

AGENUS INC
Form 10-Q
November 04, 2015

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 September 30, 2015

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 06-1562417
(State or other jurisdiction of (I.R.S. Employer

incorporation or organization) Identification No.)

3 Forbes Road, Lexington, Massachusetts 02421

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code:

(781) 674-4400

Edgar Filing: AGENUS INC - Form 10-Q

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 (Do not check if a smaller reporting company) Smaller reporting company

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

Number of shares outstanding of the issuer's Common Stock as of October 30, 2015: 84,646,215 shares

Agenus Inc.

Nine Months Ended September 30, 2015

Table of Contents

	Page
PART I	
ITEM 1. <u>Financial Statements:</u>	2
<u>Condensed Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014 (Unaudited)</u>	2
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2015 and 2014 (Unaudited)</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014 (Unaudited)</u>	4
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	5
ITEM 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
ITEM 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
ITEM 4. <u>Controls and Procedures</u>	22
PART II	
ITEM <u>Risk Factors</u>	
1A.	24
ITEM 6. <u>Exhibits</u>	47
<u>Signatures</u>	48

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30, 2015	December 31, 2014
ASSETS		
Cash and cash equivalents	\$ 184,138,960	\$ 25,714,519
Short-term investments	14,993,700	14,509,570
Inventories	88,200	95,700
Accounts Receivable	7,331,624	463,007
Prepaid expenses	1,953,486	1,247,548
Other current assets	437,311	639,957
Total current assets	208,943,281	42,670,301
Plant and equipment, net of accumulated amortization and depreciation of \$29,351,331		
and \$28,369,982 at September 30, 2015 and December 31, 2014, respectively	7,829,693	5,996,687
Goodwill	18,139,991	17,869,023
Acquired intangible assets, net of accumulated amortization of \$873,667 and \$462,248		
at September 30, 2015 and December 31, 2014, respectively	6,490,481	6,773,722
Other long-term assets	1,204,804	1,216,795
Total assets	\$ 242,608,250	\$ 74,526,528
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current portion, long-term debt	\$ 146,061	\$ 1,257,178
Current portion, deferred revenue	5,967,198	184,421
Accounts payable	3,091,199	1,710,946
Accrued liabilities	13,738,916	5,501,527
Other current liabilities	5,342,496	575,351
Total current liabilities	28,285,870	9,229,423
Long-term debt	110,553,452	4,769,359
Deferred revenue	15,498,207	3,009,568
Contingent royalty obligation	—	15,279,000
Contingent purchase price consideration	3,747,000	16,420,300
Other long-term liabilities	7,547,617	2,800,491
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Preferred stock, par value \$0.01 per share; 5,000,000 shares authorized:		
Series A-1 convertible preferred stock; 31,620 shares designated, issued, and	316	316
outstanding at September 30, 2015 and December 31, 2014; liquidation value		

of \$32,164,572 at September 30, 2015

Common stock, par value \$0.01 per share; 140,000,000 shares authorized;

84,646,215 and 62,720,065 shares issued at September 30, 2015 and

December 31, 2014, respectively	846,462	627,201
Additional paid-in capital	841,041,405	715,667,633
Accumulated other comprehensive loss	(1,331,638)	(1,970,420)
Accumulated deficit	(763,580,441)	(691,306,343)
Total stockholders' equity	76,976,104	23,018,387
Total liabilities and stockholders' equity	\$242,608,250	\$74,526,528

See accompanying notes to unaudited condensed consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Revenue:				
Research and development revenue	\$ 6,848,194	\$ 1,563,378	\$ 17,178,191	\$ 5,358,322
Total revenues	6,848,194	1,563,378	17,178,191	5,358,322
Operating expenses:				
Research and development	(18,502,063)	(5,284,607)	(52,495,316)	(14,979,844)
General and administrative	(6,407,902)	(4,919,675)	(19,910,650)	(16,209,790)
Contingent purchase price consideration fair value adjustment	6,994,000	969,000	(7,326,700)	(164,000)
Operating loss	(11,067,771)	(7,671,904)	(62,554,475)	(25,995,312)
Other (expense) income:				
Non-operating (expense) income	(653,376)	(127,367)	(7,356,139)	10,449,462
Interest expense, net	(1,401,102)	(310,080)	(2,363,484)	(962,015)
Net loss	(13,122,249)	(8,109,351)	(72,274,098)	(16,507,865)
Dividends on Series A-1 convertible preferred stock	(50,780)	(51,159)	(152,099)	(153,292)
Net loss attributable to common stockholders	\$ (13,173,029)	\$ (8,160,510)	\$ (72,426,197)	\$ (16,661,157)
Per common share data:				
Basic and diluted net loss attributable to common stockholders	\$ (0.16)	\$ (0.13)	\$ (0.95)	\$ (0.28)
Weighted average number of common shares outstanding:				
Basic and diluted	84,569,118	62,831,541	75,935,985	58,710,338
Other comprehensive income (loss):				
Foreign currency translation gain (loss)	\$ (680,993)	\$ (1,294,720)	\$ 625,132	\$ (1,161,036)
Unrealized gain on investments	7,760	1,863	13,650	3,816
Other comprehensive income (loss)	(673,233)	(1,292,857)	638,782	(1,157,220)
Comprehensive loss	\$ (13,846,262)	\$ (9,453,367)	\$ (71,787,415)	\$ (17,818,377)

See accompanying notes to unaudited condensed consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$(72,274,098)	\$(16,507,865)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,403,324	1,019,073
Share-based compensation	5,218,479	3,700,518
Non-cash interest expense	1,643,417	461,653
Loss on disposal of assets	—	1,150
Change in fair value of contingent obligations	14,190,000	(10,652,557)
In-process research and development purchase	12,245,230	—
Loss on extinguishment of debt	154,117	—
Change in fair value of assumed convertible notes	—	(205,143)
Changes in operating assets and liabilities:		
Accounts receivable	(7,232,669)	1,200
Inventories	7,500	(95,700)
Prepaid expenses	(693,981)	(425,485)
Accounts payable	1,266,219	35,207
Deferred revenue	18,465,694	(2,695,737)
Accrued liabilities and other current liabilities	8,390,007	(2,021,879)
Other operating assets and liabilities	(10,367,586)	(341,034)
Net cash used in operating activities	(27,584,347)	(27,726,599)
Cash flows from investing activities:		
Cash acquired in acquisition	—	514,470
Purchases of plant and equipment	(2,818,429)	(1,105,472)
Purchases of available-for-sale securities	(15,006,730)	(14,517,644)
Proceeds from sale of available-for-sale securities	14,534,486	—
Net cash used in investing activities	(3,290,673)	(15,108,646)
Cash flows from financing activities:		
Net proceeds from sale of equity	109,669,980	56,792,252
Proceeds from employee stock purchases and option exercises	1,963,738	150,140
Financing of plant and equipment	—	(39,156)
Proceeds from issuance of long-term debt	109,000,000	—
Debt issuance costs	(1,774,323)	—
Payments of debt	(1,111,112)	(2,500,000)
Payment of contingent purchase price consideration	(8,380,483)	—
Payment of preferred stock dividends	—	(460,963)
Payment of contingent royalty obligation	(20,000,000)	(400,000)
Net cash provided by financing activities	189,367,800	53,542,273
Effect of exchange rate changes on cash	(68,339)	327,128
Net increase in cash and cash equivalents	158,424,441	11,034,156
Cash and cash equivalents, beginning of period	25,714,519	27,351,969

Edgar Filing: AGENUS INC - Form 10-Q

Cash and cash equivalents, end of period	\$ 184,138,960	\$ 38,386,125
Supplemental cash flow information:		
Cash paid for interest	\$ 770,538	\$ 531,863
Supplemental disclosures - non-cash activities:		
Purchases of plant and equipment in accounts payable and accrued liabilities	111,903	292,106
Issuance of common stock, \$0.01 par value, issued in connection with the settlement of the contingent royalty obligation	2,142,000	—
Issuance of common stock, \$0.01 par value, issued in connection with the acquisition of the SECANT Yeast Display technology	3,000,000	—
Issuance of common stock, \$0.01 par value, for acquisition of 4-Antibody AG	—	10,102,259
Issuance of common stock, \$.01 par value, in connection with payment of the contingent purchase price obligation	344,550	—
Contingent purchase price consideration issued in connection with the acquisition of 4-Antibody AG	—	9,721,000
Issuance of common stock, \$0.01 par value, as payment of long-term debt	—	953,765

See accompanying notes to unaudited condensed consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

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 immunology company discovering and developing novel checkpoint modulators, vaccines and adjuvants to treat cancer and other diseases. Our approaches are driven by three platform technologies:

- our antibody platforms, including our proprietary Retrocyte Display™, SECANT[®] yeast display, our phage display technologies, and our antibody programs, including checkpoint modulators, or CPMs;
- our heat shock protein (HSP)-based vaccines; and
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon[®] adjuvant, or QS-21 Stimulon.

We have a portfolio of programs in pre-clinical and clinical stages, including a series of CPMs in investigational new drug (IND)-enabling studies, our Prophage vaccine, a HSP-based autologous vaccine candidate for glioblastoma multiforme, or GBM, a form of brain cancer, and a number of advanced QS-21 Stimulon-containing vaccine candidates in late stage development by our partner, GlaxoSmithKline plc (GSK).

For the treatment of cancer, our programs aim to stimulate the immune system to recognize and eradicate cancer cells and disable the mechanisms that cancer cells employ to evade detection and destruction by the immune system. Because of the breadth of our portfolio, we have the ability to combine our proprietary vaccines with a portfolio of checkpoint modulating antibodies against major checkpoint targets to explore and optimize cancer treatments. Our strategy is to develop these agents either alone or in combinations to yield best-in-class treatments. 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.

Agenus' core technologies include Retrocyte Display, a powerful proprietary platform designed to effectively discover and optimize novel, fully human and humanized monoclonal antibodies against antigens of interest. Our Retrocyte Display technology is applied to the discovery and development of antibodies, including those targeting significant checkpoint targets. Agenus and its partners currently have pre-clinical programs targeting GITR, OX40, CTLA-4, LAG-3, TIM-3, PD-1, CEACAM1 and other undisclosed check-point programs. In April 2015, we expanded our antibody discovery platform through the acquisition of key antibody assets from Celexion, LLC (Celexion); see Note L. Among the acquired assets was the SECANT yeast display platform for the generation of novel monoclonal antibodies and efficient integration of drug targets such as CPMs.

On January 9, 2015 and effective February 19, 2015, we entered into a broad, global alliance with Incyte Corporation and a wholly-owned subsidiary thereof (collectively "Incyte") to pursue the discovery and development of CPMs, initially targeting GITR, OX40, TIM-3 and LAG-3 in the fields of hematology and oncology. We also began collaborating with Merck Sharp & Dohme Corp in April 2014 to discover antibodies against two undisclosed CPM targets. We anticipate initiating clinical trials with the first of our CPM antibody candidates in 2016.

