

AGENUS INC
Form 10-Q
August 01, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended June 30, 2014

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 July 28, 2014: 62,679,445 shares

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Agenus Inc.

Quarterly Period Ended June 30, 2014

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	June 30, 2014	December 31, 2013
ASSETS		
Cash and cash equivalents	\$48,270,380	\$27,351,969
Short-term investments	14,545,393	—
Inventories	95,700	—
Accounts receivable	—	1,200
Prepaid expenses	1,131,756	658,412
Other current assets	2,988,859	162,997
Total current assets	67,032,088	28,174,578
Plant and equipment, net of accumulated amortization and depreciation of \$27,856,858 and \$27,637,443 at June 30, 2014 and December 31, 2013, respectively	4,542,907	2,784,845
Goodwill	19,550,840	2,572,203
Acquired intangible assets, net of accumulated amortization of \$219,887 at June 30, 2014	7,811,646	—
Other long-term assets	1,250,216	1,303,855
Total assets	\$100,187,697	\$34,835,481
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current portion, long-term debt	\$7,428,701	\$3,518,550
Current portion, deferred revenue	2,528,067	1,660,679
Accounts payable	929,905	834,740
Accrued liabilities	5,657,929	4,215,221
Other current liabilities	2,024,630	66,683
Total current liabilities	18,569,232	10,295,873
Other long-term debt	—	5,347,690
Deferred revenue	3,101,680	3,193,809
Contingent royalty obligation	7,360,783	18,799,141
Contingent purchase price consideration	10,854,000	—
Other long-term liabilities	2,669,293	1,679,671
Commitments and contingencies		
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, par value \$0.01 per share; 5,000,000 shares authorized at June 30, 2014 and December 31, 2013:		
Series A-1 convertible preferred stock; 31,620 shares designated, issued, and outstanding at June 30, 2014 and December 31, 2013; liquidation value of \$32,371,737 at June 30, 2014	316	316
Series B2 convertible preferred stock; 3,105 shares designated, issued, and outstanding at June 30, 2014 and December 31, 2013	31	31
Common stock, par value \$0.01 per share; 140,000,000 and 70,000,000 shares authorized at June 30, 2014 and December 31, 2013, respectively; 62,652,214 and 36,391,191 shares issued at June 30, 2014 and December 31, 2013, respectively	626,522	363,912

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Additional paid-in capital	714,088,885	644,571,866
Treasury stock, at cost; 0 and 43,490 shares of common stock at June 30, 2014 and December 31, 2013, respectively	—	(324,792)
Accumulated other comprehensive income	135,637	—
Accumulated deficit	(657,218,682)	(649,092,036)
Total stockholders' equity (deficit)	57,632,709	(4,480,703)
Total liabilities and stockholders' equity (deficit)	\$100,187,697	\$34,835,481

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Quarters Ended June 30		Six months ended June 30	
	2014	2013	2014	2013
Revenue:				
Service revenue	\$—	\$320,536	\$—	\$1,045,760
Grant revenue	29,970	—	58,738	—
Research and development revenue	3,044,118	486,860	3,736,206	870,877
Total revenues	3,074,088	807,396	3,794,944	1,916,637
Operating expenses:				
Cost of service revenue	—	(176,681)	—	(449,457)
Research and development	(5,222,704)	(3,316,763)	(9,695,237)	(5,870,885)
General and administrative	(5,847,356)	(4,642,238)	(11,290,115)	(7,533,779)
Contingent purchase price consideration fair value adjustment	(224,000)	—	(1,133,000)	—
Operating loss	(8,219,972)	(7,328,286)	(18,323,408)	(11,937,484)
Other income (expense):				
Non-operating income (expense)	754,363	(3,322,657)	10,576,829	(3,319,777)
Interest expense, net	(296,126)	(490,684)	(651,935)	(1,719,387)
Net loss	(7,761,735)	(11,141,627)	(8,398,514)	(16,976,648)
Dividends on Series A and A-1 convertible preferred stock	(51,107)	(50,785)	(102,133)	(3,057,971)
Net loss attributable to common stockholders	\$(7,812,842)	\$(11,192,412)	\$(8,500,647)	\$(20,034,619)
Per common share data:				
Basic and diluted net loss attributable to common stockholders	\$(0.12)	\$(0.40)	\$(0.15)	\$(0.76)
Weighted average number of common shares outstanding:				
Basic and diluted	62,607,779	27,845,705	56,615,583	26,466,358
Other comprehensive (loss) income:				
Foreign currency translation (loss) gain	\$(81,733)	\$—	\$133,684	\$—
Unrealized gain on investments	1,953	—	1,953	—
Other comprehensive (loss) income	(79,780)	—	135,637	—
Comprehensive loss	\$(7,892,622)	\$(11,192,412)	\$(8,365,010)	\$(20,034,619)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Six months Ended June 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$(8,398,514)	\$(16,976,648)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	589,407	311,993
Share-based compensation	2,422,244	2,526,026
Noncash interest expense	306,881	1,541,723
Loss on disposal of assets	1,150	17,944
Change in fair value of contingent obligations	(10,512,858)	—
Loss on extinguishment of debt	—	3,322,657
Changes in operating assets and liabilities:		
Accounts receivable	1,200	349,847
Inventories	(95,700)	11,999
Prepaid expenses	(88,132)	(192,880)
Accounts payable	(562,062)	(242,106)
Deferred revenue	(1,229,554)	(868,831)
Accrued liabilities and other current liabilities	544,269	409,264
Other operating assets and liabilities	(2,598,582)	230,977
Net cash used in operating activities	(19,620,251)	(9,558,035)
Cash flows from investing activities:		
Cash acquired in acquisition	514,470	—
Purchases of plant and equipment	(771,097)	(591,378)
Purchases of available-for-sale securities	(14,543,440)	—
Net cash used in investing activities	(14,800,067)	(591,378)
Cash flows from financing activities:		
Net proceeds from sales of equity	56,792,252	2,274,768
Proceeds from employee stock purchases	84,271	50,568
Financing of property and equipment	(24,114)	(21,452)
Debt issuance costs	—	(177,802)
Proceeds from issuance of long-term debt	—	10,000,000
Payments of debt	(1,666,667)	(10,000,000)
Net cash provided by financing activities	55,185,742	2,126,082
Effect of exchange rate changes on cash	152,987	—
Net increase (decrease) in cash and cash equivalents	20,918,411	(8,023,331)
Cash and cash equivalents, beginning of period	27,351,969	21,468,269
Cash and cash equivalents, end of period	\$48,270,380	\$13,444,938
Supplemental cash flow information:		
Cash paid for interest	\$367,155	\$152,747
Non-cash investing and financing activity:		
Deemed dividend on Series A convertible preferred stock	\$—	\$2,906,664
Issuance of common stock, \$0.01 par value, for acquisition of 4-Antibody AG	10,102,259	—
Contingent purchase price consideration issued in connection with the acquisition of 4-Antibody AG	9,721,000	—

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Issuance of common stock, \$0.01 par value, as payment of long-term debt	953,765	11,275,000
Contingent royalty obligation	—	19,090,658
Elimination of noncontrolling interest	—	5,580,124

See accompanying notes to unaudited condensed consolidated financial statements.

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AGENUS INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2014

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 an immuno-oncology company developing a portfolio of checkpoint modulators (CPMs), heat shock protein peptide-based vaccines and adjuvants.

Our core technology portfolio consists of our Retrocyte Display® Technology Platform and Checkpoint Modulator Antibody Programs, our Heat Shock Protein ("HSP")-Based Platform, and our Saponin Adjuvant Platform.

