things, our business strategy, our research and development, our product development efforts, our ability to commercialize our product candidates, the activities of our licensees, our prospects for initiating partnerships or collaborations, the timing of the introduction of products, the effect of new accounting pronouncements, uncertainty regarding our future operating results and our profitability, anticipated sources of funds as well as our plans, objectives, expectations, and intentions.

We have included more detailed descriptions of these risks and uncertainties and other risks and uncertainties applicable to our business that we believe 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. Although we believe we have been prudent in our plans and assumptions, no assurance can be given that any goal or plan set forth in forward-looking statements can be achieved. We caution investors not to place significant reliance on forward-looking statements contained in

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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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### Overview

We are a biotechnology company working to develop treatments for cancers and infectious diseases. We are focused on immunotherapeutic products based on our core platform technologies with multiple product candidates advancing through the clinic, including several product candidates that have advanced into late-stage clinical trials through corporate partners.

Our QS-21 Stimulon<sup>®</sup> vaccine adjuvant, is a saponin extracted from the bark of the Quillaja saponaria tree, also known as the soap bark tree or Soapbark, an evergreen tree native to warm temperate central Chile. QS-21 Stimulon has become a key component in the development of investigational preventive vaccine formulations across a wide variety of infectious diseases, including several investigational therapeutic vaccines intended to treat cancer and degenerative disorders. QS-21 Stimulon has been widely studied and approximately 50,000 patients have received vaccine candidates containing the adjuvant. QS-21 Stimulon is currently being studied in 21 vaccine indications, which include GlaxoSmithKline's ("GSK") Phase 3 vaccine programs for RTS,S for malaria, MAGE-A3 cancer immunotherapeutic for non-small cell lung cancer and melanoma and HZ/su for shingles. In addition, Janssen Alzheimer Immunotherapy's ("JANSSEN AI") QS-21 Stimulon adjuvant-containing vaccine candidate is in Phase 2 trials for the treatment of Alzheimer's disease. If any of our partners' products containing QS-21 Stimulon successfully completes clinical development and receives approval for commercial sale, we are generally entitled to receive royalties for 10 years after commercial launch, with some exceptions.

HerpV, a recombinant, synthetic vaccine containing multiple antigens derived from the herpes simplex 2 virus, is currently in a Phase 2 clinical trial, and we believe it is one of the most advanced therapeutic vaccines for the treatment of genital herpes in clinical development. Combining our heat shock protein technology and our QS-21 Stimulon adjuvant, HerpV represents a potential new approach to the treatment of genital herpes. Rather than attempting to suppress the virus, which is what antivirals do, HerpV has the potential to enable the individual's own immune system to stop the virus from causing and transmitting disease without chronic treatment.

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

Our Prophage Series cancer vaccines are autologous therapies derived from cells extracted from the patient's tumor. As a result, Prophage Series vaccines contain a precise antigenic 'fingerprint' of a patient's particular cancer and are designed to reprogram the body's immune system to target only cells bearing this fingerprint, reducing the risk that powerful anti-cancer agents will target healthy tissue and cause debilitating side effects often associated with chemotherapy and radiation therapy. Our Prophage Series G vaccines are currently being studied in two different settings of glioblastoma multiforme (GBM): newly diagnosed and recurrent disease.

In September 2013, we announced the results of a recent analysis from a multiple-center, Phase 2 clinical trial in 46 patients with newly diagnosed glioblastoma (GBM) treated with Prophage Series G-100 (HSPPC-96) in combination with the current standard of care (radiation and temozolomide) which showed, that, to date, patients treated with HSPPC-96 had a median progression free survival (PFS) of 17.8 months, with 63% of the patients progression free at 12 months and 20% of patients progression free at 24 months. These results indicate improvement when compared to

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

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

In addition to our internal development efforts, we continue to pursue partnering opportunities. We are seeking partners for select products in our portfolio, which include HerpV, QS-21 Stimulon and the Prophage G-Series vaccines, G-100 and G-200. We are also exploring in-licensing, acquisitions and sponsored research opportunities. Our business activities have included product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development, business development, and support of our collaborations. Research and development expenses for the nine months ended September 30, 2013 and the years ended December 31, 2012, 2011, and 2010, were \$9.8 million, \$10.6 million, \$11.0 million, and \$12.9 million, respectively. We have incurred significant losses since our inception. As of September 30, 2013, we had an accumulated deficit of \$643.3 million.

We have financed our operations primarily through the sale of equity and debt securities. We believe that, based on our current plans and activities, our working capital resources at September 30, 2013, plus anticipated proceeds from equity offerings and potential proceeds from license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements into 2014. We expect to attempt to raise additional funds in advance of depleting our current funds. We may attempt to raise funds by: (1) out-licensing technologies or products to one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities. Satisfying long-term liquidity needs may require the successful commercialization and/or one or more partnering arrangements for (1) HerpV, Oncophage and/or our other Prophage Series vaccines, (2) vaccines containing QS-21 Stimulon under development by our licensees, and/or (3) potential other product candidates, each of which will require additional capital. If we incur operating losses for longer than we expect and/or we are unable to raise additional capital, we may become insolvent and be unable to continue our operations.

**Historical Results of Operations****Quarter ended September 30, 2013 Compared to the Quarter Ended September 30, 2012**

**Revenue:** We generated revenue of approximately \$736,000 and \$869,000 during the three months ended September 30, 2013 and 2012, respectively. Revenue includes license fees and service revenue. During the three months ended September 30, 2013 and 2012, we recorded revenue of approximately \$378,000 and approximately \$382,000, respectively, from the amortization of deferred revenue.

**Research and Development:** Research and development expenses include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, costs of consultants, and administrative costs. Research and development expense increased 49.4% to \$3.9 million for the three months ended September 30, 2013 from \$2.6 million for the three months ended September 30, 2012. Increased expenses primarily relate to the increased activity in our HerpV program as well as increased compensation expense related to bonuses for research and development personnel partially offset by decreased amortization expense.