We have also been advancing a series of HSP-based vaccines to treat cancer and infectious disease. In June 2015, at the American Society of Clinical Oncology (ASCO) meeting, we reported positive results from a Phase 2 clinical trial with our Prophage vaccine, which showed that patients with newly-diagnosed GBM who were treated with a combination of our Prophage vaccine and standard of care showed substantial improvement both in progression-free

survival and median overall survival, as compared to historical control data. The most significant clinical improvements were seen in patients with less elevated PD-L1 expression in peripheral blood monocytes. These observations suggested that while some patients may derive the greatest benefit from standard of care and the Prophage vaccine alone, patients with more elevated PD-L1 expression on peripheral monocytes may benefit from a combination of Prophage in addition to checkpoint modulators PD-1 or PD-L1. We are currently exploring advancing our Prophage vaccine into well-controlled randomized trials designed to study Prophage versus the standard of care. In addition, efforts are currently underway to conduct adequately controlled and randomized combination studies using Prophage while we simultaneously explore partnership opportunities to license Prophage. In 2014, we also reported positive results from a Phase 2 clinical trial with our HerpV vaccine candidate for genital herpes, and while we do not expect to advance into a Phase 3 clinical trial for genital herpes, we are currently in the process of evaluating the broader application of our HSP peptide-based vaccines.

The Company's QS-21 Stimulon adjuvant is a key component in several of GSK's pre-clinical and clinical stage vaccine programs, which target prophylactic or therapeutic impact in a variety of infectious diseases and cancer. In December 2014, GSK reported that its Phase 3 clinical trial with shingles vaccine candidate, HZ/su, using our QS-21 Stimulon adjuvant, met its primary

endpoint, reducing the risk of shingles by 97.2% in adults aged 50 years and older compared to placebo. GSK also reported positive Phase 3 clinical trial results in October 2013 for its malaria vaccine candidate using QS-21 Stimulon, Mosquirix™ (RTS,S), which recently received a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency. In September 2015, we monetized a portion of the future royalties we are contractually entitled to receive from GSK from sales of its shingles and malaria vaccines through a Note Purchase Agreement and received net proceeds of approximately \$98.2 million; refer to Note E for additional information. QS-21 Stimulon is also the subject of an out-license agreement with Janssen Sciences Ireland Uc for use in a vaccine for Alzheimer's disease.

Our business activities include 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. Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing arrangements with academic and corporate collaborators and licensees and by entering into new collaborations.

We have incurred significant losses since our inception. As of September 30, 2015, we had an accumulated deficit of \$763.6 million. To date, we have financed our operations primarily through the sale of equity and debt securities. We believe that, based on our current plans and activities, our working capital resources at September 30, 2015 will be sufficient to satisfy our liquidity requirements into the first half of 2018.

We may attempt to raise additional funds by: (1) pursuing collaboration, 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 antibody discovery platforms, CPM antibody programs, HSP-based 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 pre-clinical and the further development of our HSP-based 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. Active programs involving QS-21 Stimulon depend on our collaboration 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. Certain reclassifications have been made to previously reported amounts to conform to the current presentation. Operating results for the nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. 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, 2014 filed with the Securities and Exchange Commission (the "SEC").

For our foreign subsidiaries the local currency is the functional currency. Assets and liabilities of our foreign subsidiaries 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 during the period. The cumulative translation adjustment resulting from changes in exchange rates are included in the consolidated balance sheets as a component of accumulated other comprehensive loss 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 net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our Directors' Deferred Compensation Plan, or DDCP). Diluted net loss per common share is calculated by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our DDCP) plus the dilutive effect of outstanding instruments such as warrants, stock options, nonvested shares, and convertible preferred stock. Because we reported a net loss attributable to common stockholders for all periods presented, diluted net loss per common share is the same as basic net 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:

	Nine months ended	
	September 30,	
	2015	2014
Warrants	4,351,450	2,951,450
Stock options	8,226,791	6,841,400
Nonvested shares	1,734,821	78,828
Convertible preferred stock	333,333	333,333

Note C - Investments

Cash equivalents and short-term investments consisted of the following as of September 30, 2015 and December 31, 2014 (in thousands):

	September 30, 2015		December 31, 2014	
	Cost	Estimated Fair Value	Cost	Estimated Fair Value
Institutional Money Market Funds	\$172,811	\$172,811	\$25,149	\$25,149
U.S. Treasury Bills	14,971	14,994	14,508	14,510
Total	\$187,782	\$187,805	\$39,657	\$39,659

For the nine months ended September 30, 2015, we received proceeds of approximately \$14.5 million from the sale of available-for-sale securities. No proceeds from the maturity of available-for-sale securities were received for the year ended December 31, 2014. Gross realized gains included in net loss as a result of the sale of available-for-sale securities were immaterial for the nine months ended September 30, 2015. As a result of the short-term nature of our investments, there were minimal unrealized holding gains or losses as of September 30, 2015 and December 31, 2014.

Of the investments listed above, \$172.8 million and \$25.1 million have been classified as cash equivalents and \$15.0 million and \$14.5 million as short-term investments on our condensed consolidated balance sheet as of September 30, 2015 and December 31, 2014, respectively.

Note D - Goodwill and Acquired Intangible Assets

The following table sets forth the changes in the carrying amount of goodwill for the nine months ended September 30, 2015 (in thousands):

Balance, December 31, 2014	\$17,869
Foreign currency translation adjustment	271
Balance, September 30, 2015	\$18,140

Edgar Filing: AGENUS INC - Form 10-Q

Acquired intangible assets consisted of the following at September 30, 2015 (in thousands):

	Amortization period (years)	Gross carrying amount	Accumulated amortization	Net carrying amount
Intellectual Property	15 years	\$ 4,425	\$ (479)	\$ 3,946
Trademarks	4.5 years	829	(300)	529
Other	3 years	175	(95)	80
In-process research and development	Indefinite	1,935	—	1,935
Total		\$ 7,364	\$ (874)	\$ 6,490

The weighted average amortization period of our finite-lived intangible assets is 13 years. Amortization expense related to acquired intangibles is estimated at \$134,000 for the remainder of 2015, \$512,000 for each of the years ending 2016 and 2017, \$410,000 for the year ending 2018, \$295,000 for the year ending 2019, and \$299,000 for each of the years ending 2020-2029.

The acquired in-process research and development ("IPR&D") asset relates to the pre-clinical CPM antibody programs acquired with our acquisition of 4-Antibody AG ("4-AB") 4-AB in February 2014. IPR&D acquired in a business combination is capitalized at fair value until the underlying project is completed and is subject to impairment testing at least annually. 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 - Debt

Debt obligations consisted of the following as of September 30, 2015 and December 31, 2014 (in thousands):

Debt instrument	Principal at September 30, 2015	Non-cash Interest	Unamortized Debt Issuance Costs	Unamortized Debt Discount	Balance at September 30, 2015
Current Portion:					
Debentures	\$ 146	\$ —	\$ —	\$ —	\$ 146
Long-term Portion:					
2015 Subordinated Notes	14,000	—	—	(2,510)	11,490
Note Purchase Agreement	100,000	825	(1,514)	(248)	99,063
Total long-term	\$ 114,000	\$ 825	\$ (1,514)	\$ (2,758)	\$ 110,553
Total	\$ 114,146	\$ 825	\$ (1,514)	\$ (2,758)	\$ 110,699
Debt instrument	Principal at December 31,	Non-cash Interest	Unamortized Debt	Unamortized Debt	Balance at December

Edgar Filing: AGENUS INC - Form 10-Q

	2014		Issuance Costs	Discount	31, 2014
Current Portion:					
Debentures	\$ 146	\$ —	\$ —	\$ —	\$ 146
SVB Loan	1,111	—	—	—	1,111
Total current	\$ 1,257	\$ —	\$ —	\$ —	\$ 1,257
Long-term Portion:					
2013 Notes	5,000	—	—	(231)	4,769
Total	\$ 6,257	\$ —	\$ —	\$ (231)	\$ 6,026

Subordinated Notes

On February 20, 2015, we, certain existing investors and certain additional investors entered into an Amended and Restated Note Purchase Agreement, pursuant to which we (i) canceled our senior subordinated promissory notes issued in April 2013 (the "2013 Notes") in exchange for new senior subordinated promissory notes (the "2015 Subordinated Notes") in the aggregate principal amount of \$5.0 million, (ii) issued additional 2015 Subordinated Notes in the aggregate principal amount of \$9.0 million and (iii) issued five year warrants to purchase 1,400,000 shares of our common stock at an exercise price of \$5.10 per share.

The 2015 Subordinated Notes bear interest at a rate of 8% per annum, payable in cash on the first day of each month in arrears. Among other default and acceleration terms customary for indebtedness of this type, the 2015 Subordinated Notes include default provisions which allow for the noteholders to accelerate the principal payment of the 2015 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 2015 Subordinated Notes, default on other indebtedness with an aggregate principal balance of \$13.5 million or more if such default has the effect of accelerating the maturity of such indebtedness, or become subject to a legal judgment or similar order for the payment of money in an amount greater than \$13.5 million if such amount will not be covered by third-party insurance. The 2015 Subordinated Notes are not convertible into shares of our common stock and will mature on February 20, 2018, at which point we must repay the outstanding balance in cash. The Company may prepay the 2015 Subordinated Notes at any time, in part or in full, without premium or penalty.

The exchange of the 2013 Notes for the 2015 Subordinated Notes was accounted for as a debt extinguishment under the guidance of Accounting Standards Codification (ASC) 470-50 Debt: Modifications and Extinguishments. For the nine months ended September 30, 2015 we recorded a loss on debt extinguishment of approximately \$154,000 in non-operating (expense) income in our condensed consolidated statements of operations and comprehensive loss. The debt discount of approximately \$3.0 million, which relates to the warrants issued in connection with the 2015 Subordinated Notes, is being amortized using the effective interest method over three years, the expected life of the 2015 Subordinated Notes.

Note Purchase Agreement Related to Sale of Future Royalties

On September 4, 2015, we and our wholly-owned subsidiaries, Antigenics LLC (“Antigenics”) and Aronex Pharmaceuticals, Inc. (“Aronex”), entered into a Note Purchase Agreement (the “NPA”) with Oberland Capital SA Zermatt LLC, as collateral agent (“Oberland”), an affiliate of Oberland as the lead purchaser and other purchasers. Pursuant to the terms of the NPA, on September 8, 2015 (the “Closing Date”), Antigenics issued \$100.0 million aggregate principal amount of limited recourse notes (the “Notes”) to the purchasers. Antigenics has the option to issue an additional \$15.0 million aggregate principal amount of Notes (the “Additional Notes”) to the purchasers within 15 days after approval of GSK’s shingles vaccine, HZ/su, by the Food and Drug Administration, provided such approval occurs on or before June 30, 2018.

The Notes accrue interest at a rate of 13.5% per annum, compounded quarterly, from and after the Closing Date computed on the basis of a 360-day year and the actual number of days elapsed. Principal and interest payments are due on each of March 15, June 15, September 15 and December 15, and shall be made solely from the royalties paid from GSK to Antigenics on sales of GSK’s shingles and malaria vaccines. The Notes are limited recourse and secured solely by a first priority security interest in the royalties and accounts and payment intangibles relating thereto plus various rights of Antigenics related to the royalties under its contracts with GSK (the “Collateral”). GSK will send all royalty payments to a segregated bank account, and to the extent there are insufficient royalties deposited into the account to fund a quarterly interest payment, the interest will be capitalized and added to the aggregate principal balance of the loan. The final legal maturity date of the Notes is the earlier of (i) the 10th anniversary of the first commercial sale of GSK’s shingles or malaria vaccines and (ii) September 8, 2030 (the “Maturity Date”). Antigenics’ obligation to repay all principal and accrued and unpaid interest by the Maturity Date is secured only by the Collateral.