Our Retrocyte Display® Technology Platform and Checkpoint Modulator Antibody Programs (CPM antibody programs) became part of our technology portfolio through our acquisition of 4-Antibody AG ("4-AB") in February 2014 (see Note C). We have developed a powerful fully-human and humanized monoclonal antibody drug discovery and optimization technology platform that we are using to develop a novel pipeline of antibody therapeutic drug candidates. Our proprietary discovery engine Retrocyte Display® uses a high-throughput approach incorporating IgG format human antibody libraries express in mammalian B-lineage cells. Our CPM antibody programs target GITR, OX40, CTLA-4, LAG-3, TIM-3 and PD-1.

Within our HSP Based Platform are our heat shock protein vaccines, Prophage Series for cancer and HerpV for infectious diseases, both currently in Phase 2 studies. Derived from each patient’s individual tumor, our Prophage Series vaccines contain the antigenic fingerprint of the patient’s particular cancer and are designed to reprogram the body’s immune system to target only the cancer cells bearing this fingerprint. Prophage Series vaccines are currently being studied both newly diagnosed and recurrent glioblastoma multiforme, or GBM. Our HerpV vaccine is comprised of recombinant human heat shock protein-70 complexed with 32 distinct synthetic peptides from the herpes simplex virus-2 proteome. This vaccine is being evaluated in a Phase 2 trial in patients with genital herpes.

Within our Saponin Adjuvant Platform is our QS-21 Stimulon® adjuvant, or QS-21 Stimulon, which, we believe, is one of the most widely tested vaccine adjuvants in clinical development. QS-21 Stimulon is designed to strengthen the body’s immune response to a vaccine’s antigen, potentially increasing the vaccine’s potency. QS-21 Stimulon is a key component in the development of several investigational vaccines across a wide variety of infectious diseases and therapeutic vaccines intended to treat cancer and degenerative disorders. Our QS-21 Stimulon is extensively partnered with GlaxoSmithKline (GSK) and JANSSEN Alzheimer Immunotherapy and includes several candidates in Phase 2 and Phase 3 clinical trials. If any of our partners’ products containing QS-21 Stimulon successfully complete clinical development and receive approval of commercial sale, we are generally entitled to receive milestone payments as well as royalties on product sales for ten years after commercial launch, with some exceptions.

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 the internal development of our product candidates, we continue to pursue collaborative, out-licensing and/or partnering opportunities for our portfolio programs and product candidates, as well as explore in-licensing, acquisitions and collaborative arrangements in areas of synergy with our existing programs.

We have incurred significant losses since our inception. As of June 30, 2014, we had an accumulated deficit of \$657.2 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, cash equivalents, and short-term investment balance of \$62.8 million as of June 30, 2014, plus potential proceeds from our existing license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements through the first half of 2015. 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) pursuing collaborative, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with 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 substantial out-licensing or partnering arrangements for our Retrocyte Display® Technology

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Platform, CPM antibody programs, HerpV and the Prophage Series vaccines, and vaccines containing QS-21 Stimulon under development by our licensees. Our long term success will also be dependent on the successful identification, development and commercialization of potential other product candidates, each of which will require additional capital with no certainty of timing or probability of success. 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.

Our 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 research and 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 our CPM antibody programs are preclinical, HerpV is in a Phase 2 clinical 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 or, the timing for bringing such programs to various markets or substantial partnering or out-licensing arrangements. Therefore, we cannot predict if or when 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.

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 six months ended June 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. 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, 2013 filed with the Securities and Exchange Commission.

For our subsidiary 4-AB, which operates in Switzerland and Germany, the local currency is the functional currency. Assets and liabilities of 4-AB are translated into U.S. dollars using rates in effect at the balance sheet date while revenues and expenses are translated into U.S. dollars using average exchange rates. The cumulative translation adjustment resulting from changes in exchange rates are included in the consolidated balance sheets as a component of accumulated other comprehensive income in total stockholders’ equity.

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

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	June 30,	
	2014	2013
Warrants	2,951,450	2,642,712
Stock options	6,995,648	3,705,012
Nonvested shares	87,202	130,136
Convertible preferred stock	333,333	333,333
Note C - 4-Antibody Acquisition		

On January 10, 2014, we entered into a Share Exchange Agreement providing for our acquisition of all of the outstanding capital stock of 4-AB, from the shareholders of 4-AB (the "4-AB Shareholders"). The transaction closed on February 12, 2014 (the "Closing Date"). In exchange for their shares, the 4-AB Shareholders received an aggregate of 3,334,079 shares of our common stock paid upon closing and valued at \$10.1 million. Contingent milestone payments of up to \$40 million (the "contingent purchase price consideration"), payable in cash or shares of our common stock at our option, will be due to the 4-AB Shareholders as follows (i) \$20 million upon our market capitalization exceeding \$300 million for ten consecutive trading days prior to the earliest of (a) the fifth anniversary of the Closing Date (b) the sale of the 4-AB or (c) the sale of Agenus, (ii) \$10 million upon our market capitalization exceeding \$750 million for 30 consecutive trading days prior to the earliest of (a) the tenth anniversary of the Closing Date (b) the sale of 4-AB or (c) the sale of Agenus, and (iii) \$10 million upon our market capitalization exceeding \$1.0 billion for 30 consecutive trading days prior to the earliest of (a) the tenth anniversary of the Closing Date (b) the sale of 4-AB or (c) the sale of Agenus. We assigned an estimated preliminary fair value of \$9.7 million to the contingent purchase price consideration. This acquisition provided us with the Retrocyte Display® Technology Platform for the rapid discovery and optimization of fully-human and humanized monoclonal antibodies against a wide array of molecular targets and a portfolio CPM antibodies.

The acquisition of 4-AB was accounted for under the acquisition method of accounting. The purchase price of approximately \$19.8 million has been allocated to the tangible and intangible assets acquired and liabilities assumed. The fair value estimate of assets acquired and liabilities assumed is pending completion and final review by our management. Primary areas yet to be finalized include the fair value of certain tangible assets acquired and liabilities assumed, and the valuation of intangible assets acquired. The final purchase price allocation may differ from that presented below due to adjustments that may result from completion of the valuation of the assets acquired and liabilities assumed.

The following table summarizes the purchase price of the 4-AB acquisition, the identified assets acquired and liabilities assumed at the acquisition date (in thousands):

Assets acquired:

Cash	\$514
Other current assets	600
Plant and equipment	1,340
In-process research and development	2,100
Patented technology	5,700
Other finite-lived intangible	190
Goodwill	16,891
Total assets	27,335

Liabilities assumed:

Accounts payable	649
Other current liabilities	2,889
Convertible notes	1,142
Deferred revenue	1,890
Deferred tax liability	420
Other long-term liabilities	522
Total liabilities	7,512

Total purchase price

\$19,823

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The estimated fair value of the in-process research and development ("IPR&D") and patented technology was determined using the income approach and the relief from royalty rate method, respectively, using significant inputs, including an 18% discount rate, that are not observable. We consider the fair value of the IPR&D and patented technology to be Level 3 due to the significant estimates and assumptions used by management in establishing the estimated fair values.

All of the convertible notes assumed by us in the acquisition were converted into approximately 383,000 shares of our common stock on May 8, 2014.

The following table summarizes the supplemental statements of operations information on an unaudited pro forma basis as if the 4-AB acquisition had occurred on January 1, 2013 (in thousands except per share data):

	Six months ended June 30,	
	2014	2013
Pro forma revenues	\$4,000	\$4,343
Pro forma net loss attributable to common stockholders	\$(9,093)	\$(21,526)
Basic and diluted pro forma net loss attributable to common stockholders per share	\$(0.15)	\$(0.72)

The pro forma results presented above are for illustrative purposes only for the periods presented and do not purport to be indicative of the actual results which would have occurred had the transaction been completed as of the beginning of the period, nor are they indicative of results of operations which may occur in the future. For the six months ended June 30, 2014, revenues and net loss related to 4-AB of \$961,000 and \$3.5 million, respectively, are included in our condensed consolidated statement of operations and comprehensive loss. For the three months ended June 30, 2014, revenues and net loss related to 4-AB are \$659,000 and \$1.9 million, respectively.