**General and Administrative:** General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 38.3% to \$3.6 million for the three months ended September 30, 2013 from \$2.6 million for the three months ended September 30, 2012. Increased expenses related to increased compensation expense in connection with bonuses for general and administrative personnel and increased professional fees related to our corporate activities, partially offset by decreased amortization

expense.

Non-operating (loss) income: Non-operating loss for the three months ended September 30, 2013 includes the increase in the fair value of our contingent royalty obligation partially offset by the gain on the sale of an equity investment.

Interest Expense, net: Interest expense, net decreased to approximately \$347,000 for the three months ended September 30, 2013 from \$1.2 million for the three months ended September 30, 2012 due to the extinguishment of our 2006 Notes during 2013.

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Dividends on Series A and A-1 convertible preferred stock: Dividends decreased to approximately \$51,000 for the three months ended September 30, 2013 from approximately \$198,000 for the three months ended September 30, 2012 due to the exchange of Series A for Series A-1 convertible preferred stock during the quarter ended March 31, 2013 and the related reduced dividend obligation.

Nine months ended September 30, 2013 Compared to the Nine months ended September 30, 2012

Revenue: We generated revenue of approximately \$2.7 million and \$14.9 million during the nine months ended September 30, 2013 and 2012, respectively. Revenue includes license fees and service revenue, and in 2012, royalties earned. For the nine months ended September 30, 2012, we recognized revenue of \$6.5 million through an expanded license agreement with GSK, which provided GSK with a license to use QS-21 Stimulon in an undisclosed indication, and \$6.25 million through a license of non-core technologies with an existing licensee that resulted in a buy-out of the current royalty stream related to the license. During each of the nine months ended September 30, 2013 and 2012, we recorded revenue of approximately \$1.2 million from the amortization of deferred revenue. Our revenue for the nine months ended September 30, 2012 primarily resulted from one-time payments received under amended license agreements, and, therefore is not indicative of future results.

Research and Development: Research and development expenses include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, costs of consultants, and administrative costs. Research and development expenses increased 19.2% to \$9.8 million for the nine months ended September 30, 2013 from \$8.2 million the same period ended September 30, 2012. This increase is primarily related to increased activity in our HerpV program as well as increased compensation expense related to bonuses for research and development personnel partially offset by decreased amortization expense.

General and Administrative: General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 26.0% to \$11.1 million for the nine months ended September 30, 2013 from \$8.8 million for the nine months ended September 30, 2012. Increased expenses related to increased compensation expense and increased professional fees related to our corporate activities.

Non-operating (loss) income: Non-operating loss of \$3.5 million for the nine months ended September 30, 2013 consists primarily of a loss on the extinguishment of our 2006 Notes.

Interest Expense, net: Interest expense, net decreased to \$2.1 million for the nine months ended September 30, 2013 from \$3.5 million for the nine months ended September 30, 2012 due to the extinguishment of our 2006 Notes during 2013.

Dividends on Series A and A-1 convertible preferred stock: Dividends increased to \$3.1 million for the nine months ended September 30, 2013 from approximately \$593,000 for the nine months ended September 30, 2012 due to the deemed dividend of 666,666 shares of our common stock issued to the Series A convertible preferred stock holder during the quarter ended March 31, 2013 in exchange for a reduced dividend obligation.

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 nine months ended September 30, 2013, these research and development programs consisted largely of our Prophage Series vaccines and HerpV, as indicated in the following table (in thousands).

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Research and Development Program	Product	Nine Months Ended September 30, 2013	Year Ended December 31,			Prior to 2010	Total
			2012	2011	2010		
Heat shock proteins for cancer	Prophage Series Vaccines	\$ 4,147	\$ 5,613	\$ 10,182	\$ 10,960	\$ 270,891	\$ 301,793
Heat shock proteins for infectious diseases	HerpV	5,080	4,862	734	644	17,710	29,030
Vaccine adjuvant *	QS-21 Stimulon	535	85	94	1,185	11,219	13,118
Other research and development programs		2	4	13	89	33,438	33,546
Total research and development expenses		\$ 9,764	\$ 10,564	\$ 11,023	\$ 12,878	\$ 333,258	\$ 377,487

\* Prior to 2000, costs were incurred by Aquila Biopharmaceuticals, Inc., a company we acquired in November 2000. Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions and our review of the status of each program. Our product candidates are in various stages of development and significant additional expenditures will be required if we start new clinical 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, number of patients, and trial sponsorship. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because HerpV is currently in a Phase 2 trial and the further development of our Prophage Series vaccines is subject to evaluation and uncertainty, we are unable to reliably estimate the cost of completing our research and development programs, the timing for bringing such programs to various markets, and, therefore, when, if ever, material cash inflows are likely to commence. Programs involving QS-21 Stimulon, other than our HerpV program, depend on our collaborative partners or licensees successfully completing clinical trials, successfully manufacturing QS-21 Stimulon to meet demand, obtaining regulatory approvals and successfully commercializing product candidates containing QS-21 Stimulon.

#### Liquidity and Capital Resources

We have incurred annual operating losses since inception, and we had an accumulated deficit of \$643.3 million as of September 30, 2013. We expect to incur significant losses over the next several years as we continue clinical trials, manage our regulatory processes, prepare for potential commercialization of products, and continue development of our technologies. We have financed our operations primarily through the sale of equity and debt, and interest income earned on cash, cash equivalents, and short-term investment balances. From our inception through September 30, 2013, we have raised aggregate net proceeds of \$558.2 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 other notes. In addition, during the quarter ended March 31, 2012, we received \$9.0 million from GSK for a first right to negotiate the purchase of Agenus or certain of its assets and an expanded license agreement and \$6.25 million through a license of non-core technologies with an existing licensee. We granted GSK the first right to negotiate for the purchase of the Company or certain of our assets which will expire in March 2017. The expanded license agreement provides GSK with a license to use QS-21 Stimulon in an undisclosed indication and also provides for additional royalty payments for this indication upon commercialization of a vaccine product. The license of non-core technologies converted a license grant from non-exclusive to exclusive and enabled the licensee to

buy-out the current royalty stream structure.