At our option, we may redeem all, but not less than all, of the Notes at any time prior to the Maturity Date. The redemption price is equal to the outstanding principal amount of the Notes, plus all accrued and unpaid interest thereon, plus a premium payment that would yield an aggregate internal rate of return (“IRR”) for the purchasers as follows: (i) an IRR of 20% if the redemption occurs within 24 months of the Closing Date, (ii) an IRR of 17.5% if the redemption occurs after 24 months but within 48 months of the Closing Date, and (iii) an IRR of 15% if the redemption occurs more than 48 months after the Closing Date (the “Redemption Payment”).

On September 8, 2018, each purchaser has the option to require Antigenics to repurchase up to 15% of the Notes issued to such purchaser on the Closing Date (the “Put Notes”) at a purchase price equal to the principal amount thereof plus accrued and unpaid interest thereon (the “Put Payment”). Antigenics is required to complete any such repurchase

within 90 days after September 8, 2018.

On the earlier of (i) September 8, 2027 and (ii) the Maturity Date, Antigenics is required to pay the purchasers an amount equal to the following (the "Make-Whole Payment"): \$100.0 million (or \$115.0 million if the Additional Notes are sold) minus the aggregate amount of all payments made in respect of the Notes (regardless of whether characterized as principal or interest at the time of payment), including the original principal amount of any repaid Put Notes.

The NPA specifies a number of events of default (some of which are subject to applicable cure periods), including (i) failure to cause royalty payments to be deposited into the segregated bank account, (ii) payment defaults, (iii) breaches of representations and warranties made at the time the Notes were issued, (iv) covenant defaults, (v) a final and unappealable judgment against Antigenics for the payment of money in excess of \$1.0 million, (vi) bankruptcy or insolvency defaults, (vii) the failure to maintain a first-priority perfected security interest in the Collateral in favor of the collateral agent and (viii) the occurrence of a change of control of Agenus. Upon the occurrence of an event of default, subject to cure periods in certain circumstance and some limited exceptions, Oberland may declare the Notes immediately due and payable, in which case Antigenics would owe a payment equal to the Redemption

Payment (the “Accelerated Default Payment”). Upon the occurrence and during the continuance of any event of default, interest on the Notes also increases by 2.5% per annum.

Agenus and Aronex (together, the “Guarantors”), are parties to the NPA as guarantors of certain of Antigenics’ obligations under the NPA. The Guarantors generally guarantee the Put Payment, the Make-Whole Payment, the Redemption Payment and the Accelerated Default Payment.

In accordance with the guidance of ASC 470-10-25 Debt: Recognition, we determined the NPA represents a debt transaction and does not purport to be a sale; the balance of the outstanding notes and interest will be repaid over the estimated term of the NPA. We will periodically assess the expected royalties using a combination of historical results, internal projections and forecasts from external sources. To the extent such payments are greater or less than our initial estimates or the timing of such payments is materially different than our original estimates, we will prospectively adjust the estimated time period over which the debt and interest will be repaid. There are a number of factors that could materially affect the amount and timing of royalty payments from GSK, all of which are not within our control. Such factors include, but are not limited to, changing standards of care, the introduction of competing products, manufacturing or other delays, biosimilar competition, patent protection, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates, and other events or circumstances that could result in reduced royalty payments from GSK, all of which would result in a reduction of royalty revenues and the interest expense over the life of the NPA.

As royalties are remitted to the purchasers, we will record non-cash royalty revenues and non-cash interest expense within our consolidated statements of operations and comprehensive loss over the term of the NPA as interest accrues and royalties are generated. We did not recognize any royalty revenue and recorded \$825,000 in non-cash interest expense for the three and nine months-ended September 30, 2015 within our condensed consolidated statement of operations and comprehensive loss.

In connection with the execution of the NPA, we reimbursed the purchasers for legal fees of \$250,000 and incurred debt issuance costs of approximately \$1.5 million. Under the relevant accounting guidance, legal fees and debt issuance costs have been recorded as a reduction to the gross proceeds. These amounts are being amortized over 12 years, the expected term of the Notes, using the effective interest rate method.

Other

In April 2015, we made our final payment of approximately \$278,000 under our \$5.0 million Loan and Security Agreement with Silicon Valley Bank (the “SVB Loan”) in accordance with the terms of the SVB Loan. We have no further outstanding indebtedness or obligations under the SVB Loan.

Note F – Revenue Interest Assignment Termination

On April 15, 2013, we and Antigenics entered into a Revenue Interests Assignment Agreement (the “Original Agreement”) with Ingalls & Snyder Value Partners, L.P. and Arthur Koenig (together, “Ingalls”), pursuant to which we and Antigenics sold to Ingalls 20% of all the royalties Antigenics was entitled to receive from GSK and Janssen Sciences Ireland Uc on products associated with Agenus’s QS-21 Stimulon (collectively, the “Assigned Interests”).

On September 4, 2015, we and Antigenics entered into a Revenue Interest Assignment and Termination Agreement (the “Assignment and Termination Agreement”) with Ingalls, pursuant to which we terminated the Original Agreement and repurchased the Assigned Interests in exchange for (i) \$20.0 million in cash and (ii) 300,000 shares of Agenus common stock for total consideration of approximately \$22.1 million. The closing under the Assignment and Termination Agreement took place on September 8, 2015 immediately prior to the closing under the NPA. Effective

September 8, 2015, we have no further obligations under the Original Agreement.

For the three months ended September 30, 2015 we recorded a fair value adjustment of approximately \$495,000 upon settlement of the contingent royalty obligation recorded within non-operating (expense) income in our condensed consolidated statement of operations and comprehensive loss.

Note G - Accrued and Other Current Liabilities

Accrued liabilities consisted of the following as of September 30, 2015 and December 31, 2014 (in thousands):

	September 30, 2015	December 31, 2014
Payroll	\$ 3,592	\$ 3,134
Professional fees	3,349	1,438
Contract Manufacturing Costs	2,495	245
License Fees Payable	2,200	—
Other	2,103	685
Total	\$ 13,739	\$ 5,502

Other current liabilities consisted of the following as of September 30, 2015 and December 31, 2014 (in thousands):

	September 30, 2015	December 31, 2014
Current portion of deferred purchase price (Note L)	\$ 4,933	\$ —
Other	409	575
Total	\$ 5,342	\$ 575

Note H - Collaborations

Incyte Corporation-

On January 9, 2015 and effective February 19, 2015, we entered into a global license, development and commercialization agreement (the “Collaboration Agreement”) with Incyte pursuant to which the parties plan to develop and commercialize novel immuno-therapeutics using our proprietary antibody discovery platforms. The Collaboration Agreement is initially focused on four checkpoint modulator programs directed at GITR, OX40, LAG-3 and TIM-3. In addition to the four identified antibody programs, the parties have an option to jointly nominate and pursue the development and commercialization of antibodies against additional targets during a five year discovery period which, upon mutual agreement of the parties for no additional consideration, can be extended for an additional three years.

On January 9, 2015 we also entered into a Stock Purchase Agreement with Incyte Corporation (the “Stock Purchase Agreement”) whereby, for an aggregate purchase price of \$35.0 million, Incyte purchased approximately 7.76 million shares of our common stock; see Note K for more details.

Agreement Structure

Under the terms of the Collaboration Agreement, we received a non-creditable, nonrefundable upfront payment of \$25.0 million. In addition, the parties will share all costs and profits for the GITR and OX40 antibody programs on a 50:50 basis (profit-share products), and we are eligible to receive up to \$20 million in future contingent development milestones under these programs. Incyte is obligated to reimburse us for all development costs that we incur in connection with the TIM-3 and LAG-3 antibody programs (royalty-bearing products) and we are eligible to receive (i) up to \$155 million in future contingent development, regulatory, and commercialization milestone payments and (ii)

tiered royalties on global net sales at rates generally ranging from 6% to 12%. For each royalty-bearing product, we will also have the right to elect to co-fund 30% of development costs incurred following initiation of pivotal clinical trials in return for an increase in royalty rates. Additionally, we retain co-promotion participation rights in the United States on any profit-share product. Through the direction of a joint steering committee, the parties anticipate that, for each program, we will serve as the lead for pre-clinical development activities through investigational new drug application filing, and Incyte will serve as the lead for clinical development activities. The parties expect to initiate the first clinical trials of antibodies arising from these programs in 2016. For each additional program beyond GITR, OX40, TIM-3 and LAG-3 that the parties elect to bring into the collaboration, if any, we will have the option to designate it as a profit-share product or a royalty-bearing product.

The Collaboration Agreement will continue as long as (i) any product is being developed or commercialized or (ii) the discovery period remains in effect. After the first anniversary of the effective date of the Collaboration Agreement, Incyte may terminate the Collaboration Agreement or any individual program for convenience upon 12 months' notice. The Collaboration Agreement may also be terminated by either party upon the occurrence of an uncured material breach of the other party or by us if Incyte challenges patent rights controlled by us. In addition, either party may terminate the Collaboration Agreement as to any program if the other party is acquired and the acquiring party controls a competing program.

Collaboration Revenue

For the three and nine months ended September 30, 2015, we have recognized revenue of approximately \$6.5 million and \$16.1 million, respectively, under the Collaboration Agreement, of which, \$2.6 million and \$6.6 million, respectively, is related to the amortization of the \$25.0 million non-creditable, nonrefundable upfront payment. As of September 30, 2015, we have deferred revenue outstanding under the Collaboration Agreement of approximately \$18.4 million, of which approximately \$5.8 million and \$12.6 million are classified as current and long-term, respectively, on our condensed consolidated balance sheet.

Note I - Fair Value Measurements

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

The fair value of our \$3.7 million contingent purchase price consideration is based on significant inputs not observable in the market, which require it to be reported as a Level 3 liability within the fair value hierarchy. The valuation of this liability uses assumptions we believe would be made by a market participant. In particular, the fair value of our contingent purchase price consideration is based on estimates from a Monte Carlo simulation of our market capitalization and other factors impacting the probability of triggering the milestone payments. Market capitalization was evolved using a geometric brownian motion, calculated daily for the life of the contingent purchase price consideration.

We completed the valuation analysis for the contingent royalty obligation using discounted cash flow based on the sum of the economic income that an asset is anticipated to produce in the future. In this case, that asset was the potential royalty income to be paid to us as a result of certain license agreements for QS-21 Stimulon. The fair value of the contingent royalty obligation was estimated by applying a risk adjusted discount rate (10.2%) to the probability adjusted royalty revenue stream based on expected approval dates. These fair value estimates were most sensitive to changes in the probability of regulatory approvals.