Note D - Goodwill and Acquired Intangible assets

The following table sets forth the changes in the carrying amount of goodwill for the six months ended June 30, 2014 (in thousands):

Balance, December 31, 2013	\$2,572
Goodwill from 4-AB acquisition	16,891
Foreign currency translation adjustment	88
Balance, June 30, 2014	\$19,551

Acquired intangible assets consisted of the following at June 30, 2014 (in thousands):

	Amortization period (years)	Gross carrying amount	Accumulated amortization	Net carrying amount
Intellectual Property	15 years	\$4,826	\$(121)	\$4,705
Trademarks	4.5 years	905	(75)	830
Other	3 years	191	(24)	167
In-process research and development	Indefinite	2,110	—	2,110
Total		\$8,032	\$(220)	\$7,812

The weighted average amortization period of our finite-lived intangible assets is 13 years. Amortization expense related to acquired intangibles is estimated at \$293,000 for the balance of 2014, \$586,000 for each of the years ending 2015 and 2016, \$531,000 for the year ending 2017, \$448,000 for the year ending 2018, and \$322,000 for each of the years 2019-2028, and \$38,000 for the year ending 2029.

The acquired IPR&D asset relates to the six pre-clinical CPM antibody programs acquired in the transaction. IPR&D acquired in a business combination is capitalized at fair value until the underlying project is completed and is subject to impairment testing. Once the project is completed, the carrying value of IPR&D is amortized over the estimated useful life of the asset. Post-acquisition research and development expenses related to the acquired IPR&D are expensed as incurred.

Note E - 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

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ratably 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 six months ended June 30, 2014 is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2013	4,163,100	\$5.72		
Granted	2,976,400	3.01		
Exercised	(12,781)) 3.41		
Forfeited	(68,045)) 3.80		
Expired	(63,026)) 13.86		
Outstanding at June 30, 2014	6,995,648	\$4.52	8.3	\$884,687
Vested or expected to vest at June 30, 2014	6,250,015	\$4.69	8.1	\$665,567
Exercisable at June 30, 2014	2,848,648	\$6.31	6.7	\$110,445

The weighted average grant-date fair values of stock options granted during the six months ended June 30, 2014 and 2013, were \$1.82 and \$2.64, respectively.

As of June 30, 2014, \$6.5 million of total unrecognized compensation cost, \$390,000 of which pertains to performance awards for which performance has not yet been achieved, related to stock options granted to employees and directors is expected to be recognized over a weighted average period of 2.4 years.

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 six months ended June 30, 2014 is presented below:

	Nonvested Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2013	147,274	\$3.99
Granted	—	—
Vested	(43,864)) 4.32
Forfeited	(16,208)) 3.40
Outstanding at June 30, 2014	87,202	

As of June 30, 2014, there was \$236,000 of unrecognized share-based compensation expense related to these nonvested shares awarded to employees expected to be recognized over a weighted average period of 2.4 years. As of June 30, 2014, unrecognized expense for nonvested shares awarded to outside advisors is \$27,000. The total intrinsic value of shares vested during the six months ended June 30, 2014, was \$141,000.

We issue new shares upon stock option exercises, purchases of stock under our 2009 Employee Stock Purchase Plan, vesting of nonvested stock, issuances under the DDCP, and in lieu of approximately 33% of the base salary of our Chief Executive Officer. During the six months ended June 30, 2014, 18,149 shares were issued under the 2009 Employee Stock Purchase Plan, 43,864 shares were issued as a result of the vesting of nonvested stock, 12,781 shares were issued as a result of stock option exercises, and 25,989 shares were issued to our Chief Executive Officer in lieu of cash salary. Effective June 2014, our Chief Executive Officer will no longer receive shares of our stock in lieu of base salary.

The impact on our results of operations from share-based compensation for the six months ended June 30, 2014, and 2013, was as follows (in thousands):

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	Quarter Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Research and development	\$407	\$442	\$662	\$658
General and administrative	1,060	1,375	1,760	1,868
Total share-based compensation expense	\$1,467	\$1,817	\$2,422	\$2,526

Note F - Accrued and Other Current Liabilities

Accrued liabilities consist of the following as of June 30, 2014 and December 31, 2013 (in thousands):

	June 30, 2014	December 31, 2013
Professional fees	\$2,183	\$1,121
Payroll	1,727	1,635
Clinical trials	821	1,021
Other	927	438
	\$5,658	\$4,215

Other current liabilities consist of the following as of June 30, 2014 and December 31, 2013 (in thousands):

	June 30, 2014	December 31, 2013
Due to collaborator	\$1,375	\$—
Other	650	67
	\$2,025	\$67

Note G - Fair Value Measurements

We measure our short-term investments, contingent royalty obligation and contingent purchase price consideration at fair value. Our short-term investments are comprised solely of U.S. Treasury securities that are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized as Level 1 liabilities.

The fair values of our contingent royalty obligation and our contingent purchase price consideration, \$7.4 million and \$10.9 million, respectively, are based on significant inputs not observable in the market, which require them 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 for the royalty obligation 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 obligation is estimated by applying a risk adjusted discount rate (12.5%) 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 obligation.

The fair value of our purchase price consideration is based on estimates from Monte Carlo simulation of our market capitalization. Market capitalization was evolved using a geometric brownian motion, calculated daily for the life of the contingent purchase price consideration.

The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3) , as of June 30, 2014 (amounts in thousands):

Balance, December 31, 2013	\$18,799	
Contingent purchase price consideration	9,721	
Change in fair value of contingent royalty obligation during the period	(11,438)
Change in fair value of contingent purchase price consideration during the period	1,133	
Balance, June 30, 2014	\$18,215	

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The decrease in fair value of the contingent royalty obligation liability is included in non-operating (loss) income in our condensed consolidated statement of operations for the periods ended June 30, 2014, and related primarily to the termination by GSK of its Phase 3 clinical trial of a vaccine using our QS-21 Stimulon adjuvant in patients with non-small cell lung cancer. 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 our long-term debt at June 30, 2014 and December 31, 2013, was \$7.9 million and \$9.6 million respectively, based on the Level 2 valuation hierarchy of the fair value measurements standard using a present value methodology. The principal value of our long-term debt at June 30, 2014 and December 31, 2013 was \$7.9 million and \$9.6 million, respectively.

In connection with the acquisition of 4-AB, we assumed convertible notes which upon a change of control of 4-AB had the ability to convert into shares of our common stock. All of the convertible notes assumed in connection with the acquisition of 4-AB were converted into approximately 383,000 shares of our common stock on May 8, 2014. We have elected to account for these convertible notes using fair value as a Level 1 liability. The fair value of our convertible notes on the date of settlement was approximately \$954,000.

Note H - Equity

In February 2014, we issued and sold 22,236,000 shares of our common stock in a public underwritten offering. Net proceeds after deducting offering expenses were approximately \$56.2 million. This offering was made under an effective shelf registration statement and proceeds from the offering will be used for general corporate purposes.

In February 2014, our Board of Directors retired 43,490 shares of our treasury stock then outstanding and returned those shares to authorized and unissued shares of our common stock.

We issued an aggregate of 3,334,079 shares of our common stock in exchange for all of the outstanding capital stock of 4-AB as detailed in Note C.

On April 24, 2014, we amended our certificate of incorporation to increase the authorized number of shares of our common stock from 70,000,000 to 140,000,000 shares.

All of the convertible notes assumed in connection with the acquisition of 4-AB were converted into approximately 383,000 shares of our common stock on May 8, 2014.

Note I - Recent Accounting Pronouncements

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. The adoption of ASU 2013-11 did not have any impact on our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, ("ASU 2014-09"). ASU 2014-09 amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. This new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2016. We are currently evaluating the potential impact that ASU 2014-09 may have on our financial position and results of operations.