We also maintain an effective registration statement to sell an aggregate of up to ten million shares of our common stock from time to time pursuant to an At the Market Issuance Sales Agreement with MLV & Co. LLC, as sales agent. As of September 30, 2013, we have 6.3 million shares available for sale under this agreement.

As of September 30, 2013, we had debt outstanding of \$10.2 million in principal. On April 15, 2013, we entered into a Securities Exchange Agreement with the holders of our 2006 Notes whereby we exchanged all of the 2006 Notes, including accrued and unpaid interest, for \$10.0 million in cash, 2,500,000 shares of our common stock, and a contractual right to the proceeds of 20% of our revenue interests from certain QS-21 Stimulon partnered programs and a 0.5% royalty on net sales of HerpV. To finance the cash portion of this exchange we entered into two new debt arrangements. On April 15, 2013, we

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entered into a Loan and Security Agreement with Silicon Valley Bank for senior secured debt in the aggregate principal amount of \$5.0 million (the "SVB Loan"). The SVB Loan bears interest at a rate of 6.75% per annum, payable in cash on the first day of each month with principal payments beginning November 2013 and ending with the final principal payment in April 2015. We also entered into a Note Purchase Agreement with various investors for senior subordinated notes (the "Subordinated Notes") in the aggregate principal amount of \$5.0 million due in April 2015. The Subordinated Notes bear interest at a rate of 10% per annum, payable in cash on the first day of each month in arrears. We also issued to the holders of the Subordinated Notes four year warrants to purchase 500,000 unregistered shares of our common stock at an exercise price of \$4.41 per share.

Our cash and cash equivalents at September 30, 2013 were \$30.2 million, an increase of \$8.7 million from December 31, 2012. We believe that, based on our current plans and activities, our cash balance of \$30.2 million as of September 30, 2013, plus anticipated proceeds from equity offerings and potential proceeds from license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements through 2014. We continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be feasible, restrict capital expenditures and/or reduce the scale of our operations.

We expect to attempt to raise additional funds in advance of depleting our current funds. In order to fund our operations beyond 2014, we will need to contain costs and raise additional funds. We may attempt to raise funds by: (1) out-licensing technologies or products to one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities. Our ability to successfully enter into any such arrangements is uncertain, and if funds are not available, or not available on terms acceptable to us, we may be required to revise our planned clinical trials, other development activities, capital expenditures, and/or the scale of our operations. While we expect to attempt to raise additional funds in advance of depleting our current funds, we may not be able to raise funds or raise amounts sufficient to meet the long-term needs of the business. Satisfying long-term liquidity needs may require the successful commercialization and/or one or more partnering arrangements for (1) HerpV and the Prophage Series vaccines, (2) vaccines containing QS-21 Stimulon under development by our licensees, and/or (3) potential other product candidates, each of which will require additional capital.

Our future cash requirements include, but are not limited to, supporting clinical trial and regulatory efforts and continuing our other research and development programs. Since inception, we have entered into various agreements with institutions and clinical research organizations to conduct and monitor our clinical studies. Under these agreements, subject to the enrollment of patients and performance by the applicable institution of certain services, we have estimated our total payments to be \$52.6 million over the term of the studies. Through September 30, 2013, we have expensed \$50.0 million as research and development expenses and \$48.5 million has been paid related to these clinical studies. The timing of expense recognition and future payments related to these agreements is subject to the enrollment of patients and performance by the applicable institution of certain services.

We have also entered into sponsored research agreements related to our product candidates that required payments of \$6.6 million, all of which have been paid as of September 30, 2013. We plan to enter into additional sponsored research agreements, and we anticipate significant additional expenditures will be required to advance our clinical trials, apply for regulatory approvals, continue development of our technologies, and bring our product candidates to market. Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing collaborative arrangements with academic and collaborative partners and licensees and by entering into new collaborations. As a result of our collaborative agreements, we will not completely control the efforts to attempt to bring those product candidates to market. For example, we have various agreements with collaborative partners and/or licensees that allow the use of our QS-21 Stimulon adjuvant in numerous vaccines. These agreements grant exclusive worldwide rights in some fields of use and co-exclusive or non-exclusive rights in others. These agreements generally call for royalties to be paid to us on future sales of licensed vaccines that include QS-21 Stimulon, which may or may not be achieved. Significant investment in manufacturing capacity could be required if we were to retain our manufacturing and supply rights.

Net cash used in operating activities for the nine months ended September 30, 2013 was \$14.0 million while cash provided by operating activities for nine months ended September 30, 2012 was \$4.3 million. This decrease in cash provided by operating activities for the nine months ended September 30, 2013 primarily resulted from one-time payments received in 2012 under amended license agreements. During the nine months ended September 30, 2012, we recognized revenue of \$12.8 million related to expanded license agreements. We continue to support and develop our QS-21 Stimulon partnering collaborations. Data from two trials being conducted by our licensees using QS-21 Stimulon have been reported during 2013. If applications for marketing approval of vaccines that are submitted by our licensees are approved by the FDA, the first products containing QS-21 Stimulon are anticipated to be launched in 2015. We are generally entitled to royalties on sales by our licensees of vaccines using QS-21 Stimulon for at least 10 years after commercial launch, with some exceptions. Our future ability to generate cash from operations will depend on achieving regulatory approval and market acceptance of our product

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candidates, achieving benchmarks as defined in existing collaborative agreements, and our ability to enter into new collaborations.