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

Description	September 30, 2015	Significant		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Short-term investments	\$ 14,994	\$ 14,994	\$ —	\$ —
Liabilities:				

Edgar Filing: AGENUS INC - Form 10-Q

Description	2014	December 31, (Level 1)	Quoted Prices in Active Markets for Identical Assets (Level 2)	Other Observable Inputs (Level 3)	Significant Unobservable Inputs (Level 3)
Significant					
Significant					
Unobservable					
Inputs					
Inputs					
(Level 3)					
Assets:					
Short-term investments	\$ 14,510	\$ 14,510	\$ —	\$ —	
Liabilities:					
Contingent royalty obligation	15,279	—	—	15,279	
Contingent purchase price consideration	16,420	—	—	16,420	
Total	\$ 31,699	\$ —	\$ —	\$ 31,699	

Edgar Filing: AGENUS INC - Form 10-Q

The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3), as of September 30, 2015 (amounts in thousands):

Balance, December 31, 2014	\$31,699
Change in fair value of contingent royalty obligation during the	
period	6,863
Change in fair value of contingent purchase price consideration	
during the period	7,327
Payment of contingent purchase price milestone	(20,000)
Settlement of contingent royalty obligation	(22,142)
Balance, September 30, 2015	\$3,747

The change in fair value of the contingent royalty obligation liability is included in non-operating (expense) income in our condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2015. There were no changes in the valuation techniques during the period and there were no transfers into or out of Levels 1 and 2.

On January 23, 2015, we achieved the first contingent milestone pursuant to the terms of our Share Exchange Agreement dated January 10, 2014, by and among us, 4-AB, the former shareholder of 4-AB and Vischer AG, as Representative (the "Share Exchange Agreement"), and accordingly we paid \$20.0 million.

As outlined in Note F, we settled our contingent royalty obligation owed to Ingalls for consideration of \$22.1 million as of the transaction date, which we concluded approximated its fair value.

The estimated fair values of all of our financial instruments, excluding our outstanding debt, approximate their carrying amounts in the condensed consolidated balance sheets. The fair value of our outstanding 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 outstanding debt balance at September 30, 2015 and December 31, 2014 was \$116.2 million and \$6.1 million, respectively, based on the Level 2 valuation hierarchy of the fair value measurements standard using a present value methodology. The principal amount of our outstanding debt balance at September 30, 2015 and December 31, 2014 was \$114.1 million and \$6.3 million, respectively.

Note J - Share-based Compensation Plans

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

Edgar Filing: AGENUS INC - Form 10-Q

A summary of option activity for the nine months ended September 30, 2015 is presented below:

	Options	Weighted Average Exercise Price	Weighted Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2014	6,525,724	\$ 4.40		
Granted	2,585,544	5.93		
Exercised	(458,678)	3.83		
Forfeited	(292,426)	3.77		
Expired	(133,373)	9.87		
Outstanding at September 30, 2015	8,226,791		7.63	\$5,965,193
Vested or expected to vest at September 30, 2015	7,522,580	\$ 4.79	7.47	\$5,372,584
Exercisable at September 30, 2015	4,134,451	\$ 5.07	6.62	\$2,825,031

The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2015 and 2014, were \$3.85 and \$1.85, respectively.

Edgar Filing: AGENUS INC - Form 10-Q

As of September 30, 2015, \$8.8 million of total unrecognized compensation cost related to stock options granted to employees and directors is expected to be recognized over a weighted average period of 1.8 years.

As of September 30, 2015, unrecognized expense for options granted to outside advisors for which performance (vesting) has not yet been completed but the exercise price of the option is known is \$651,000. Such amount is subject to change each reporting period based upon changes in the fair value of our common stock, expected volatility, and the risk-free interest rate, until the outside advisor completes his or her performance under the option agreement.

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

A summary of nonvested stock activity for the nine months ended September 30, 2015 is presented below:

	Weighted Average	
	Nonvested	Grant Date
	Shares	Fair Value
Outstanding at December 31, 2014	78,828	\$ 3.93
Granted	1,720,430	8.70
Vested	(35,332)	3.97
Forfeited	(29,105)	8.57
Outstanding at September 30, 2015	1,734,821	\$ 8.58

As of September 30, 2015, there was \$11.7 million of unrecognized share-based compensation expense related to these nonvested shares awarded to employees of which \$108,000 is expected to be recognized over a weighted average period of 1.4 years. The remaining \$11.6 million of unrecognized share-based compensation expense relates to performance based awards for which, if all milestones are achieved, will be recognized over a 3 year period. As of September 30, 2015, unrecognized expense for nonvested shares awarded to outside advisors is \$28,000. The total intrinsic value of shares vested during the nine months ended September 30, 2015, was \$140,000.

During the nine months ended September 30, 2015, 63,539 shares were issued under the 2009 Employee Stock Purchase Plan, 35,332 shares were issued as a result of the vesting of nonvested stock and 458,678 shares were issued as a result of stock option exercises.

The impact on our results of operations from share-based compensation for the three and nine months ended September 30, 2015, and 2014, was as follows (in thousands):

	Three months ended		Nine months ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Research and development	\$ 453	\$ 274	\$ 1,695	\$ 936
General and administrative	320	1,005	3,523	2,765

Total share-based compensation expense	\$ 773	\$ 1,279	\$ 5,218	\$ 3,701
----------------------------------------	--------	----------	----------	----------

Note K - Equity

On January 9, 2015, in connection with the execution of the Collaboration Agreement, we also entered into the Stock Purchase Agreement with Incyte Corporation, pursuant to which Incyte purchased approximately 7.76 million shares of our common stock (the "Shares") in February 2015 for an aggregate purchase price of \$35.0 million, or approximately \$4.51 per share. Under the Stock Purchase Agreement, Incyte has agreed not to dispose of any of the Shares for a period of 12 months and we agreed to register the Shares for resale under the Securities Act of 1933, as amended (the "Securities Act").

In connection with the achievement of the first contingent milestone pursuant to the Share Exchange Agreement, in March and April 2015, we issued 50,596 shares of our common stock valued at approximately \$217,000 and 29,897 shares of our common stock valued at approximately \$128,000, respectively, as payment of a portion of our obligation.

In April 2015, in accordance with the payment terms of an asset purchase agreement, as detailed in Note L, we issued 574,140 shares of our common stock to the members of Celexion valued at \$3.0 million.

In May 2015, we issued and sold 12,650,000 shares of our common stock in an underwritten public offering. Net proceeds after deducting offering expenses were approximately \$75.0 million.

In September 2015, in accordance with the terms of the Assignment and Termination Agreement detailed in Note F, we issued 300,000 shares of our common stock to Ingalls valued at \$2.1 million.

Note L - Asset Purchase Agreement

On April 7, 2015 (the "Celexion Closing Date"), we entered into an Asset Purchase Agreement (the "Purchase Agreement") with Celexion and each of the members of Celexion, pursuant to which, we acquired Celexion's SECANT yeast display antibody discovery platform, its full-length IgG antibody library, its technology for the discovery of molecules targeting cell membrane-associated antigens, and certain other related intellectual property assets (collectively, the "Purchased Assets"). As consideration for the Purchased Assets, on the Celexion Closing Date we paid Celexion \$1.0 million in cash and issued Celexion 574,140 shares of our common stock valued at approximately \$5.23 per share. As additional consideration for the Purchased Assets, we agreed under the Purchase Agreement to pay to Celexion (i) \$1.0 million in cash payable on each of the 9-month and 18-month anniversaries of the Celexion Closing Date and (ii) \$4.0 million on each of the 12-month and 24-month anniversaries of the Celexion Closing Date payable at our discretion in cash, shares of our common stock, or any combination thereof. If we elect to pay any of the additional consideration in shares of our common stock, such shares will be issued at a price per share equal to the simple average of the daily closing volume weighted average price over the 20 trading days preceding the date of issuance. We agreed to file one or more registration statements under the Securities Act to cover the resale of all shares issued as consideration under the Purchase Agreement. In May 2015, we filed a registration statement covering the resale of 574,140 shares issued to Celexion, and the SEC declared the registration statement effective in June 2015. This transaction was accounted for as an asset acquisition in accordance with ASC 805 Business Combinations. In accordance with ASC 730 Research and Development, the purchase price of approximately \$13.2 million was recorded as research and development expense in our condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2015 as the IPR&D was deemed to have no future alternative use, no expense was recorded for the three months ended September 30, 2015.

Note M - Benefit Plans

We maintain a multiple employer benefit plan that covers all of our international employees. The annual measurement date for this plan is December 31. Benefits are based upon years of service and compensation.

For the three and nine months ended September 30, 2015 we contributed approximately \$26,000 and \$80,000, respectively, and for the three and nine months ended September 30, 2014 we contributed approximately \$27,000 and \$81,000, to our international multiple employer benefit plan. For the remainder of the year ending December 31, 2015 we expect to contribute approximately \$24,000 to the plan.

Note N - Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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, 2017. We are currently evaluating the potential impact that ASU 2014-09 may have on our financial position and results of operations.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, ("ASU 2014-15"). ASU 2014-15 describes how an entity should assess its ability to meet obligations and sets rules for how this information should be disclosed in the financial statements. The standard provides accounting that will be used along with existing auditing standards. ASU 2014-15 applies to all entities and is effective for the annual period ending after December 15, 2016, and for annual and interim periods thereafter with early adoption permitted. We are currently evaluating the potential impact that ASU 2014-15 may have on our consolidated financial statements and related disclosures.

In April 2015, the FASB issued ASU No. 2015-03, Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs, ("ASU 2015-03"). ASU 2015-03 simplifies the presentation of debt issuance costs, as this new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt

issuance costs are not affected by this update. This guidance is effective for annual reporting beginning after December 15, 2015, including interim periods within the year of adoption, and calls for retrospective application, with early application permitted. We adopted ASU 2015-03 with the interim period ended September 30, 2015. During the quarter ended September 30, 2015, in connection with the execution of the NPA as described in Note E, the Company incurred approximately \$1.5 million in debt issuance costs that are classified as a reduction to long-term debt in our condensed consolidated balance sheet. No debt issuance costs required retrospective application as the result of the adoption of ASU 2015-03. The amortization of the debt issuance costs for the three and nine months ended September 30, 2015 was minimal.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations
Forward Looking Statements

This Quarterly Report on Form 10-Q and other written and oral statements we make from time to time contain certain "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). You can identify these forward-looking statements by the fact they use words such as "could," "expect," "anticipate," "estimate," "target," "may," "project," "guidance," "intend," "plan," "potential," "opportunity," "future" and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to relate to, among other things, our business strategy, our research and development, our product development efforts, our ability to commercialize our product candidates, the activities of our licensees, our prospects for initiating partnerships or collaborations, the timing of the introduction of products, the effect of new accounting pronouncements, uncertainty regarding our future operating results and our profitability, anticipated sources of funds as well as our plans, objectives, expectations, and intentions.

We have included more detailed descriptions of these risks and uncertainties and other risks and uncertainties applicable to our business that we believe could cause actual results to differ materially from any forward-looking statements in Part II-Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q. We encourage you to read those descriptions carefully. Although we believe we have been prudent in our plans and assumptions, no assurance can be given that any goal or plan set forth in forward-looking statements can be achieved. We caution investors not to place significant reliance on forward-looking statements contained in this document; such statements need to be evaluated in light of all the information contained in this document. Furthermore, the statements speak only as of the date of this document, and we undertake no obligation to update or revise these statements.

Oncophage[®], Stimulon[®], Retrocyte Display[™], and SECANT[®] are trademarks of Agenus Inc. and its subsidiaries. All rights reserved.