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

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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 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 an immuno-oncology company developing a portfolio of checkpoint modulators (CPMs), heat shock protein (HSP)-based vaccines and adjuvants. 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. We assess the development, commercialization and/or partnering strategies with respect to each of our internal product candidates periodically based on several factors, including clinical trial results, competitive positioning, and funding requirements and resources.

Our Retrocyte Display[®] Technology Platform and CPM antibody programs became part of our portfolio with the acquisition of 4-Antibody AG, a European-based biopharmaceutical company (“4-AB”) in February 2014. The Retrocyte Display[®] Technology Platform is intended to enable, among other things, the rapid generation and optimization of fully-human and humanized monoclonal antibodies against a broad range of target antigens of interest. We currently have six pre-clinical CPM antibody programs which target GITR, OX40, CTLA-4, PD-1, TIM-3 and LAG-3. We have selected two GITR agonists and one CTLA-4 antagonist to advance into investigational new drug applications (“INDs”) enabling development. Although we envision using Retrocyte Display[®] to drive the discovery of future CPM antibody candidates, not all candidates will necessarily be derived from the use of this technology. For example, our current antibody candidates targeting GITR were derived independently of Retrocyte Display[®]. We plan to identify development candidates for the other four CPM antibody programs during the second half of 2014, in order to be in a position to file INDs on at least four candidates within the next two years. During the quarter ended June 30, 2014, we entered into a collaboration and license agreement with Merck to discover and optimize fully-human antibodies against two undisclosed cancer targets using the Retrocyte Display[®]. Under this agreement, Merck will be responsible for the clinical development and commercialization of antibodies generated under the collaboration, and we are eligible to receive approximately \$100 million in potential payments associated with the completion of certain clinical, regulatory and commercial milestones, as well as royalty payments on worldwide product sales. We are exploring other potential partnering opportunities for our Retrocyte Display[®] Technology Platform and CPM antibody programs.

Our Prophage Series cancer vaccines are based on our HSP-Based Platform. Our Prophage Series 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. We believe that in contrast to many other autologous vaccines that are based on cellular preparations, the Prophage Series vaccines are based on a stable protein preparation produced by a less complex manufacturing process. Our Prophage Series vaccines are currently being studied in two different settings of glioblastoma multiforme, or GBM: newly diagnosed and recurrent disease. In July 2014, we announced final results from a single-arm, open-label Phase 2 trial showing that patients with newly-diagnosed glioblastoma

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who received the Prophage vaccine in addition to the standard of care had a survival benefit over patients who received standard of care alone.

Also within our HSP-Based Platform is HerpV, a recombinant, synthetic vaccine containing multiple antigens derived from the herpes simplex 2 virus. Combining our HSP-Based technology and our QS-21 Stimulon adjuvant, HerpV represents a potential new approach to the treatment of genital herpes. In November 2013, we released top line results from a Phase 2, randomized, double blind, multicenter clinical trial of HerpV in HSV-2 positive genital herpes patients, which showed that the trial met its primary endpoint. In June 2014, we announced that the majority of patients showed an immune response to the HSV antigens after a series of vaccinations and a booster dose at six months. More than half of those vaccinated developed a robust anti-HSV cytotoxic T-cell immune response, and in those patients there was a statistically significant reduction in viral load, which is believed to be relevant in the reduction of transmission and symptoms. After the booster shot, HerpV demonstrated a durable reduction in viral shedding approximating 14%, and remains consistent with the reduction in viral shedding observed during the initial treatment period. HerpV evokes immune responses to the mix of HSV2 peptides contained in the vaccine in a substantial majority of patients. We believe that this is the first demonstration of a correlation between immune response and a statistically significant reduction in viral load. We are currently seeking a partner for the further development of our HerpV program. Notwithstanding these data, it is uncertain whether the degree of benefit conferred by HerpV will be sufficient to (i) warrant additional clinical trials funded by us or (ii) attract a development partner.

Within our Saponin Adjuvant Platform is our QS-21 Stimulon[®] vaccine adjuvant, or QS-21 Stimulon, a saponin extracted from the bark of the Quillaja saponaria tree, 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 and, investigational therapeutic vaccines intended to treat cancer and degenerative disorders. QS-21 Stimulon has been studied in approximately 50,000 patients. Our QS-21 Stimulon is extensively partnered with GlaxoSmithKline ("GSK") and JANSSEN Alzheimer Immunotherapy ("JANSSEN AI") and includes several vaccine candidates in Phase 2 and Phase 3 clinical trials. In June 2014, GSK submitted to the European Medicines Agency an application for marketing approval of its malaria vaccine candidate incorporating QS-21 Stimulon. If any of our partners' products containing QS-21 Stimulon successfully complete clinical development and receive approval for commercial sale, we are generally entitled to receive milestone payments as well as royalties for 10 years after commercial launch, with some exceptions.

In addition to our internal development efforts, we continue to pursue collaborative, out-licensing and/or partnering opportunities for our portfolio programs and product candidates, as well as explore in-licensing, acquisitions and collaborative arrangements in areas of synergy with our existing programs. 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.

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 June 30, 2014, plus potential proceeds from our existing license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements through the first half of 2015. We expect to attempt to raise additional funds in advance of depleting our current funds. We may attempt to raise funds by: (1) pursuing collaborative, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with 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 substantial out-licensing or partnering arrangements for our Retrocyte Display[®] Technology Platform, CPM antibody programs, HerpV and the Prophage Series vaccines, and vaccines containing QS-21 Stimulon under development by our licensees. Our long term success will also be dependent on the successful identification, development and commercialization of potential other product candidates, each of which will require additional capital with no certainty of timing or probability of success. 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 June 30, 2014 Compared to the Quarter Ended June 30, 2013

Revenue: We generated revenue of approximately \$3.1 million and \$807,000 during the three months ended June 30, 2014 and 2013, respectively. In 2014, revenue includes license fees, grant revenue and milestone recognition related to our license agreement with GSK, and in 2013, license fees and service revenue. During the three months ended June 30, 2014 and 2013, we recorded revenue of approximately \$1.0 million and \$487,000, respectively, from the amortization of deferred revenue.

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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 57.5% to \$5.2 million for the three months ended June 30, 2014 from \$3.3 million for the three months ended June 30, 2013. Increased expenses in 2014 primarily relate to the increased compensation expense related to increased headcount as well as the research and development costs of the CPM antibody program, in each case as a result of the acquisition of 4-AB.

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 \$5.8 million for the three months ended June 30, 2014 from \$4.6 million for the three months ended June 30, 2013. Increased expenses in 2014 primarily related to increased professional fees related to our corporate activities and the inclusion of the expenses of 4-AB as a result of the acquisition.

Contingent consideration fair value adjustment: Contingent consideration fair value adjustment represents the increase in the fair value of our purchase price consideration during the three months ended June 30, 2014. The fair value of our purchase price consideration is based on estimates from a Monte Carlo simulation of our market capitalization.

Non-operating income: Non-operating income for the three months ended June 30, 2014 represents the change in the fair value of our contingent royalty obligation and our convertible notes.

Interest Expense, net: Interest expense, net decreased to approximately \$296,000 for the three months ended June 30, 2014 from \$491,000 for the three months ended June 30, 2013 due to the extinguishment of our 8% senior secured convertible notes due August 2014 (the "2006 Notes") during 2013.

Six months ended June 30, 2014 Compared to the six months ended June 30, 2013

Revenue: We generated revenue of approximately \$3.8 million and \$1.9 million during the six months ended June 30, 2014 and 2013, respectively. In 2014 revenue includes license fees, grant revenue and milestone recognition related to our license agreement with GSK, and in 2013, revenue includes license fees and service revenue. During the six months ended June 30, 2014 and 2013, we recorded revenue of approximately \$1.7 million and \$869,000, 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 65.1% to \$9.7 million for the six months ended June 30, 2014 from \$5.9 million for the six months ended June 30, 2013. Increased expenses in 2014 primarily relate to the increased compensation expense related to increased headcount and bonuses for research and development personnel as well as the research and development costs of the CPM antibody program.