Recent Accounting Pronouncements

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

In July 2013, the FASB issued Accounting Standards Update No. 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists, ("ASU 2013-11"). ASU 2013-11 amends Accounting Standards Codification 740, Income Taxes, by providing guidance on the financial statement presentation of an unrecognized benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists ("ASC 740"). ASU 2013-11 does not affect the recognition or measurement of uncertain tax positions under ASC 740. ASU 2013-11 will be effective for interim and annual periods beginning after December 15, 2013, with early adoption permitted. We do not expect the adoption of ASU 2013-11 to have any impact on our consolidated financial statements.

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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, 2012. However, commercialization of any of our product candidates outside of the United States could result in increased foreign currency exposure.

We had cash and cash equivalents at September 30, 2013 of \$30.2 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, our carrying value approximates the fair value of these investments at September 30, 2013, however, we are subject to investment risk.

We invest our cash and cash equivalents in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs, and maximize yields. We review our investment policy annually and amend it as deemed necessary. Currently, the investment policy prohibits investing in any structured investment vehicles and asset-backed commercial paper. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer, or type of investment. We do not invest in derivative financial instruments. Accordingly, we do not believe that there is currently any material market risk exposure with respect to derivatives or other financial instruments that would require disclosure under this item.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Exchange Act. Based on this evaluation, our Principal Executive Officer and our Principal 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 Principal Executive Officer and Principal 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 Principal Executive Officer and Principal 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 nine months ended September 30, 2013, 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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PART II - OTHER INFORMATION

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. You should consider carefully the following information about risks below in evaluating our business. If any of the following risks actually occurs, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline. These risk factors restate and supersede the risk factors set forth under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2012.

Risks Related to our Business

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

Our net losses for the nine months ended September 30, 2013, and for the years ended December 31, 2012, 2011, and 2010, were \$24.3 million, \$11.3 million, \$23.3 million, and \$21.9 million, respectively. We expect to incur additional losses over the next several years as we continue research and clinical development of our technologies and pursue partnering opportunities, regulatory strategies, commercialization, and related activities. Furthermore, our ability to generate cash from operations is dependent on the success of our licensees and collaborative partners, as well as the likelihood and timing of new strategic licensing and partnering relationships and/or successful development and commercialization of vaccines containing QS-21 Stimulon, our Prophage Series vaccines and our other product candidates. From our inception through September 30, 2013, we have incurred net losses totaling \$643.3 million. On September 30, 2013, we had \$30.2 million in cash and cash equivalents. We believe that, based on our current plans and activities, our working capital resources at September 30, 2013, plus anticipated proceeds from equity offerings and potential proceeds from license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements through 2014. We expect to attempt to raise additional funds in advance of depleting our funds although additional funding may not be available on favorable terms, or at all. For the nine months ended September 30, 2013, our average monthly cash used in operating activities was approximately \$1.6 million. We do not currently anticipate significant capital expenditures during the remainder of 2013.

We have financed our operations primarily through the sale of equity, and debt securities. In order to finance future operations, we will be required to raise additional funds in the capital markets, through arrangements with collaborative partners, or from other sources. Additional financing may not be available on favorable terms, or at all. If we are unable to raise additional funds when we need them or if we incur operating losses for longer than we expect, we may not be able to continue some or all of our operations, or we may become insolvent. We also may be forced to license or sell technologies to others under agreements that allocate to third parties substantial portions of the potential value of these technologies.

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

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our future product candidates, and conducting preclinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our and our licensees' product candidates;
- the cost of manufacturing;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property rights;  
the costs associated with any successful commercial operations; and

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•the timing, receipt and amount of sales of, or royalties on, our future products, if any.

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

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

In April 2013 we exchanged our 8% senior secured convertible notes due August 2014 (the "2006 Notes"), including accrued and unpaid interest, for \$10.0 million in cash, 2,500,000 shares of our common stock, a revenue interest in certain QS-21 Stimulon partnered programs and a royalty interest in HerpV. The \$10.0 million cash payment was financed by entering into a Loan and Security Agreement with Silicon Valley Bank for a \$5.0 million loan that bears interest at 6.75% annually (the "SVB Loan"), and a Note Purchase Agreement with various investors to issue senior subordinated notes in the aggregate principal amount of \$5.0 million with annual interest at 10% (the "Subordinated Notes"). The SVB Loan is payable in equal monthly installments of approximately \$278,000 due monthly beginning November 2013 and ending in April 2015. The Subordinated Notes are due in April 2015.

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

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

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

Other than for the year ended December 31, 2012, we have had negative cash flows from operations. The net cash provided by operations of \$1.0 million for the year ended December 31, 2012 primarily resulted from one-time payments received under amended license agreements and therefore our net cash provided by operations for the year ended December 31, 2012 is not indicative of future results. For the nine months ended September 30, 2013 and for the years ended December 31, 2011, and 2010, net cash used in operating activities was \$14.0 million, \$16.2 million, and \$14.8 million, respectively.

Our outstanding debt instruments contain significant restrictive and affirmative covenants.

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

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

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

- covenant defaults;
- other non-payment defaults;
- bankruptcy;
- certain penalties and judgments from a governmental authority;



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- cross-defaults in respect of indebtedness over \$50,000; and
- insolvency defaults.

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

The Subordinated Notes also include default provisions which allow for the acceleration of the principal payment of the Subordinated Notes in the event we become involved in certain bankruptcy proceedings, become insolvent, fail to make a payment of principal or (after a grace period) interest on the Subordinated Notes, default on other indebtedness with an aggregate principal balance of \$5 million or more if such default has the effect of accelerating the maturity of such indebtedness, or become subject to a legal judgment or similar order for the payment of money in an amount greater than \$5 million if such amount will not be covered by third-party insurance.