Overview

We are an immunology company discovering and developing novel checkpoint modulators, vaccines and adjuvants to treat cancer and other diseases. Our approaches are driven by three platform technologies:

- our antibody platforms, including our proprietary Retrocyte Display, SECANT yeast display, our phage display technologies, and our antibody programs, including checkpoint modulators, or CPMs;
- our heat shock protein (HSP)-based vaccines; and
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon adjuvant, or QS-21 Stimulon.

We have a portfolio of programs in pre-clinical and clinical stages, including a series of CPMs in investigational new drug (IND)-enabling studies, a HSP-based autologous vaccine candidate for glioblastoma multiforme, or GBM, a form of brain cancer, and a number of advanced QS-21 Stimulon-containing vaccine candidates in late stage development by our partner, GlaxoSmithKline plc (GSK).

For the treatment of cancer, our programs aim to stimulate the immune system to recognize and eradicate cancer cells and disable the mechanisms that cancer cells employ to evade detection and destruction by the immune system. Because of the breadth of our portfolio, we have the ability to combine our proprietary vaccines with a portfolio of checkpoint modulating antibodies against major checkpoint targets to explore and optimize cancer treatments. Our strategy is to develop these agents either alone or in combinations to yield best-in-class treatments. 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 antibody discovery platforms have been applied to the discovery and development of CPMs targeting significant checkpoint targets. Agenus and its partners have pre-clinical programs targeting GITR, OX40, CTLA-4, LAG-3, TIM-3, PD-1, CEACAM1 and other undisclosed checkpoints. In April 2015, we expanded our antibody discovery platform through the acquisition of key antibody assets from Celexion. Among the assets we acquired from Celexion was the SECANT yeast display platform for the generation of novel monoclonal antibodies and efficient integration of drug targets such as CPMs. In July 2015, we entered into a license agreement with Diatheva s.r.l pursuant to which we acquired rights to antibodies targeting CEACAM1, further expanding our antibody capabilities and CPM targets.

17

In January 2015, we announced a broad, global alliance with Incyte Corporation, or Incyte, to pursue the discovery and development of CPMs that initially target GITR, OX40, TIM-3 and LAG-3, and potentially other antibodies for the treatment of patients with cancer. We also began collaborating with Merck Sharp & Dohme Corp, or Merck, in April 2014 to discover antibodies against two undisclosed checkpoint targets. We plan to file two INDs in 2015 for CPM antibody candidates targeting GITR and CTLA-4, and we anticipate initiating clinical trials with the first of our CPM antibody candidates in 2016.

In addition to our internal development efforts, we continue to pursue collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates, as well as explore in-licensing, acquisitions and collaboration 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 activities, and support of our collaborations.

To date, we have financed our operations primarily through the sale of equity and debt securities. We believe that, based on our current plans and activities, our working capital resources at September 30, 2015 will be sufficient to satisfy our liquidity requirements into the first half of 2018. We may attempt to raise additional funds by: (1) pursuing collaboration, 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 antibody discovery platforms, CPM antibody programs, HSP-based 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

Three months ended September 30, 2015 compared to the three months ended September 30, 2014

Revenue: We recognized revenue of approximately \$6.8 and \$1.6 million during the three months ended September 30, 2015 and 2014, respectively. Revenues primarily include fees earned under our license agreements, including approximately \$3.9 million for the three months ended September 30, 2015, related to reimbursement of development costs under our Collaboration Agreement with Incyte, and \$2.7 million and \$1.2 million for the three months ended September 30, 2015 and 2014, 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 and contract manufacturing costs, costs of consultants, and certain administrative costs. Research and development expense increased 250% to \$18.5 million for the three months ended September 30, 2015 from \$5.3 million for the three months ended September 30, 2014. Increased expenses in 2015 primarily relate to an increase in third-party services of \$7.9 million primarily relating to the advancement of our CPM antibody programs, \$1.7 million increase in payroll related expenses due in increases in headcount, and \$2.5 million in one-time technology license fees.

General and administrative: General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 30% to \$6.4 million for the three months ended September 30, 2015 from \$4.9 million for the three months ended September 30, 2014. Increased general and administrative expenses in 2015 primarily relate to a \$1.5 million increase in professional fees related to our corporate activities.

Contingent purchase price consideration fair value adjustment: Contingent purchase price consideration fair value adjustment represents the change in the fair value of our contingent purchase price consideration which has decreased due to our decreased market capitalization during the periods and the corresponding estimated length of time to achieve the second and third milestones under our 4-AB Share Exchange Agreement.

Non-operating (expense) income: Non-operating expense for the three months ended September 30, 2015 represents the fair value adjustment of our contingent royalty obligation of \$495,000 and foreign currency translation loss of \$158,000. Non-operating income for the three months ended September 30, 2014 represents the change in the fair value of our contingent royalty obligation and our then outstanding convertible notes.

Interest expense, net: Interest expense, net increased to approximately \$1.4 million for the three months ended September 30, 2015 from \$310,000 for the three months ended September 30, 2014 due to the issuance of our 2015 Subordinated Notes in February 2015 and the issuance of the Notes under our NPA which was executed in September 2015.

Edgar Filing: AGENUS INC - Form 10-Q

Nine months ended September 30, 2015 compared to the nine months ended September 30, 2014

Revenue: We generated revenue of approximately \$17.2 million and \$5.4 million during the nine months ended September 30, 2015 and 2014, respectively. Revenues primarily include fees earned under our license agreements, including approximately \$9.6 million for the nine months ended September 30, 2015, related to reimbursement of development costs under our Collaboration Agreement with Incyte and \$6.7 million and \$3.0 million for the nine months ended September 30, 2015 and 2014, 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 and contract manufacturing costs, costs of consultants, and administrative costs. Research and development expense increased 250% to \$52.5 million for the nine months ended September 30, 2015 from \$15.0 for the nine months ended September 30, 2014. Increased expenses in 2015 primarily relate to the \$16.0 million increase in third-party services and other expenses relating largely to the advancement of our CPM antibody programs, our \$13.2 million asset acquisition which was expensed as in-process research and development, a \$3.6 million increase in payroll related costs due to increased headcount, and a \$3.6 million in one-time license technology fees.

General and administrative: General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 23% to \$19.9 million for the nine months ended September 30, 2015 from \$16.2 million for the nine months ended September 30, 2014. Increased general and administrative expenses in 2015 primarily relate to a \$1.9 million increase in professional fees related to our corporate activities, and \$1.0 million increase in payroll related expenses due to increased headcount.

Contingent consideration fair value adjustment: Contingent consideration fair value adjustment represents the change in the fair value of our purchase price consideration during the nine months ended September 30, 2015 which resulted in expense of \$7.3 million related to the changes in our market capitalization, including the achievement of the first milestone under our 4-AB Share Exchange Agreement.

Non-operating (expense) income: Non-operating expense for the nine months ended September 30, 2015 represents the change in the fair value of our contingent royalty obligation of \$6.9 million, as well as our foreign currency exchange loss and our loss on extinguishment of our 2013 Notes. Non-operating income for the nine months ended September 30, 2014 represents the change in the fair value of our contingent royalty obligation and our then outstanding convertible notes.

Interest expense, net: Interest expense, net increased to approximately \$2.4 million for the nine months ended September 30, 2015 from \$962,000 for the nine months ended September 30, 2014 due to the issuance of our 2015 Subordinated Notes in February 2015 and the issuance of the Notes under our NPA which was executed in September 2015.

Research and Development Programs

During the nine months ended September 30, 2015, our research and development programs consisted largely of our CPM antibody programs as indicated in the following table (in thousands).

Nine	Year Ended December 31,
months	
ended	

Edgar Filing: AGENUS INC - Form 10-Q

September 30,

2015

Research and Development Program	Product	2015	2014	2013	2012	Prior to 2012	Total
	Prophage Series						
Heat shock proteins for cancer	Vaccines	\$ 3,370	\$6,153	\$5,882	\$5,613	\$292,033	\$313,051
Heat shock proteins for infectious diseases	HerpV	273	2,443	6,358	4,862	19,088	33,024
	QS-21						
Vaccine adjuvant	Stimulon	126	321	753	85	12,498	13,783
Checkpoint modulator programs*		48,263	13,422	—	—	—	61,685
Other research and development programs		463	10	12	4	33,540	34,029
Total research and development expenses		\$ 52,495	\$22,349	\$13,005	\$10,564	\$357,159	\$455,572

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

19

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 pre-clinical, and because further development of HSP-based vaccines is dependent on successful partnering or funding efforts, among other factors, 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. Active programs involving QS-21 Stimulon depend on our collaboration 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 \$763.6 million as of September 30, 2015. We expect to incur significant losses over the next several years as we continue development of our technologies and product candidates, manage our regulatory processes, initiate and continue clinical trials, and prepare for potential commercialization of products. To date, we have financed our operations primarily through the sale of equity and debt securities, and interest income earned on cash, cash equivalents, and short-term investment balances. From our inception through September 30, 2015, we have raised aggregate net proceeds of approximately \$837.5 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 and other notes. In February 2015, we received aggregate proceeds of \$60.0 million through our collaboration and stock purchase agreements with Incyte Corporation and issued \$9.0 million in new 2015 Subordinated Notes. In May 2015, we received net proceeds of approximately \$75.0 million through an underwritten public offering of approximately 12,650,000 shares of our common stock after deducting underwriting discounts and commissions and offering expenses (the "May 2015 Public Offering"). In September 2015, we received net proceeds of approximately \$78 million from Antigenics' issuance of limited recourse notes under the Note Purchase Agreement (NPA) with Oberland and the other purchasers.

We also maintain an effective registration statement (the "Shelf Registration Statement"), which originally covered the offering of up to \$150.0 million of common stock, preferred stock, warrants, debt securities and units. The Shelf Registration was used to complete the May 2015 Public Offering, and as of September 30, 2015, \$70.3 million remains available thereunder. The Shelf Registration Statement includes a prospectus covering the offering, issuance and sale of up to ten million shares of our common stock from time to time in "at the market offerings" pursuant to an At Market Sales Issuance Agreement (the "Sales Agreement") entered into with MLV & Co. LLC (the "Sales Agent"). Pursuant to the Sales Agreement, sales will be made only upon instructions by us to the Sales Agent, and we cannot provide any assurances that we will issue any shares pursuant to the Sales Agreement. As of September 30, 2015, we have 10 million shares available for sale under the Sales Agreement.

As of September 30, 2015, we had \$114.1 million of debt outstanding. In April 2013, we entered into a Note Purchase Agreement with various investors for senior subordinated notes (the "2013 Notes") in the aggregate principal amount of \$5.0 million due in April 2015. In February 2015, we exchanged the 2013 Notes for new senior subordinated notes (the "2015 Subordinated Notes") in the aggregate principal amount of \$5.0 million with annual interest at 8% and also issued additional 2015 Subordinated Notes in the aggregate principal amount of \$9.0 million, such notes are due February 2018. In addition, we also issued to the holders of the 2015 Subordinated Notes five year warrants to purchase 1.4 million unregistered shares of our common stock at an exercise price of \$5.10 per share. In September 2015, we and Antigenics entered into a Note Purchase Agreement with Oberland pursuant to which

Antigenics issued, and we guaranteed, limited recourse notes in the aggregate principal amount of \$100.0 million, with an option to issue an additional \$15.0 million principal amount of limited recourse notes. The limited recourse notes are due on the earlier of (i) the 10th anniversary of the first commercial sale of GSK's shingles or malaria vaccines and (ii) September 8, 2030.