General and Administrative: General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 49.9% to \$11.3 million for the six months ended June 30, 2014 from \$7.5 million for the six months ended June 30, 2013. Increased expenses in 2014 resulted from increased compensation expense in connection with bonuses for general and administrative personnel and increased professional fees related to our corporate activities and the acquisition of 4-AB.

Contingent consideration fair value adjustment: Contingent consideration fair value adjustment represents the increase in the fair value of our purchase price consideration during the six months ended June 30, 2014. The fair value of our purchase price consideration is based on estimates from a Monte Carlo simulation of our market capitalization.

Non-operating income: Non-operating income for the six months ended June 30, 2014 represents the change in the fair value of our contingent royalty obligation and our convertible notes.

Interest Expense, net: Interest expense, net decreased to approximately \$652,000 for the six months ended June 30, 2014 from \$1.7 million for the six months ended June 30, 2013 due to the extinguishment of our 2006 Notes during 2013.

Dividends on Series A and A-1 convertible preferred stock: Dividends decreased to approximately \$102,000 for the six months ended June 30, 2014 from approximately \$3.1 million for the six months ended June 30, 2013 due to the deemed dividend issued during 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 subsequent to the exchange.

Research and Development Programs

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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 six months ended June 30, 2014, these research and development programs consisted largely of our Prophage Series vaccines, HerpV and CPM antibody programs as indicated in the following table (in thousands).

Research and Development Program	Product	Six Months Ended	Year Ended December 31,			Prior to 2011	Total
		June 30, 2014	2013	2012	2011		
Heat shock protein-based vaccine candidates for cancer	Prophage Series Vaccines	\$3,525	\$5,882	\$5,613	\$10,182	\$281,851	\$307,053
Heat shock protein-based vaccine candidates for infectious diseases	HerpV	2,167	6,358	4,862	734	18,354	32,475
Vaccine adjuvant *	QS-21 Stimulon	189	753	85	94	12,404	13,525
Checkpoint Modulator antibody program**		3,810	—	—	—	—	3,810
Other research and development programs		4	12	4	13	33,527	33,560
Total research and development expenses		\$9,695	\$13,005	\$10,564	\$11,023	\$346,136	\$390,423

* Prior to 2000, costs were incurred by Aquila Biopharmaceuticals, Inc., a company we acquired in November 2000.

** Prior to 2014, costs were incurred by 4-Antibody AG, a company we acquired in February 2014.

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 total cost of any particular 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 our CPM antibody programs are preclinical, HerpV is currently in a Phase 2 trial with further development dependent on clinical trial data and successful partnering efforts, among other factors, 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 or, the timing for bringing such programs to various markets, or substantial partnering or out-licensing arrangements, 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 \$657.2 million as of June 30, 2014. 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 June 30, 2014, we

have raised aggregate net proceeds of \$618.4 million through the sale of common and preferred stock, the exercise of stock options and warrants, proceeds from our employee stock purchase plan, and the issuance of convertible notes and other notes. In addition, during 2012, we received \$9.0 million from GSK for a first right to negotiate the purchase of the Company or certain of our assets and an expanded license agreement and \$6.25 million through a license of non-core technologies with an existing licensee. GSK's first right to negotiate 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

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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 June 30, 2014, we have 5 million shares available for sale under this agreement.

As of June 30, 2014, we had \$7.9 million of debt outstanding. In April 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. We concurrently 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. In addition, in connection with the acquisition of 4-AB, we assumed convertible notes which were converted into approximately 383,000 shares of our common stock during the second quarter of 2014.

Our cash, cash equivalents, and short-term investments at June 30, 2014 were \$62.8 million, an increase of \$35.5 million from December 31, 2013 principally as a result of the completion in February 2014 of a public offering of 22,236,000 shares of our common stock, with net proceeds of \$56.2 million. We believe that, based on our current plans and activities, our cash, cash equivalents, and short-term investments of \$62.8 million as of June 30, 2014, plus potential proceeds from our existing license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements through the first half of 2015. 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) pursuing collaborative, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with 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 substantial out-licensing or partnering arrangements for our Retrocyte Display® Technology Platform, CPM antibody programs, HerpV and the Prophage Series vaccines, and vaccines containing QS-21 Stimulon under development by our licensees. Our long term success will also be dependent on the successful identification, development and commercialization of potential other product candidates, each of which will require additional capital with no certainty of timing or probability of success. 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.

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 June 30, 2014, we have expensed \$51.2 million as research and development expenses and \$50.3 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 June 30, 2014. 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

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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 six months ended June 30, 2014 and June 30, 2013, was \$19.6 million and \$9.6 million, respectively. This increase primarily resulted from increased personnel costs, costs related to the acquisition of 4-AB, costs incurred by 4-AB, as well as the reduced service revenue period to period. We continue to support and develop our QS-21 Stimulon partnering collaborations. If applications for marketing approval of vaccines that are submitted by our licensees are approved, the first products containing QS-21 Stimulon are anticipated to be launched in 2016. 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 candidates, achieving benchmarks as defined in existing collaborative agreements, and our ability to enter into new collaborations.

Recent Accounting Pronouncements

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. The adoption of ASU 2013-11 did not have an impact on our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, ("ASU 2014-09"). ASU 2014-09 amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. This new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2016. We are currently evaluating the potential impact that ASU 2014-09 may have on our financial position and results of operations.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our primary market risk exposure is foreign currency exchange rate risk. International revenues and expenses are generally transacted by our foreign subsidiaries and are denominated in local currency. Approximately 14% and 0% of our operating expenses for the six months ended June 30, 2014 and the year ended December 31, 2013, respectively, were from foreign subsidiaries. Additionally, 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 and Swiss Franc, in large part due to our acquisition of 4-AB, a company with operations in Switzerland and Germany. There has been no material change to our interest rate exposure and our approach toward interest rate and foreign currency exchange rate exposures, as described in our Annual Report on Form 10-K for the year ended December 31, 2013. However, commercialization of any of our product candidates outside of the United States could result in increased foreign currency exposure.

We had cash, cash equivalents, and short-term investments at June 30, 2014 of \$62.8 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 and US Treasury Securities, our carrying value approximates the fair value of these investments at June 30, 2014.

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

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 occurred during the second quarter ended June 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. However, in the first quarter of 2014, we completed the acquisition of 4-Antibody AG ("4-AB"), at which time 4-AB became our wholly-owned subsidiary. We are currently in the process of assessing and integrating 4-AB's internal controls over financial reporting into our financial reporting systems.

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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, 2013.

We cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See "Forward-Looking Statements" in Part I, Item 2 of this Quarterly Report on Form 10-Q. Factors that could cause or contribute to such differences include those factors discussed below.

Risks Related to our Business

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

Our net losses for the years ended December 31, 2013, 2012, and 2011, were \$30.1 million, \$11.3 million, and \$23.3 million, respectively. During the six months ended June 30, 2014, we generated net loss of \$8.4 million due primarily to a fair value adjustment to our contingent royalty obligation at June 30, 2014.

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, and such losses may increase as a result of our acquisition of 4-AB. 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 June 30, 2014, we have incurred net losses totaling \$657.2 million.

On June 30, 2014, we had \$62.8 million in cash, cash equivalents, and short-term investments. We believe that, based on our current plans and activities, our working capital resources at June 30, 2014, and potential proceeds from our existing license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements through the first half of 2015. 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 six months ended June 30, 2014, our average monthly cash used in operating activities was approximately \$3.3 million.

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;

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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

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.

Certain of our outstanding debt instruments contain significant restrictive and affirmative covenants and we may not be able to make interest or principal payments when due or otherwise remain in compliance with their terms.

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 until April 2015. The Subordinated Notes are due in April 2015.

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;
- 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

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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.

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 six months ended June 30, 2014 and for the years ended December 31, 2013, and 2011, net cash used in operating activities was \$19.6 million, \$19.5 million, and \$16.2 million, respectively.