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

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

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

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

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

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

Our patent on QS-21 Stimulon composition of matter has expired in virtually all territories, and our patent rights are limited to protecting certain combinations of QS-21 Stimulon with other adjuvants or formulations of QS-21 Stimulon with other agents. Although our licenses also rely on unpatented technology, know-how, and confidential information, these intellectual property rights may not be enforceable in certain jurisdictions and, we may not be able to collect

anticipated revenue from our licensees. Any such inability would have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

Our ability to successfully develop and commercialize the Prophage Series vaccines for a particular cancer depends in part on our, and following successful technology transfer to NewVac LLC (“NewVac”), our licensee for Oncophage in the Russian Federation and certain other CIS countries its ability to purify heat shock proteins from that type of cancer. If we or NewVac experience difficulties in purifying heat shock proteins for a sufficiently large number of patients in our clinical trials, we may face delays in enrolling sufficient patients and subsequently utilize more internal resources to satisfy enrollment requirements. Manufacturing failures may also lower the probability of a successful analysis of the data from clinical trials and, ultimately, the ability to obtain regulatory approvals and generate commercial sales. Manufacturing difficulties may also adversely affect NewVac’s ability to commercialize Oncophage in its licensed territory. We have successfully manufactured product across many different cancer types, however, the success rate per indication has varied. We have evolved our manufacturing processes to better accommodate a wider range of tumor types. Our current manufacturing technologies have been successful in manufacturing product from approximately 92% of the RCC tumors received and approximately 85% of the tumors received from patients enrolled in Phase 2 clinical trials in glioma. In addition, we may encounter problems with other types of cancer or patients as we expand our research. If we cannot overcome these problems, the number of patients or cancer types that our heat shock protein product candidates could treat would be limited. In addition, if we commercialize our heat shock protein

product candidates, we may not be able to replicate past manufacturing success rates and we may face claims from patients for whom we are unable to produce a vaccine.

Manufacturing problems or increased demand may cause delays, unanticipated costs, or loss of revenue streams. If the future clinical or commercial demand for our products or product candidates is substantially greater than we anticipate, our capacity may not be able to meet product demand. In addition, higher manufacturing loads may result in higher manufacturing failure rates as the operation becomes more complex. We currently manufacture our Prophage Series vaccines in



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

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

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

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

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

We have in the past, and may continue to seek, marketing and regulatory approvals of our product candidates in non-U.S. jurisdictions. For example, our Oncophage vaccine is approved for sale in Russia for the treatment of kidney cancer patients at intermediate risk for disease recurrence, and we have partnered with NewVac to commercialize this product in the Russian Federation. Various risks associated with foreign operations may impact our success. Possible risks include fluctuations in the value of foreign and domestic currencies, disruptions in the import, export, and transportation of patient tumors and our product, the product and service needs of foreign customers, difficulties in building and managing foreign relationships, the performance of our licensees or collaborators, geopolitical instability, and unexpected regulatory, economic, or political changes in foreign markets. See “Risk Factors- Even if we receive marketing approval for our product candidates, such product approvals could be subject to restrictions or withdrawals. Regulatory requirements are subject to change.”

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

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

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

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

Our product candidates and the product candidates in development by our collaborative partners may fail because of competition from major pharmaceutical companies and specialized biotechnology companies that market products, or that are engaged in the development of product candidates, directed at cancer, infectious diseases and degenerative disorders. Many of our competitors, including large pharmaceutical companies, have greater financial and human resources and more experience than we do. Our competitors may:

- commercialize their product candidates sooner than we commercialize our own;
- develop safer or more effective therapeutic drugs or preventive vaccines and other therapeutic products;
- implement more effective approaches to sales and marketing and capture some of our potential market share;
- establish superior intellectual property positions;
- discover technologies that may result in medical insights or breakthroughs, which render our drugs or vaccines obsolete, possibly before they generate any revenue; or
- adversely affect our ability to recruit patients for our clinical trials.

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

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

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We are aware of compounds that claim to be comparable to QS-21 Stimulon that are being used in clinical trials. Several other vaccine adjuvants are in development and could compete with QS-21 Stimulon for inclusion in vaccines in development. These adjuvants include, but are not limited to, oligonucleotides, under development by Pfizer, Idera, Colby, and Dynavax, MF59 under development by Novartis, IC31, under development by Intercell, and MPL, under development by GSK. In the past, we have provided QS-21 Stimulon to other entities under materials transfer arrangements. In at least one instance, it is possible that this material was used unlawfully to develop synthetic formulations and/or derivatives of QS-21. In addition, companies such as Adjuvance Technologies, Inc. CSL Limited, and Novavax, Inc., as well as academic institutions and manufacturers of saponin extracts, are developing saponin adjuvants, including derivatives and synthetic formulations. These sources may be competitive with our ability to do future partnering and licensing deals with QS-21 Stimulon.

We are also aware of a third party that manufactures pre-clinical material purporting to be comparable to QS-21 Stimulon. The claims being made by this third party may create marketplace confusion and have an adverse effect on the goodwill generated by us and our partners with respect to QS-21 Stimulon. Any diminution of this goodwill may have an adverse effect on our ability to commercialize this technology, either alone or with a third party.

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

As vaccines from our Prophage Series are potentially developed in other indications, they could face additional competition in those indications. In addition, and prior to regulatory approval, our Prophage Series vaccines and all of our other product candidates may compete for access to patients with other products in clinical development, with products approved for use in the indications we are studying, or with off-label use of products in the indications we are studying. We anticipate that we will face increased competition in the future as new companies enter markets we seek to address and scientific developments surrounding immunotherapy and other traditional cancer therapies continue to accelerate.

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

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

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

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

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

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

• exposure to unknown liabilities;

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

• inability to retain key employees of any acquired businesses;

• difficulty in managing multiple product development programs; and

• inability to successfully develop new products or clinical failure.

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

Failure to enter into 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 any of our Prophage Series vaccines other than the agreement with NewVac giving them an exclusive license to manufacture, market and sell Oncophage as well as pursue a development program in the Russian Federation and certain other CIS countries. Companies may not be interested in pursuing patient-specific vaccines like our Prophage Series vaccines, and many other companies have been and may continue to be unwilling to commit to an agreement prior to receipt of additional clinical data, if at all.