Our cash, cash equivalents, and short-term investments at September 30, 2015 were \$199.1 million, an increase of \$158.9 million from December 31, 2014, principally as a result of (i) our collaboration and stock purchase agreements with Incyte which generated aggregate proceeds of \$60.0 million, (ii) our 2015 Subordinated Notes which generated an aggregate of \$9.0 million of new proceeds, (iii) our May 2015 Public Offering in which we received net proceeds of approximately \$75.0 million and (iv) our NPA in which we generated net proceeds of approximately \$78 million. We believe that, based on our current plans and activities, our cash, cash equivalents, and short-term investments of \$199.1 million as of September 30, 2015 will be sufficient to satisfy our liquidity requirements into the first half of 2018. 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 collaboration, 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 antibody discovery platforms, CPM antibody programs, HSP-based 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 contract manufacturers, institutions, and clinical research organizations (collectively "third party providers") to perform pre-clinical activities and to conduct and monitor our clinical studies. Under these agreements, subject to the enrollment of patients and performance by the applicable third party provider, we have estimated our total payments to be \$84.6 million over the term of the related activities. Through September 30, 2015, we have expensed \$65.4 million as research and development expenses and \$61.5 million has been paid under these agreements. The timing of expense recognition and future payments related to these agreements is subject to the enrollment of patients and performance by the applicable third party provider. We have also entered into sponsored research agreements related to our product candidates that required payments of \$6.7 million, all of which have been paid as of September 30, 2015. We plan to enter into additional agreements with third party providers as well as sponsored research agreements, and we anticipate significant additional expenditures will be required to initiate and advance our various programs.

Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing collaboration arrangements with academic and collaboration partners and licensees and by entering into new collaborations. As a result of our collaboration agreements, we will not completely control the efforts to attempt to bring those product candidates to market. For example, our collaboration with Incyte for the development, manufacture and commercialization of CPM antibodies against certain targets is managed by a joint steering committee with equal representation from Agenus and Incyte. We also have agreements with licensees that allow the use of our QS-21 Stimulon adjuvant in numerous vaccines, which 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 products that result from these agreements, which may or may not be achieved. As noted above, in September 2015 we monetized the anticipated royalties related to GSK's shingles and malaria vaccines through our NPA with Oberland and the other purchasers.

Net cash used in operating activities for the nine months ended September 30, 2015 and 2014 was \$27.5 million and \$27.7 million, respectively. This decrease primarily resulted from the receipt of the upfront fees under our Collaboration Agreement with Incyte, partially offset by the payment related to our contingent purchase price consideration during 2015. 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 the 2017 time - frame. 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. In September 2015, we entered into a Note Purchase Agreement and partially monetized the potential royalties we are entitled to receive from GSK. 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 collaboration agreements, and our ability to enter into new collaborations. Under our Collaboration Agreement with Incyte, we are required to share costs with Incyte on a 50:50 basis under the G1TR and OX40 programs; there is a potential for these costs to be high and the development program budgets for these antibodies to not be in our complete control.

Recent Accounting Pronouncements

In May 2014, ASU No. 2014-09 was issued which 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, 2017 for public entities. We are currently evaluating the potential impact that ASU 2014-09 may have on our financial position and results of operations.

In August 2014, ASU No. 2014-15 was issued which describes how an entity should assess its ability to meet obligations and sets rules for how this information should be disclosed in the financial statements. The standard provides accounting guidance that will be used along with existing auditing standards. ASU 2014-15 applies to all entities and is effective for the annual period ending after

December 15, 2016, and for annual and interim periods thereafter with early adoption permitted. We are currently evaluating the potential impact that ASU 2014-15 may have on our consolidated financial statements and related disclosures.

In April 2015, ASU 2015-03 was issued which simplifies the presentation of debt issuance costs, this new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by this update. This guidance is effective for annual reporting beginning after December 15, 2015, including interim periods within the year of adoption, and calls for retrospective application, with early application permitted. We adopted ASU 2015-03 during the period ended September 30, 2015. The adoption of this guidance did not have a material impact on our financial position, overall results of operations or cash flows. During the quarter ended September 30, 2015, in connection with the execution of the NPA as described in Note E, the Company incurred approximately \$1.5 million in debt issuance costs that are classified as a reduction to long-term debt in our condensed consolidated balance sheet. No debt issuances costs required retrospective application as the result of the adoption of ASU 2015-03. The amortization of the debt issuance costs for the three and nine months ended September 30, 2015 were minimal.

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 17% and 22% of our operating expenses for the nine months ended September 30, 2015 and the year ended December 31, 2014, respectively, were from a foreign subsidiary. 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 wholly-owned subsidiary, 4-Antibody, 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, 2014.

We had cash, cash equivalents and short-term investments at September 30, 2015 of \$199.1 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 U.S. Treasury Bills, our carrying value approximates the fair value of these investments at September 30, 2015.

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.

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 third quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 occur, 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2015.

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 "Management's Discussion and Analysis of Financial Condition and Results of Operations-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, 2014, 2013, and 2012, were \$42.5 million, \$30.1 million, and \$11.3 million, respectively. During the nine months ended September 30, 2015, we generated a net loss of \$72.3 million.

We expect to incur additional losses over the next several years as we continue research and development of our technologies and pursue partnering opportunities, regulatory strategies, commercialization, and related activities. Furthermore, our ability to generate cash from operations is dependent on the success of our licensees and collaboration partners, as well as the likelihood and timing of new strategic licensing and partnering relationships and/or successful development and commercialization of product candidates, including through our collaboration with Incyte, our HSP-based vaccines, and vaccines containing QS-21 Stimulon.

On September 30, 2015, we had \$199.1 million in cash, cash equivalents, and short-term investments. We believe that, based on our current plans and activities, our working capital resources at September 30, 2015, will be sufficient to satisfy our liquidity requirements into the first half of 2018. We expect to attempt to raise additional funds in advance of depleting our current funds although additional funding may not be available on favorable terms, or at all. For the nine months ended September 30, 2015, our average monthly cash used in operating activities was approximately \$3.1 million. This average monthly cash used in operating activities primarily resulted from one-time upfront payments of \$25.0 million received under our Collaboration Agreement with Incyte in the first quarter of 2015, and therefore, our net cash used in operations for the nine months ended September 30, 2015 is not indicative of future results.

To date, we have financed our operations primarily through the sale of equity and debt securities. In order to finance future operations going forward, we will be required to raise additional funds in the capital markets, through arrangements with collaboration partners, such as our global alliance with Incyte, 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 are on unfavorable terms or 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 and our partners pursue;
- our ability to successfully develop, manufacture, and commercialize product candidates, including pursuant to our collaboration agreement with Incyte;
- our ability to find a partner or alternative means of financing for Prophage;
- the scope, progress, results and costs of researching and developing our future product candidates, and conducting pre-clinical and clinical trials, including with respect to our GITR and OX40 antibody programs, for which we have agreed to share all costs and profits with Incyte on a 50:50 basis;
- the timing of, and the costs involved in, obtaining regulatory approvals for our and our licensees' product candidates;
- the cost of manufacturing;

24

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such arrangements;
- 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 and those of our partners, 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 future products, if any, could also be adversely impacted, thereby limiting our potential revenue. In addition, any negative impacts from any deterioration in the credit markets on our collaboration partners could limit potential revenue from our product candidates.

Our and our subsidiaries' obligations related to our monetization of royalties payable to us by GlaxoSmithKline in respect of its shingles vaccine, HZ/su, along with our 2015 Subordinated Notes, could materially and adversely affect our liquidity.

In September 2015, we and our wholly-owned subsidiary, Antigenics LLC ("Antigenics"), entered into a Note Purchase Agreement (the "Note Purchase Agreement") with Oberland Capital SA Zermatt LLC, as collateral agent, an affiliate of Oberland as the lead purchaser and certain other purchasers, pursuant to which Antigenics issued \$100.0 million aggregate principal amount of limited recourse notes (the "Notes") to the purchasers. Antigenics has the option to issue an additional \$15.0 million aggregate principal amount of Notes (the "Additional Notes") to the purchasers within 15 days after approval of GlaxoSmithKline's ("GSK") shingles vaccine, HZ/su, by the Food and Drug Administration, provided such approval occurs on or before June 30, 2018. The Notes accrue interest at a rate of 13.5% per annum, compounded quarterly, from and after September 8, 2015 (the "Closing Date"). Principal and interest payments are due on each of March 15, June 15, September 15 and December 15, and shall be made solely from the royalties paid from GSK to Antigenics on sales of GSK's shingles and malaria vaccines. GSK will send all royalty payments to a segregated bank account, and to the extent there are insufficient royalties deposited into the account to fund a quarterly interest payment, the interest will be capitalized and added to the aggregate principal balance of the loan. The final legal maturity date of the Notes is the earlier of (i) the 10th anniversary of the first commercial sale of GSK's shingles or malaria vaccines and (ii) September 8, 2030 (the "Maturity Date").

On September 8, 2018, each purchaser has the option to require Antigenics to repurchase up to 15% of the Notes issued to such purchaser on the Closing Date (the "Put Notes") at a purchase price equal to the principal amount thereof plus accrued and unpaid interest thereon (the "Put Payment"). On the earlier of (i) September 8, 2027 and (ii) the Maturity Date, Antigenics is required to pay the purchasers an amount equal to the following (the "Make-Whole Payment"): \$100 million (or \$115 million if the Additional Notes are sold) minus the aggregate amount of all payments made in respect of the Notes (regardless of whether characterized as principal or interest at the time of payment), including the original principal amount of any repaid Put Notes.

The Note Purchase Agreement specifies a number of events of default (some of which are subject to applicable cure periods), including (i) failure to cause royalty payments to be deposited into the segregated bank account, (ii) payment defaults, (iii) breaches of representations and warranties made at the time the Notes were, or the Additional Notes are, issued, (iv) covenant defaults, (v) a final and unappealable judgment against Antigenics for the payment of money in excess of \$1.0 million, (vi) bankruptcy or insolvency defaults, (vii) the failure to maintain a first-priority perfected security interest in the collateral in favor of the collateral agent and (viii) the occurrence of a change of control of Agenus. Upon the occurrence of an event of default, subject to cure periods in certain circumstance and some limited exceptions, the collateral agent may declare the Notes immediately due and payable, in which case Antigenics would owe a payment equal to the following (the "Accelerated Default Payment"): the outstanding principal amount of the Notes, plus all accrued and unpaid interest thereon, plus a premium payment that would yield an aggregate internal rate of return ("IRR") for the purchasers as follows: (i) an IRR of 20% if the event of default occurs within 24 months of the Closing Date, (ii) an IRR of 17.5% if the event of default occurs after 24 months but within 48 months of the

Closing Date, and (iii) an IRR of 15% if the event of default occurs more than 48 months after the Closing Date. Upon the occurrence and during the continuance of any event of default, interest on the Notes also increases by 2.5% per annum.

We are a party to the Note Purchase Agreement as a guarantor of Antigenics, and we generally guarantee the Put Payment, the Make-Whole Payment and the Accelerated Default Payment. If we are obligated to make the Put Payment or the Make-Whole Payment, our liquidity would be materially and adversely affected. If we or Antigenics default on the Notes and we are obligated to pay the Accelerated Default Payment, our liquidity would be materially and adversely affected. Satisfaction of the Notes will depend upon the future sales of GSK's shingles and malaria vaccines, if approved, and, if we are obligated to make the Put Payment, the Make-Whole Payment or the Accelerated Default Payment, our future performance, which is subject to many factors, including the factors identified in this "Risk Factors" section and other factors beyond our control.