We may fail to realize the benefits we expect to realize as a result of the acquisition of 4-AB and/or we may suffer a loss in productivity as a result of the integration process.

The long-term success of the acquisition of 4-AB will depend, in part, on our ability to realize the anticipated synergies, business opportunities and growth prospects from combining the businesses of Agenus and 4-AB. We may never realize these anticipated synergies, business opportunities and growth prospects. We might experience increased competition that limits our ability to expand our business, and we might not be able to capitalize on expected business opportunities, including maintaining current collaboration relationships and advancing the development of the 4-AB CPM antibody programs. Moreover, assumptions underlying estimates of expected costs as a result of the acquisition may be inaccurate, and general industry and business conditions might deteriorate. If any of these factors limit our ability to integrate the operations of Agenus and 4-AB successfully or on a timely basis, or to develop the business opportunities that we expect to realize from the acquisition of 4-AB, the expectations of future results of operations, including certain cost savings and synergies expected to result from the acquisition, might not be met.

In addition, integrating operations is complex and requires significant efforts and expenditures for us and 4-AB.

During or as a result of the integration process, employees might leave, be terminated, or have decreased productivity, and our management might have its attention diverted from core business objectives while trying to integrate operations and corporate and administrative infrastructures.

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 Adjuvant 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. For example, in April 2014, GSK announced the termination of a Phase 3 trial of its MAGE-A3 cancer immunotherapeutic (a vaccine containing QS-21 Stimulon) in non-small cell lung cancer and in 2013 they announced

the Phase 3 trial of their MAGE-A3 cancer immunotherapeutic in melanoma missed its first co-primary endpoint and the study would continue until completion of its second co-primary endpoint, which is expected in 2015. The results of these trials and other trials conducted by our licensees, as well as other factors, may cause our licensees to terminate additional programs containing QS-21 Stimulon, which could materially diminish future potential revenue from our QS-21 adjuvant. In addition, in the event that our licensees develop vaccines using QS-21 Stimulon, there is

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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.

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 inability to receive anticipated revenues, or a reduction in revenues, generated from QS-21 Stimulon could 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.

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 released top line results from a Phase 2, randomized, double blind, multicenter clinical trial of HerpV in HSV-2 positive genital herpes patients, which showed that the trial met its primary endpoint. In June 2014, we announced that the majority of patients showed an immune response to the HSV antigens after a series of vaccinations and a booster dose at six months. More than half of those vaccinated develop a robust anti-HSV cytotoxic T-cell immune response, and in those patients there was a statistically significant reduction in viral load, which is believed to be relevant in the reduction of transmission and symptoms. After the booster shot, HerpV demonstrated a durable reduction in viral shedding approximating 14%, and remains consistent with the reduction in viral shedding observed during the initial treatment period. We are currently seeking a partner for the further development of our HerpV program. The findings to date from our clinical trials, while positive, are limited in size and scope and may be insufficient to attract a partnering arrangement, despite our ongoing effort to do so, or warrant further development of the HerpV program. In addition, even if we proceed with further HerpV development, there is no guarantee that future clinical trials will be successful, that a reduction in viral shedding will translate into clinical benefit, or that the safety profile will be considered acceptable. In addition, the success of future clinical trials, if any, is 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. Furthermore, it is possible that research and discoveries by others will render our product candidate obsolete or noncompetitive.

We may not be able to advance clinical development or commercialize Prophage Series Vaccines.

The probability of future clinical development efforts leading to marketing approval and commercialization of Prophage Series vaccines is highly uncertain. Prophage Series vaccines have been in clinical development for over 15 years, including multiple Phase 1 and 2 trials in eight different tumor types as well as randomized Phase 3 trials in metastatic melanoma and adjuvant renal cell carcinoma. To date, none of our clinical trials with Prophage Series vaccines has resulted in a marketing approval, except in Russia where commercialization of the approved product has not been successful by us or NewVac LLC ("NewVac") our licensee for Oncophage® in the Russian Federation and certain other CIS countries. The license agreement with NewVac is expected to terminate in December 2014. Due to our limited resources or a shift in corporate priorities, we may be unable or limited in our ability to support on-going clinical studies with Prophage Series vaccines, perform additional studies, or extend the license agreement with NewVac.

We do not currently sponsor any on-going clinical trials with Prophage Series vaccines and therefore we lack the ability to control trial design, timelines and data availability. Current and future studies may eventually be terminated due to, among other things, slow enrollment, lack of probability that they will yield useful translational and/or efficacy data, lengthy timelines, or unlikelihood that results will support timely or successful regulatory filings. Currently, the

only actively enrolling Prophage Series vaccine clinical study is a Phase 2 trial of Prophage Series vaccine in combination with Avastin® (bevacizumab) in patients with surgically resectable recurrent glioma. This trial is being conducted under the sponsorship of the Alliance for Clinical Trials in Oncology, a cooperative group of the NCI. To date, clinical site activation and patient enrollment have not met expectations, which could curtail the viability of sustaining the trial. Furthermore, potential changes in clinical practices trending away from the administration of Avastin for the treatment of recurrent glioma could exacerbate enrollment issues and/or render the trial design impractical. In January 2014 we announced the initiation of a randomized Phase 2 trial with Prophage Series vaccine and Bristol-Myers Squibb's Yervoy® (ipilimumab), for the treatment of Stage III and IV metastatic melanoma. This study is being sponsored by an investigator at the University of Texas and, although the investigator-held investigational new drug application (IND) has been activated to allow initiation of the trial, patient enrollment has not yet begun.

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Modifications to this study protocol are being contemplated to include additional therapies or combinations (i.e. combination of checkpoint modulators) due to the changing landscape of treatment options available for patients with metastatic melanoma. While we believe the combination of Prophage and ipilimumab has the potential to trigger a more effective immune response against the tumor than ipilimumab alone, there is no guarantee that this trial will be completed or that it will yield useful translational and/or efficacy data.

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 of Prophage Series vaccines.

The successful development and commercialization of Prophage Series vaccines for a particular cancer depends in part on the ability of NewVac to purify sufficient heat shock proteins from that type of cancer. If we or NewVac have difficulties in purifying heat shock proteins for a sufficiently large number of patients in clinical trials, we may experience enrollment delays and/or lower the probability of a successful analysis of the data from clinical trials. 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 for the treatment of recurrent glioma. In addition, we may encounter problems with other types of cancer or patients if we expand our research. If we cannot overcome these problems, the number of patients or cancer types that our heat shock protein-based product candidates could treat would be limited. In addition, if we commercialize our heat shock protein-based 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.

Changes in our manufacturing strategies, manufacturing problems, or increased demand may cause delays, unanticipated costs, or loss of revenue streams within or across our programs.

We currently manufacture our Prophage Series vaccines in our Lexington, MA facility. There is no guarantee that we will be able to meet future manufacturing demand for Prophage Series vaccines, and a failure to do so could cause a delay or cessation in the further development of our Prophage Series vaccine 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 financial, personnel, and manufacturing resources and there is no assurance that we will be able to allocate resources necessary for the continued manufacturing of Prophage Series vaccines in light of competing corporate priorities. In addition, 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 Prophage Series vaccines in addition to other product candidates in our current facility.

We have given our key QS-21 Stimulon licensees, GSK and JANSSEN AI, manufacturing rights for QS-21 Stimulon for use in their product programs. If they or their third party contract manufacturers encounter problems with QS-21 Stimulon manufacturing, their programs containing QS-21 Stimulon could be delayed or terminated, and this could have an adverse effect on our license fees, milestone payments and royalties that we may otherwise receive from these programs. We have retained the right to manufacture QS-21 for ourselves and third parties, although no other such programs are anticipated to bring us substantial revenues in the near future, if ever.