In addition, we would consider license and/or co-development opportunities to advance HerpV. However, collaborative partners or licensees may defer discussions until final results from our Phase 2 clinical trial become available, or they may not engage in such discussions at all.

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

Part of our strategy is to develop and commercialize a majority of our product candidates by continuing or entering into arrangements with academic, government, or corporate collaborators and licensees. Our success depends on our ability to



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negotiate such agreements and on the success of the other parties in performing research, preclinical and clinical testing, completing regulatory applications, and commercializing product candidates. For example, the development of candidates from the Prophage G Series is currently dependent in a large part on the efforts of our institutional collaborators, such as the Brain Tumor Research Center at the University of California, San Francisco, which has conducted or is in the process of conducting Phase 2 clinical trials of Prophage Series vaccines G-100 and G-200 for the treatment of glioma and the Alliance for Clinical Trials in Oncology, a National Cancer Institute cooperative group, which is sponsoring a Phase 2 clinical trial of G-200 in patients with surgically resectable recurrent glioma. When our licensees or third party collaborators sponsor clinical trials using our product candidates, we cannot control the timing or quality of such trials or related activities. In addition, substantially all product candidates containing QS-21 Stimulon, other than HerpV, depend on the success of our collaborative partners or licensees, and our relationships with these third parties. Such product candidates depend on our collaborators and licensees successfully enrolling patients and completing clinical trials, being committed to dedicating the resources to advance these product candidates, obtaining regulatory approvals, and successfully commercializing product candidates. We have granted NewVac an exclusive license to manufacture, market and sell Oncophage in the Russian Federation and certain other CIS countries. NewVac has faced challenges establishing manufacturing capabilities and securing government reimbursement, which has impacted its ability to commercialize the product in the licensed territory. NewVac may terminate this agreement at any time without cause. We do not expect to receive financial or other benefits, if any, from our relationship with NewVac or the sale of Oncophage in the Russian Federation or CIS countries. Development activities may fail to produce marketable products due to unsuccessful results or abandonment of these programs, failure to enter into future collaborations or license agreements, or the inability to manufacture product supply requirements for our collaborators and licensees. Several of our agreements also require us to transfer important rights and regulatory compliance responsibilities to our collaborators and licensees. As a result of these collaborative agreements, we will not control the nature, timing, or cost of bringing these product candidates to market. Our collaborators and licensees could choose not to devote resources to these arrangements or, under certain circumstances, may terminate these arrangements early. They may cease pursuing product candidates or elect to collaborate with different companies. In addition, these collaborators and licensees, outside of their arrangements with us, may develop technologies or products that are competitive with those that we are developing. From time to time, we may also become involved in disputes with our collaborators or licensees. Such disputes could result in the incurrence of significant expense, or the termination of collaborations. We may be unable to fulfill all of our obligations to our collaborators, which may result in the termination of collaborations. As a result of these factors, our strategic collaborations may not yield revenue. Furthermore, we may be unable to enter into new collaborations or enter into new collaborations on favorable terms. Failure to generate significant revenue from collaborations would increase our need to fund our operations through sales of debt or equity securities and would negatively affect our business prospects.

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

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

Effective December 1, 2005, we entered into an employment agreement with Dr. Armen. Subject to the earlier termination as provided in the agreement, the agreement had an original term of one year and is automatically extended thereafter for successive terms of one year each, unless either party provides notice to the other at least ninety days prior to the expiration of the original or any extension term. Dr. Armen plays an important role in our day-to-day activities. We do not carry key employee insurance policies for Dr. Armen or any other employee. We also rely on a small staff of highly trained and experienced senior management and scientific, administrative and operations personnel and consultants to conduct our business. Reductions in our staffing levels have eliminated redundancies in key capabilities and skill sets among our full time staff and required us to rely more heavily on

outside consultants and third parties. In addition, if in the future we need to perform sales, marketing and distribution functions for commercial and/or international operations, we will need to recruit experienced personnel and/or engage external consultants incurring significant expenditures.

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



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### Risks Related to Regulation of the Biopharmaceutical Industry

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

Clinical development, including preclinical testing and the process of obtaining and maintaining regulatory approvals for new therapeutic products, is lengthy, expensive, and uncertain. As of September 30, 2013, we have spent approximately 19 years and \$301.8 million on our research and development program in heat shock proteins for cancer. It also can vary substantially based on the type, complexity, and novelty of the product. We must provide regulatory authorities with manufacturing, product characterization, and preclinical and clinical data demonstrating that our product candidates are safe and effective before they can be approved for commercial sale. It may take us many years to complete our testing, and failure can occur at any stage of testing. Interim results of preclinical studies or clinical trials do not necessarily predict their final results, and acceptable results in early studies might not be seen in later studies. Any preclinical or clinical test may fail to produce results satisfactory to regulatory authorities for many reasons, including but not limited to insufficient product characterization, poor study structure conduct or statistical analysis planning, failure to enroll a sufficient number of patients or failure to prospectively identify the most appropriate patient eligibility criteria, and collectability of data. Preclinical and clinical data can be interpreted in different ways, which could delay, limit, or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, adverse medical events during a clinical trial, or safety issues resulting from products of the same class of drug could require a preclinical study or clinical trial to be repeated or cause a program to be terminated, even if other studies or trials relating to the program are successful. We or the FDA, other regulatory agencies, or an institutional review board may suspend or terminate human clinical trials at any time on various grounds.