In February 2015, we exchanged the senior subordinated promissory notes that we issued in 2013 for new senior subordinated promissory notes in the aggregate principal amount of \$5.0 million with annual interest at 8%, and we issued an additional \$9.0 million principal amount of such notes, or the 2015 Subordinated Notes. The 2015 Subordinated Notes are due February 2018 and include default provisions that allow for the acceleration of the principal payment of the 2015 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 2015 Subordinated Notes, default on other indebtedness with an aggregate principal balance of \$13.5 million or more if such default has the effect of accelerating the maturity of such indebtedness, or become subject to a legal judgment or similar order for the payment of money in an amount greater than \$13.5 million if such amount will not be covered by third-party insurance. If we default on the 2015 Subordinated Notes and the repayment of such indebtedness is accelerated, our liquidity could be materially and adversely affected.

If we do not have sufficient cash on hand to pay any of the Put Payment, the Make-Whole Payment or the Accelerated Default Payment when due, or to otherwise service our 2015 Subordinated Notes, 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 favorable terms, if at all.

We are dependent upon our collaboration with Incyte to further develop, manufacture and commercialize CPM antibodies against certain targets. If we or Incyte fail to perform as expected, the potential for us to generate future revenues under the collaboration would be significantly reduced, the development and/or commercialization of these CPM antibodies may be terminated or substantially delayed, and our business would be severely harmed.

Under the terms of our Collaboration Agreement with Incyte, we and Incyte have created a joint steering committee that oversees and manages worldwide regulatory, development, manufacturing, and commercialization activities for our CPM antibody product candidates with equal representation from both parties. We anticipate that, for each program, Agenus will serve as the lead for pre-clinical development activities through the filing of an investigational new drug application, or IND, and Incyte will serve as the lead for clinical development activities. Accordingly, the timely and successful completion by Incyte of clinical development activities will significantly affect the timing and amount of any revenues we may receive under the collaboration agreement. Incyte's activities will be influenced by, among other things, the efforts and allocation of resources by Incyte, which we cannot control. If Incyte does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, manufacturing, regulatory approval, and commercialization efforts related to CPM antibodies under the collaboration could be delayed or terminated, and it could become necessary for us to assume the responsibilities for the clinical development, manufacturing, regulatory approval or commercialization of the CPM antibodies at our own expense. Accordingly, there can be no assurance that any of the development, regulatory or sales milestones will be achieved, that we will receive any future milestone or royalty payments under the collaboration agreement, or that we will share in any revenues under the Collaboration Agreement.

In addition, our collaboration with Incyte may be unsuccessful due to other factors, including, without limitation, the following:

- After February 19, 2016, Incyte may terminate the agreement or any individual program for convenience upon 12 months' notice;
- We may have disagreements with Incyte that are not settled amicably or in our favor, particularly on the joint steering committee where Incyte will under most circumstances have the deciding vote in the event of a

disagreement;

- Incyte may change the focus of its development and commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to our collaboration;
- Incyte may choose not to develop and commercialize CPM products, if any, in all relevant markets or for one or more indications, if at all; and
 - If Incyte is acquired during the term of our collaboration, the acquirer may have competing programs or different strategic priorities that could cause it to reduce its commitment to our collaboration.

If Incyte terminates our Collaboration Agreement, we would need to raise additional capital and may need to identify and come to agreement with another collaboration partner to advance our CPM programs. Even if we are able to find another partner, this effort

could cause delays in our timelines and/or additional expenses, which could adversely affect our business prospects and the future of our CPM antibody product candidates.

Our CPM programs are in pre-clinical development, and there is no guarantee that they will be successful or produce any revenues from CPM antibody product candidates, if any.

Our CPM programs are currently in pre-clinical development. Even if our pre-clinical studies produce positive results, they may not necessarily be predictive of the results of future clinical trials in humans. Many companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in pre-clinical development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including adverse events. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials nonetheless failed to obtain regulatory approval. If we fail to produce positive results in future clinical trials of CPM antibodies, our business and financial prospects would be materially adversely affected.

We are undergoing significant growth across multiple locations, and we may encounter difficulties in managing this growth, which could disrupt our operations.

From January 1, 2014 to September 30, 2015 we increased our employee headcount from 68 to 175, 62 of whom are employees of our wholly-owned subsidiary 4-Antibody AG (4-AB), which we acquired in February 2014. In addition, through 4-AB, we also expanded our research and development activities internationally to Switzerland and Germany. We anticipate opening additional locations in the future. In April 2015, we further expanded our antibody discovery platform through the acquisition of antibody platform assets from Celexion, LLC. We expect to continue increasing our headcount as we continue to build our research and development capabilities and integrate our acquired technology platforms. To manage this anticipated growth and expansion, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit, train and retain qualified personnel. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate revenue could be reduced, and we may not be able to implement our business strategy.

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

We currently rely upon and expect to continue to rely upon third party licensees, particularly GSK, to develop, test, market and manufacture vaccines that utilize our QS-21 Stimulon adjuvant.

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. In addition, clinical trials being conducted by our licensees 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, GSK announced the Phase 3 trial of their MAGE-A3 cancer immunotherapeutic in melanoma missed its first co-primary endpoint and that the study would continue until completion of its second co-primary endpoint. As previously disclosed, this trial failed to demonstrate a statistically significant improvement for its second co-primary endpoint or any subgroup analysis. 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 QS-21 Stimulon. In addition, even if our licensees successfully complete clinical trials with vaccine candidates using QS-21 Stimulon or these vaccine candidates receive positive decisions from regulatory bodies, there is no guarantee that these products will ultimately obtain regulatory approval or, if so approved, will generate any future milestones or royalty payments.

In September 2015, we entered into the Note Purchase Agreement and partially monetized the potential royalties we are entitled to receive from GSK on future sales of its shingles and malaria vaccines, if any. All of the royalties that are payable to us from GSK on sales of these products candidates, if any, will be used entirely to satisfy our obligations to the purchasers of the Notes. If and when we have received enough royalties to satisfy all principal and interest on the Notes, then we will be entitled to keep any remaining royalties. However, there is no guarantee that GSK's vaccines will be approved and generate enough sales to produce any such remaining royalties for us or to satisfy our obligations under the Note Purchase Agreement.

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 HSP peptide-based platform for infectious diseases is in early stage development, and there is no guarantee that a product candidate will progress from this platform.

In June 2014, we reported positive results from a Phase 2 trial with our HerpV vaccine candidate for genital herpes, which includes QS-21 Stimulon. While the HerpV Phase 2 trial met its formal endpoints, it is unclear that the magnitude of the effect on viral load would be sufficient to significantly reduce the incidence, severity, or duration of herpetic lesions or reduce the risk of viral transmission. We do not currently expect to advance this program into a Phase 3 trial. We are currently in the process of evaluating the broader application of our HSP peptide-based vaccines beyond genital herpes, but there is no guarantee that a product candidate will progress from this platform. Furthermore, it is possible that research and discoveries by others will render any product candidate obsolete or noncompetitive.

We may not be able to advance clinical development or commercialize Prophage vaccines or realize any benefits from this program without a partner or alternative means of financing.

The probability of future clinical development efforts leading to marketing approval and commercialization of Prophage vaccines is highly uncertain. Prophage 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 vaccines have resulted in a marketing approval, except in Russia where commercialization of the approved product was unsuccessful. Although we have been considering initiating a pivotal clinical trial in newly diagnosed GBM in 2015, we have limited resources and competing corporate priorities, and do not currently plan to do so without the support of a partner or alternative means of financing. We are exploring these options, but are currently not in advanced discussions with any potential partner or funding source. In addition, while we believe Prophage vaccines may provide clinical benefit to some patients as a monotherapy and in combination with other therapies, there is no guarantee that we will be in a position to conduct these trials or that, if completed, they would yield useful translational and/or efficacy data.

We do not currently sponsor any of the on-going clinical trials with Prophage 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 the unlikelihood that results will support timely or successful regulatory filings. Currently, the only actively enrolling Prophage vaccine clinical trial is a Phase 2 trial of Prophage vaccine in combination with 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 National Cancer Institute (NCI). While the NCI Alliance has confirmed a commitment to completion of the trial, 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 bevacizumab for the treatment of recurrent glioma could exacerbate enrollment issues and/or render the trial design impractical. In January 2014, we initiated a randomized Phase 2 trial with Prophage vaccine and Bristol-Myers Squibb's 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 IND was activated to allow initiation of the trial, patient enrollment has not yet begun. While we believe the combination of Prophage vaccines 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.

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.

Our CPM antibody programs, including those partnered with Incyte, will require substantial manufacturing development and investment to progress. Our CPM antibody programs are pre-clinical, 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. We rely on contract manufacturing organizations (CMOs) and contract research organizations (CROs), to support our CPM antibody programs. Our dependence on external CMOs for the manufacture of our antibodies results in intrinsic risks to our performance, timelines, and costs of our accelerated development plans. We may need to secure additional manufacturing capacity with our current or additional CMOs and/or develop or secure our own manufacturing capabilities, all of which would cause us to incur additional costs and risk. Such efforts could also divert resources away from our CPM antibody programs and/or lead to delays in the development of our product candidates. We may 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 qualified 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 currently manufacture our Prophage vaccines in our Lexington, MA facility. Manufacturing of the Prophage vaccines is complex, and various factors could cause delays or an inability to supply the 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 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 vaccines in addition to other product candidates in our current facility.

We have given our corporate QS-21 Stimulon licensees, GSK and Janssen Sciences Ireland Uc, manufacturing rights for QS-21 Stimulon for use in their product programs. If GSK or its third party CMO encounters problems with QS-21 Stimulon manufacturing, any of their programs containing QS-21 Stimulon could be delayed or terminated, and this could have an adverse effect on our potential license fees, milestone payments and royalties that we may otherwise receive from these programs and use to satisfy our obligations under the Note Purchase Agreement. 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.

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, pre-clinical studies, clinical trials, and any future 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.

As mentioned above, 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 a product candidate. In addition, facilities are subject to on-going 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 research and development operations in Switzerland and Germany and anticipate additional locations outside of the United States. We expect to pursue pathways to develop and commercialize our product candidates in both U.S. non-U.S. jurisdictions. 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 requirements to comply with various jurisdictional requirements such as data privacy regulations, 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. For example, in 2008 our Oncophage® vaccine was approved for sale in Russia, but we have never received, and do not expect to receive, any revenues from sales in Russia. 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. Further, even if we receive marketing approval, we may not receive sufficient coverage and adequate reimbursement for our products.”

Our competitors 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 collaboration 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:

- develop safer or more effective therapeutic drugs or preventive vaccines and other therapeutic products;
- 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, if ever;
- adversely affect our ability to recruit patients for our clinical trials;
- solidify partnerships or strategic acquisitions that may increase the competitive landscape;
 - commercialize their product candidates sooner than we commercialize our own, if ever; or
- implement more effective approaches to sales and marketing and capture some of our potential market share.