The CPM antibody programs, new to our business through the acquisition of 4-AB, will require substantial manufacturing development and investment to progress. The CPM antibody programs are preclinical, and we have only recently initiated the development of the reagents, cell lines and systems required to manufacture our antibody candidates. If these development-stage efforts are delayed or do not produce the desired outcomes, this will cause delays in development timelines and increased costs, which may cause us to limit the size and scope of our efforts and studies. In addition, our staff has limited experience in the manufacture and development of the CPM antibody programs and we currently rely on consultants and advisors to advance these operations. We are in the process of identifying a contract manufacturer (CMO) for our CPM antibody programs. During the early development stages of the CPM antibody programs, we will likely be using only one CMO, and will not have a backup manufacturer in place. In the future, we may need to secure additional CMOs and we will also need to develop or secure later phase and/or commercial manufacturing capabilities, all of which would cause us to incur additional costs and risk. In the

event that our CPM antibody programs require progressively larger production capabilities, our options for CMOs may become more limited. In addition, while we currently have our own cGMP manufacturing facility in Lexington, MA, our facility is not currently configured or equipped to adequately support manufacturing of the required cell lines or the downstream production of cGMP antibody product candidates.

We may elect to alter our manufacturing strategy and hire CMOs to manufacture our internally manufactured products, which would require additional time and resources to identify suitable CMOs and transfer the technology and systems. Such an effort could divert resources away from the CPM antibody programs and lead to delays in the development of product

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candidates. In addition, our ability to efficiently manufacture our products is contingent upon a CMO's ability to ramp up production in a timely manner without the benefit of years of experience and familiarity with the processes, which we may not be able to adequately transfer.

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 either our manufacturing facility or the facilities of our CMOs 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 CMOs 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.

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 pursue pathways to develop and commercialize 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 to commercialize this product in the Russian Federation with NewVac, who has been unsuccessful to date in doing so. In addition, due to the acquisition of 4-AB, we now have research and development operations in Switzerland and Germany. Various risks associated with foreign operations may impact our success. Possible risks of foreign operations include fluctuations in the value of foreign and domestic currencies, disruptions in the import, export, and transportation of patient tumors and our products or product candidates, the product and service needs of foreign customers, difficulties in building and managing foreign relationships, the performance of our licensees or collaborators, geopolitical instability, unexpected regulatory, economic, or political changes in foreign markets and limitations on the flexibility of our operations and costs imposed by local labor laws. 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" and "Risk Factors - We may fail to realize the benefits we expect to realize as a result of the acquisition of 4-AB or suffer a loss of productivity as a result of the integration process."

If we, or our licensees, fail to obtain market demand or adequate levels of reimbursement for our product candidates, there may be no commercial or partnering opportunities for these products, or such opportunities may be significantly limited.

We or our current and future strategic alliance partners, if any, may be unable to dedicate sufficient resources to the commercialization of our current and future products and product candidates or may otherwise fail in their commercialization due to factors beyond our control. Although our Oncophage® vaccine is approved for sale in Russia for the treatment of kidney cancer patients at intermediate risk for disease recurrence, our licensee, NewVac,

has been unsuccessful in securing reimbursement or market demand for this product, and it is unlikely that it will be able to do so. The license agreement with NewVac is expected to expire in December 2014. In addition, as we advance our CPM antibody programs, we will be competing in a very crowded industry. If products that compete directly or indirectly with our products or product candidates prove superior to existing antibodies, market demand for our products or product candidates could be hampered or non-existent. We and our strategic partners, if any, will face competition from other products currently approved or that will be approved in the future for the same therapeutic indications.

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In addition, 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 commercialization and/or partnering efforts. 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 any potential future sales for our product candidates.

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.

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.

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If vaccines from our Prophage Series are 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.

We have six preclinical CPM antibody programs that have been commenced by 4-AB, our wholly-owned subsidiary. We are aware of several large companies that have antibody-based products on the market or in clinical development that are directed to the same biological target as some of these programs, including Bristol-Myers Squibb, which markets ipilimumab, an anti-CTLA-4 antibody, and has an anti-PD1 antibody in development, Medimmune, which has anti-CTLA-4, OX-40 and PD1 antibodies in development, Merck and Curetech, which each has an anti-PDI antibody in development, and Pfizer, which has an anti-CTLA-4 antibody in development. Tesaro also has antibody programs targeting PD-1, TIM-3 and LAG-3 and these include both monospecific and dual reactive antibody drug candidates.

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:

- 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 and/or maintain significant licensing, distribution and/or collaboration agreements on favorable terms to us may hinder or cause us to cease our efforts to develop and commercialize our product candidates, increase our development timelines, and/or increase our need to rely on partnering or financing mechanisms, such as sales of debt or equity securities, to fund our operations and continue our current and anticipated programs.

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.

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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 to which we granted an exclusive license to manufacture, market and sell Oncophage as well as pursue a development program in the Russian Federation and certain other CIS countries. To date, the NewVac arrangement has not provided substantial benefit to us, and it is unlikely that it will. NewVac has experienced challenges establishing manufacturing capabilities and securing government reimbursement, and has not met certain milestones set within the license agreement which is expected to expire in December 2014. In addition, other 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.

We would consider license and/or co-development opportunities to advance HerpV and antibody candidates derived from the Retrocyte Display® Technology Platform, as well as collaborations to develop antibodies derived from the Retrocyte Display® Technology Platform against targets of interest. However, collaborative partners or licensees may defer discussions until these assets are further developed or validated, or they may not engage in such discussions on terms acceptable to us or at all.

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

Part of our strategy is to develop and commercialize a majority of our product candidates by continuing or entering into arrangements with academic, government, or corporate collaborators and licensees. Our success depends on our ability to negotiate such agreements on favorable terms and on the success of the other parties in performing research, preclinical and clinical testing, completing regulatory applications, and commercializing product candidates. For example, development of Prophage Series vaccine for the treatment of patients with recurrent glioma is dependent, in large part, on the efforts of the the Alliance for Clinical Trials in Oncology, a National Cancer Institute cooperative group, which is sponsoring a Phase 2 clinical trial of this product candidate in this indication. When our licensees or third party collaborators sponsor clinical trials using our product candidates, we cannot control the timing of enrollment, data readout, 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 and it is expected to otherwise terminate in December 2014. We do not expect to receive financial or other benefits from our relationship with NewVac or the sale of Oncophage® in the Russian Federation or CIS countries.

In addition, our research, development, and commercialization efforts with respect to antibody candidates from the Retrocyte Display® Technology Platform include the participation of institutional and corporate collaborators. For example, 4-AB has or has had collaborative arrangements with Ludwig Cancer Research (LCR) and Brazil-based Recepta Biopharma SA, among others. The initial term of the license agreement with LCR has expired and we are in discussions with LCR regarding a new arrangement. If we are not able to come to agreement on terms or maintain and optimize these arrangements, as well as advance other current or potential collaborations on terms favorable to us, this could have a negative impact on our operations.

Development activities for our collaborative programs 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, or be unable to, devote resources to these arrangements or adhere to required timelines, 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

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favorable terms. Failure to generate significant revenue from collaborations could 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.

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 June 30, 2014, we have spent approximately 19 years and \$307.1 million on our research and development program in heat shock protein-based vaccines 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.

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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.

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.

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

Issued patents may be challenged, narrowed, invalidated or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

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.

Our strategy depends on our ability to identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent

applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

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The patent landscape in the field of therapeutic antibody development, manufacture and commercialization is crowded. For example, we are aware of third party patents directed to methods for identifying and producing therapeutic antibodies. We are also aware of third party patents directed to antibodies to numerous targets for which we also seek to identify, develop, and commercialize antibodies, including without limitation CTLA-4, PD-1, GITR, OX40, TIM-3, and LAG-3. For example, some patents claim antibodies based on competitive binding with existing antibodies, some claim antibodies based on specifying sequence or other structural information, and some claim various methods of discovery, production, or use of such antibodies. These or other third party patents could impinge on or foreclose our freedom to operate in relation to our technology platforms, including Retrocyte Display®, as well as in relation to development and commercialization of antibodies identified by us as therapeutic candidates. As we discover and develop our candidate antibodies, we will continue to conduct analyses of these third party patents to determine whether we believe we might infringe them, and if so, whether they would be likely to be deemed valid and enforceable if challenged. If we determine that a license for a given patent or family of patents is necessary or desirable, there can be no guarantee that a license would be available on favorable terms, or at all. Inability to obtain a license on favorable terms, should such a license be determined to be necessary or desirable, could, without limitation, result in increased costs to design around the third party patents, delay product launch, or result in cancellation of the affected program or cessation of use of the affected technology.