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

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

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

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

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

Regulatory authorities generally approve products for particular indications. If an approval is for a limited indication, this limitation reduces the size of the potential market for that product. Product approvals, once granted, are subject to continual review and periodic inspections by regulatory authorities. Our operations and practices are subject to regulation and scrutiny by the United States government, as well as governments of any other countries in which we do business or conduct activities. Later discovery of previously unknown problems or safety issues, and/or failure to comply with domestic or foreign laws, knowingly or unknowingly, can result in various adverse consequences, including, among other things, possible delay in approval or refusal to approve a product, warning letters, fines,

injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the government to renew marketing applications, complete withdrawal of a marketing application, and/or criminal prosecution, withdrawal of an approved product from the market, and/or exclusion from government health care programs. Such regulatory enforcement could have a direct and negative impact on the product for which approval is granted, but also could have a negative impact on the approval of any pending applications for marketing approval of new drugs or supplements to approved applications.

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

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

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

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

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

### Risks Related to Intellectual Property Rights

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

If we are not able to protect our proprietary technology, trade secrets, and know-how, our competitors may use our past developments and technologies to develop competing products. We have exclusive rights to approximately 66 issued United States patents and approximately 104 issued foreign patents. We also have exclusive rights to six pending United States patent applications and approximately 15 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 ("USPTO") uses to grant patents, and the standards which courts use to interpret patents, are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, the level of protection, if any, that will be provided by our patents if we attempt to enforce them, and they are challenged, is uncertain. In addition, the type and extent of patent claims that will be issued to us in the future is uncertain. Any patents that are issued may not contain claims that permit us to stop competitors from using similar technology.

Furthermore, the product development timeline for biotechnology products is lengthy and it is possible that our issued patents covering our product candidates in the United States and other jurisdictions may expire prior to commercial

launch. In addition, because our patent on QS-21 Stimulon composition of matter has already expired in virtually all territories, our patent rights are limited to protecting certain combinations of QS-21 Stimulon with other adjuvants or formulations of QS-21 Stimulon with other agents, 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 Stimulon in combination with such adjuvants or formulate it with the other agents covered by our patents. We are aware of other companies that claim to produce material comparable to QS-21 Stimulon. At least one other party has also developed derivatives of QS-21, which have shown biological activity.

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Furthermore, for patent applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law with the passage of the America Invents Act (2011) which brings into effect significant changes to the U.S. patent laws that are yet untried and untested, and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a “first to file” system in the U.S. This requires us to be cognizant after March 16, 2013 of the time from invention to filing of a patent application. Additionally, for applications containing a claim not entitled to priority before March 16, 2013, there is a risk that a third party will initiate a post grant review following the issuance of a patent.

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.

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

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held liable for significant damages. We may not be able to obtain any required licenses on commercially acceptable terms or at all.

During the course of any patent litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. 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.

### Risks Related to Litigation

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

We may currently be a party, or may become a party, to legal proceedings, claims and investigations that arise in the ordinary course of business such as, but not limited to, patent, employment, commercial and environmental matters. While we currently believe that the ultimate outcome of any of these proceedings will not have a material adverse effect on our financial position, results of operations, or liquidity, litigation is subject to inherent uncertainty. Furthermore, litigation consumes both cash and management attention.

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

We are also exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. We may not be able to prevent a director, executive or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team.

Product liability and other claims against us may reduce demand for our products and/or result in substantial damages. We face an inherent risk of product liability exposure related to testing our product candidates in human clinical trials and commercial sales of Oncophage in Russia, and may face even greater risks if we sell our other product candidates commercially. An individual may bring a product liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. Product liability claims may result in:

- decreased demand for our product candidates;
- regulatory investigations;

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- injury to our reputation;
- withdrawal of clinical trial volunteers;
- costs of related litigation; and
- substantial monetary awards to plaintiffs.

We manufacture the Prophage Series vaccines from a patient's cancer cells, and medical professionals must inject the vaccines into the same patient from which they were manufactured. A patient may sue us if a hospital, a shipping company, or we fail to receive the removed cancer tissue or deliver that patient's vaccine. We anticipate that the logistics of shipping will become more complex if the number of patients we treat increases and that shipments of tumor and/or vaccines may be lost, delayed, or damaged. Additionally, complexities unique to the logistics of commercial products may delay shipments and limit our ability to move commercial product in an efficient manner without incident. We do not have any other insurance that covers loss of or damage to the Prophage Series vaccines or tumor material, and we do not know whether such insurance will be available to us at a reasonable price or at all. We have limited product liability coverage for use of our product candidates. Our product liability policy provides \$10.0 million aggregate coverage and \$10.0 million per occurrence coverage. This limited insurance coverage may be insufficient to fully cover us for future claims.

We are also subject to laws generally applicable to businesses, including but not limited to, federal, state and local wage and hour, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects.

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

We use or may use hazardous, infectious, and radioactive materials, and recombinant DNA in our operations, which have the potential of being harmful to human health and safety or the environment. We store these hazardous (flammable, corrosive, toxic), infectious, and radioactive materials, and various wastes resulting from their use, at our facilities pending use and ultimate disposal. We are subject to a variety of federal, state, and local laws and regulations governing use, generation, storage, handling, and disposal of these materials. We may incur significant costs complying with both current and future environmental health and safety laws and regulations. In particular, we are subject to regulation by the Occupational Safety and Health Administration, the Environmental Protection Agency, the Drug Enforcement Agency, the Department of Transportation, the Centers for Disease Control and Prevention, the National Institutes of Health, the International Air Transportation Association, and various state and local agencies. At any time, one or more of the aforementioned agencies could adopt regulations that may affect our operations. We are also subject to regulation under the Toxic Substances Control Act and the Resource Conservation Development programs.

Although we believe that our current procedures and programs for handling, storage, and disposal of these materials comply with federal, state, and local laws and regulations, we cannot eliminate the risk of accidents involving contamination from these materials. Although we have a workers' compensation liability policy, we could be held liable for resulting damages in the event of an accident or accidental release, and such damages could be substantially in excess of any available insurance coverage and could substantially disrupt our business.

### Risks Related to our Common Stock

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

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

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

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us without the consent of our Board of Directors. Our certificate of incorporation provides for a staggered board and

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removal of directors only for cause. Accordingly, stockholders may elect only a minority of our Board at any annual meeting, which may have the effect of delaying or preventing changes in management. In addition, under our certificate of incorporation, our Board of Directors may issue additional shares of preferred stock and determine the terms of those shares of stock without any further action by our stockholders. Our issuance of additional preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock and thereby effect a change in the composition of our Board of Directors. Our certificate of incorporation also provides that our stockholders may not take action by written consent. Our bylaws require advance notice of stockholder proposals and director nominations and permit only our president or a majority of the Board of Directors to call a special stockholder meeting. These provisions may have the effect of preventing or hindering attempts by our stockholders to replace our current management. In addition, Delaware law prohibits a corporation from engaging in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our Board of Directors may use this provision to prevent changes in our management. Also, under applicable Delaware law, our Board of Directors may adopt additional anti-takeover measures in the future.

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

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

Between our initial public offering on February 4, 2000 and September 30, 2013, and for the nine months ended September 30, 2013, the closing price of our common stock has fluctuated between \$1.80 and \$315.78 per share and \$2.71 and \$4.93 per share, respectively. The average daily trading volume for the nine months ended September 30, 2013 and for the year ended December 31, 2012 was approximately 277,000 shares and 176,000 shares, respectively. 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;

- quarterly fluctuations in our financial results;
- variations in the level of expenses related to any of our product candidates or clinical development programs;
- additions or departures of key management or scientific personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;

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other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;

changes in accounting principles;

general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In the past, securities class action litigation has often been brought against a company following a significant decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally experience significant stock price volatility.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock, or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

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

The sale by us or the resale by stockholders of a significant number of shares of our common stock could cause the market price of our common stock to decline. As of September 30, 2013, we had approximately 35,228,000 shares of common stock outstanding. All of these shares are eligible for sale on Nasdaq, although certain of the shares are subject to sales volume and other limitations. We have filed registration statements to permit the sale of approximately 8,200,000 shares of common stock under our equity incentive plans. We have also filed registration statements to permit the sale of approximately 167,000 shares of common stock under our employee stock purchase plan, to permit the sale of 225,000 shares of common stock under our Directors' Deferred Compensation Plan, to permit the sale of approximately 8,274,000 shares of common stock pursuant to various private placement agreements and to permit the sale of approximately 10,000,000 shares of our common stock pursuant to our At Market Issuance Sales Agreement. As of September 30, 2013, an aggregate of 13.3 million of these shares remain available for sale. The market price of our common stock may decrease based on the expectation of such sales.

As of September 30, 2013, warrants to purchase approximately 3,643,000 shares of our common stock with a weighted average exercise price per share of \$11.53 were outstanding.

As of September 30, 2013, options to purchase 4,164,965 shares of our common stock with a weighted average exercise price per share of \$5.74 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, 2013 we have 147,413 nonvested shares outstanding.

We may issue additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options or warrants are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock or the exercise of stock options or warrants would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of securities held by existing investors.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 and to comply with changing regulation of corporate governance and public disclosure could have a material adverse effect on our operating results and the price of our common stock.

The Sarbanes-Oxley Act of 2002 and rules adopted by the Securities and Exchange Commission and Nasdaq have resulted in significant costs to us. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations regarding the required assessment of our internal control over financial reporting, and our independent registered public accounting firm's audit of internal control over financial reporting, have required commitments of significant management time. We expect these commitments to continue.

Our internal control over financial reporting (as defined in Rules 13a-15 of the Exchange Act) is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated

financial statements for external purposes in accordance with U.S. GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect all deficiencies or weaknesses in our financial reporting. While our management has concluded that there were no material weaknesses in our internal control over financial reporting as of December 31, 2012, our procedures are subject to the risk that our controls may become inadequate because of changes in conditions or as a result

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of a deterioration in compliance with such procedures. No assurance is given that our procedures and processes for detecting weaknesses in our internal control over financial reporting will be effective. Changing laws, regulations and standards relating to corporate governance and public disclosure, are creating uncertainty for companies. Laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided, which could result in continuing uncertainty regarding compliance matters and higher costs caused by ongoing revisions to disclosure and governance practices. If we fail to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the Securities and Exchange Commission. Any such action could adversely affect our operating results and the market price of our common stock.

Item 6. Exhibits

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

(b) Exhibits

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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 8, 2013 AGENUS INC.

/s/ CHRISTINE M. KLASKIN

Christine M. Klaskin

VP, Finance, Principal Financial Officer, Principal Accounting Officer



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Exhibit Index

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Antigenics Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 10, 2002 and incorporated herein by reference.
3.1.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Antigenics Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 11, 2007 and incorporated herein by reference.
3.1.2	Certificate of Ownership and Merger changing the name of the corporation to Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 6, 2011 and incorporated herein by reference.
3.1.3	Certificate of Second Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 30, 2011 and incorporated herein by reference.
3.1.4	Certificate of Third Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1.4 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2012 and incorporated herein by reference.
3.2	Fifth Amended and Restated By-laws of Agenus Inc. Filed as Exhibit 3.2 to our Current Report on Form 8-K (File No. 0-29089) filed on January 6, 2011 and incorporated herein by reference.
3.3	Certificate of Designation, Preferences and Rights of the Series A Convertible Preferred Stock of Agenus Inc. filed with the Secretary of State of the State of Delaware on September 24, 2003. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 25, 2003 and incorporated herein by reference.
3.4	Certificate of Designations, Preferences and Rights of the Class B Convertible Preferred Stock of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 5, 2007 and incorporated herein by reference.
3.5	Certificate of Designations, Preferences and Rights of the Series A-1 Convertible Preferred Stock of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on February 5, 2013 and incorporated herein by reference.
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith.
32.1(1)	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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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.

XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act of 1933, as amended, is deemed not (2) 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.