Third parties may also seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

We have ownership of or exclusive rights to approximately 62 issued United States patents and approximately 96 issued foreign patents. We also have ownership of or exclusive rights to approximately 13 pending United States patent applications and approximately 41 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, or 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.

The issued patents that cover the Prophage Series vaccines expire at various dates between 2015 and 2024. The issued patents related to HerpV expire at various dates between 2015 and 2029. Our QS-21 Stimulon composition of matter patent family expired in 2008. Additional protection for QS-21 Stimulon in combination with other agents is provided by our other issued patents which expire between 2017 and 2022. We continue to explore means of extending the life cycle of our patent portfolio.

Through our acquisition of 4-AB, we also own a number of patents and patent applications directed to various methods and compositions, including methods for identifying therapeutic antibodies and product candidates arising out of 4-AB's technology platforms. In particular, we own patents and patent applications relating to Retrocyte Display® Technology Platform, a high throughput antibody expression platform for the identification of fully-human and humanized monoclonal antibodies. This patent family is projected to expire between 2029 and 2030. In addition, as we advance our research and development efforts with our institutional and corporate collaborators, we intend to seek patent protection for newly-identified therapeutic antibodies and product candidates. We can provide no assurance that any of our patents, including the patents that were newly acquired from 4-AB, will have commercial value, or that any of our existing or future patent applications, including the patent applications that were newly acquired with 4-AB, will result in the issuance of valid and enforceable patents.

The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Outside the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, we cannot predict whether additional patents protecting our technology will issue in the United States or in foreign jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide competitive advantage. Moreover, we cannot predict whether third parties will be able

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to successfully obtain claims or the breadth of such claims. The allowance of broader claims may increase the incidence and cost of patent interference proceedings, opposition proceedings, post-grant review, inter partes review, and/or reexamination proceedings, the risk of infringement litigation, and the vulnerability of the claims to challenge. On the other hand, the allowance of narrower claims does not eliminate the potential for adversarial proceedings, and may fail to provide a competitive advantage. Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage.

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

Our QS-21 Stimulon composition of matter patent family has expired, 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, such as 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 that have shown biological activity. 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.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Even after they have been issued, our patents and any patents which we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights;

- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;

- third parties may initiate opposition proceedings, post-grant review, inter partes review, or reexamination proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and/or licensors to participate in such proceedings to defend the validity and scope of our patents;

- there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us;

- the USPTO may initiate an interference or derivation proceeding between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our collaborators and/or licensors to participate in an interference or derivation proceeding to determine the priority of invention, which could jeopardize our patent rights; or

- third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. There is a risk that a court or administrative body could decide that our

patents are invalid or not infringed by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents could limit our ability to assert our patents against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

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The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;

- we might not have been the first to make the inventions covered by patents or pending patent applications;

- we might not have been the first to file patent applications for these inventions;

- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or

- we may not develop additional proprietary technologies that are patentable.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties.

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. In particular, as a result of the acquisition of 4-AB, we now have six preclinical CPM antibody programs, and the patent landscape around the discovery, development, manufacture and commercial use of therapeutic antibodies is crowded.

Patents that we may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to any technology that we require may also materially harm our business, financial condition, and results of operations. Furthermore, we would be exposed to a threat of litigation.

In the biopharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;

- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or other proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;

- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and

- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our

obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is a risk that a court would decide that we or our collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our collaborators may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us or our

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collaborators to pay the other party damages. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

The biopharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

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

We are currently party to various intellectual property license agreements. These license agreements impose, and we expect that future license agreements may impose, various diligence, milestone payment, royalty, insurance and other obligations on us. These licenses typically include an obligation to pay an upfront payment, yearly maintenance payments and royalties on sales. If we fail to comply with our obligations under the licenses, the licensors may have the right to terminate their respective license agreements, in which event we might not be able to market any product that is covered by the agreements. Termination of the license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, which could adversely affect our competitive business position and harm our business.

If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in

related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition

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and results of operations. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery. As is common in the biopharmaceutical industry, we employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel or service providers to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. In addition, we are responsible for the payment of patent fees for patent rights that we have licensed from other parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights.

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.

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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;
- 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

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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 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 June 30, 2014, and for the six months ended June 30, 2014, the closing price of our common stock has fluctuated between \$1.80 and \$315.78 per share and \$2.41 and \$5.10 per share, respectively. The average daily trading volume for the six months ended June 30, 2014 was approximately 873,000 shares while the average daily trading volume for the year ended December 31, 2013 was approximately 367,000 shares. The market may experience significant price and volume fluctuations that are often unrelated to the operating performance of individual companies. In addition to general market volatility, many factors may have a significant adverse effect on the market price of our stock, including:

- continuing operating losses, which we expect over the next several years as we continue our development activities;
- announcements of decisions made by public officials;

• results of our preclinical studies and clinical trials;
• announcements of new collaboration agreements with strategic partners or developments by our existing collaborative partners;

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• announcements of technological innovations, new commercial products, failures of products, or progress toward commercialization by our competitors or peers;

• failure to realize the anticipated benefits of the acquisition of 4-AB;

• 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;

• 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 June 30, 2014, we had 62,652,214 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 12,200,000 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 June 30, 2014, an aggregate of approximately 15.0 million of these shares remain available for sale. Contingent milestone payments, payable in cash or shares of our common stock at our option, will be due to the 4-AB Shareholders as follows (i) \$20 million upon our market capitalization exceeding \$300 million for ten consecutive trading days prior to the earliest of (a) the fifth anniversary of the Closing Date, (b) the sale of 4-AB or (c) the sale of Agenus; (ii) \$10 million upon our market capitalization exceeding \$750 million for 30 consecutive trading days prior to the earliest of (a) the tenth anniversary of the Closing Date (b) the sale of 4-AB or (c) the sale of Agenus, and (iii) \$10 million upon our market capitalization exceeding \$1.0 billion for 30 consecutive trading days prior to the earliest of (a) the tenth anniversary of the Closing Date, (b) the sale of 4-AB or (c) the sale of Agenus.

As of June 30, 2014, warrants to purchase approximately 2,951,000 shares of our common stock with a weighted average exercise price per share of \$10.87 were outstanding.

As of June 30, 2014, options to purchase 6,995,648 shares of our common stock with a weighted average exercise price per share of \$4.52 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 June 30, 2014 we have 87,202 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

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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 SEC 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, 2013, our procedures are subject to the risk that our controls may become inadequate because of changes in conditions or as a result of a deterioration in compliance with such procedures. No assurance is given that our procedures and processes for detecting weaknesses in our internal control over financial reporting will be effective.

We anticipate additional commitments of management time to ensure that our internal control over financial reporting of the operations of 4-AB complies with Section 404 of the Sarbanes-Oxley Act of 2002. Prior to the acquisition, 4-AB was a privately held company organized under the laws of Switzerland and, as such, it had not been subject to financial reporting requirements applicable to public companies and was not required to prepare and publish audited financial statements in accordance with U.S. GAAP. Accordingly, our on-going efforts to ensure that our internal control over the financial reporting of the operations of 4-AB will cause us to incur significant additional costs.

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

Item 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: August 1, 2014

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.
3.1.5	Certificate of Fourth 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 April 25, 2014 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	

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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. 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.

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(2) 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 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.