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

We have CPM antibody programs currently in pre-clinical development targeting GITR, OX40, CTLA-4, LAG-3, TIM-3, PD-1 and CEACAM1. We are aware of many companies that have antibody-based products on the market or in clinical development that are directed to the same biological target as some of our programs, including, without limitation, the following: (1) Bristol-Myers Squibb markets ipilimumab, an anti-CTLA-4 antibody, and nivolumab, an anti-PD-1 antibody, and is developing an anti-LAG-3 antibody and agonist to OX-40 (2) Merck has an approved anti-PD-1 antibody in the United States, and is developing an anti-GITR agonist and anti-CEACAM antibodies (3) Ono Pharmaceuticals has an approved anti-PD-1 antibody in Japan, (4) AstraZeneca /Medimmune has anti-CTLA-4, OX-40 and PD1 antibodies in development, (5) Curetech has an anti-PD-1 antibody in development, (6) Pfizer has an anti-CTLA-4 antibody in development, (7) Tesaro has antibody programs targeting PD-1, TIM-3 and LAG-3, which include both monospecific and dual reactive antibody drug candidates, (8) Novartis has anti-PD-1 and anti-TIM-3 antibodies in discovery, and anti-LAG-3 and GITR agonist in clinical trials (9) Roche/Genetech has an anti-OX40 agonist in development. There is no guarantee that our antibody product candidates will be able to compete with our competitors' antibody products and product candidates.

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, (1) oligonucleotides, under development by Pfizer, Idera, Colby, and Dynavax, (2) MF59, under development by Novartis, (3) IC31, under development by Intercell, and (4) 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 to our ability to execute future partnering and licensing arrangements involving QS-21 Stimulon. The existence of products developed by these and other competitors, or other products of which we are not aware or which other companies may develop in the future, may adversely affect the marketability of products we and our partners develop.

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 future products, if any, incorporating this technology, either alone or with a third party.

In competition with our Prophage product candidates, Genentech markets bevacizumab, and Eisai and Arbor Pharmaceuticals market carmustine. In addition, TVAX Biomedical and Stemline Therapeutics are developing immunotherapy candidates TVI-Brain-1 and SL-701, respectively, for recurrent glioma. Other companies are

developing vaccine candidates for the treatment of patients with newly diagnosed glioma, such as ImmunoCellular Therapeutics (ICT-107), Northwest Biotherapeutics (DC-Vax), Immatics (IMA-950), Activartis Biotech (GBM-Vax), Annias Immunotherapeutics (CMV Vaccine) and Celldex (CDX-110). Other companies may begin development programs as well.

If any of our Prophage Services vaccines are developed in other indications or in combination with other product candidates, such as with CPMs, they could face additional competition in those indications or in those combinations. In addition, and prior to regulatory approval, if ever, our Prophage vaccines and all of our other product candidates may compete for access to patients with other products in clinical development, with products approved for use in the indications we are studying, or with off-label use of products in the indications we are studying. We anticipate that we will face increased competition in the future as new companies

enter markets we seek to address and scientific developments surrounding immunotherapy and other traditional cancer therapies continue to accelerate.

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

An important part of our business strategy is to continue to identify and advance 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 technologies, products or product candidates;
 - 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 technologies, operations and personnel of any acquired businesses with our technologies, 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 to 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.

As previously noted, our ability to advance our CPM programs depends in part on collaboration agreements such as our collaboration with Incyte. See "Risk Factors—Risks Related to Our Business—We are dependent upon our collaboration with Incyte to further develop, manufacture and commercialize CPM antibodies against certain targets using our proprietary antibody discovery platforms. If we or Incyte fail to perform as expected, the potential for us to generate future revenues under the collaboration would be significantly reduced, the development and/or commercialization of these CPM antibodies may be terminated or substantially delayed, and our business would be severely harmed." In addition, from time to time we engage in efforts to enter into licensing, distribution and/or collaboration agreements with one or more pharmaceutical or biotechnology companies to assist us with development and/or commercialization of our other 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 product candidates may be undermined. In addition, if we do not raise funds through any such agreements, we will need to rely on other financing mechanisms, such as sales of debt or equity securities, to fund our operations. Such financing mechanisms, if available, may not be sufficient or timely enough to advance our programs forward in a meaningful way in the short-term.

While we have been pursuing these business development efforts for several years for our Prophage vaccine, we have not entered into a substantial agreement other than the agreement with NewVac to sell Oncophage in Russia, which was unsuccessful and expired in 2014. In addition, other companies may not be interested in pursuing patient-specific vaccines like our Prophage 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.

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, pre-clinical and clinical testing, completing regulatory applications, and commercializing product candidates. Our research, development, and commercialization efforts with respect to antibody candidates from the Retrocyte Display and SECANT technology platforms are, in part, contingent upon the participation of institutional and corporate collaborators. For example, 4-AB has or has had collaboration arrangements with Ludwig Cancer Research, or LCR, and Brazil-based Recepta Biopharma SA, or Recepta, among others. In December 2014, we entered into a new license agreement with LCR, which replaced the prior agreement for some of our target programs. We are in continued discussions with LCR and Recepta with respect to certain of our other target programs. 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. In February 2015 we began a broad collaboration with Incyte to pursue the discovery and development of CPMs. See “Risk Factors-Risks Related to our Business-We are dependent upon our collaboration with Incyte to further develop, manufacture and commercialize CPM antibodies against certain targets using our proprietary antibody discovery platforms. If we or Incyte fail to perform as expected, the potential for us to generate future revenues under the collaboration would be significantly reduced, the development and/or commercialization of these CPM antibodies may be terminated or substantially delayed, and our business would be severely harmed.”

In addition, substantially all product candidates containing QS-21 Stimulon depend on the success of our collaboration 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 necessary to advance these product candidates, obtaining regulatory approvals, and successfully manufacturing and commercializing product candidates.

To date, the development of Prophage vaccine for the treatment of patients with glioma is dependent, in large part, on the efforts of the Alliance for Clinical Trials in Oncology, a NCI 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 depend on the success of our collaboration 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 manufacturing and commercializing product candidates. We previously granted NewVac an exclusive license to manufacture, market and sell Oncophage in the Russian Federation and certain other CIS countries, but the relationship was unsuccessful and expired in 2014 with no benefit to us.

Development activities for our collaboration 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 collaboration 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 not be able to enter into new collaborations on favorable terms or at all. 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.

Our ability to use net operating loss carryforwards to reduce future tax payments may be limited or restricted.

We have generated significant net operating loss carryforwards, or NOLs, as a result of our incurrence of losses since inception. We generally are able to carry NOLs forward to reduce taxable income in future years. However, our ability to utilize the NOLs is subject to the rules of Section 382 of the Internal Revenue Code of 1986, as amended. Section 382 generally restricts the use of NOLs after an “ownership change.” An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation’s common stock or are otherwise treated as 5% stockholders under Section 382 and the United States Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation’s stock by more than 50 percentage points over the lowest percentage of the stock

owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carry forwards. This annual limitation is generally equal to the product of the value of the corporation's stock on the date of the ownership change, multiplied by the long-term tax-exempt rate published monthly by the Internal Revenue Service. Any unused annual limitation may be carried over to later years until the applicable expiration date for the respective NOL carry forwards. We may have experienced an "ownership change" within the meaning of Section 382 in the past and there can be no assurance that we have not experienced additional ownership changes. As a result, our NOLs may be subject to limitations and we may be required to pay taxes earlier and in larger amounts than would be the case if our NOLs were freely usable. Any such limitation could have a material adverse effect on our results of operations in future years. We are currently in the process of completing a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership changes since our inception.

Our internal computer systems, or those of our third-party clinical research organizations, licensees, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption in our business and operations.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs, CMOs, licensees, collaborators and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, on-going or future clinical trials could result in delays in our regulatory approval efforts and significant costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our drug candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development and commercialization of our product candidates could be delayed.

We are highly reliant on our Chief Executive Officer, Chief Scientific 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.

Both Garo H. Armen, Ph.D., the Chairman of our Board of Directors and our Chief Executive Officer who co-founded the Company in 1994, and Dr. Robert Stein, our Chief Scientific Officer who joined the Company in February 2014, are integral to building our company and developing our technology. If either Dr. Armen or Dr. Stein is unable or unwilling to continue his relationship with Agenus, our business may be adversely impacted.

Effective December 31, 2005, we entered into an employment agreement with Dr. Armen. Subject to the early termination of 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 90 days prior to the expiration of the original or any extension term. Effective June 30, 2015, we entered into an employment agreement with Dr. Stein. Subject to the early termination of the agreement, the agreement has 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 120 days prior to the expiration of the original or any extension term. Dr. Armen and Dr. Stein play important roles in our day-to-day activities. We do not carry key employee insurance policies for Dr. Armen, Dr. Stein or any other employee.

Our future growth success depends to a significant extent on the skills, experience and efforts of our executive officers and key members of our clinical and scientific staff. We face intense competition for qualified individuals from other pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions.

We may be unable to retain our current personnel or attract or assimilate other highly qualified management and clinical personnel in the future on acceptable terms. The loss of any or all of these individuals could harm our business and could impair our ability to support our collaboration with Incyte or to support our expected growth. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate revenue could be reduced and we may not be able to implement our business strategy.

We rely on a small staff of highly trained and experienced senior management and scientific, administrative and operations personnel and consultants to conduct our business in certain key areas of our organization.

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 pre-clinical testing and the process of obtaining and maintaining regulatory approvals for new therapeutic products, is lengthy, expensive, and uncertain. For example, as of September 30, 2015, we have spent approximately 20 years and \$313.1 million on our research and development program in heat shock proteins for cancer. The development and regulatory approval process also can vary substantially based on the type, complexity, and novelty of the product. We must provide regulatory authorities with manufacturing, product characterization, and pre-clinical 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 pre-clinical 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 pre-clinical 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. Pre-clinical and clinical data can be interpreted in different ways, which could delay, limit, or prevent regulatory approval. Negative or inconclusive results from a pre-clinical 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 pre-clinical study or clinical trial to be repeated or cause a program to be terminated, even if other studies or trials relating to the program are successful. We or the FDA, other regulatory agencies, or an institutional review board may suspend or terminate human clinical trials at any time on various grounds.

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

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

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

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

Even if we receive marketing approval for our product candidates, such product approvals could be subject to restrictions or withdrawals. Regulatory requirements are subject to change. Further, even if we receive marketing approval, we may not receive sufficient coverage and adequate reimbursement for our products.

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, corrective action requirements, 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 licensees' or collaborators', and/or our 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 governmental officials for the purpose of obtaining or retaining business abroad.

From time to time, new legislation is passed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA and other foreign health authorities. Additionally, regulations and guidance are often revised or reinterpreted by health agencies in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted, or whether regulations, guidance, or interpretations will change, and what the impact of such changes, if any, may be. For example, the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, collectively, the ACA, enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. With regard to pharmaceutical products, among other things, ACA is expected to expand, increase, and change the methodology regarding industry rebates for drugs covered under Medicaid programs; impose an annual, nondeductible fee on any entity that manufactures or imports specific branded prescription drugs and biologic agents, apportioned among those entities according to market share in certain government healthcare programs; expand eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level; expand the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; create a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; 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. Even if our product candidates are approved, the commercial success of our products will depend substantially on the extent to which they are covered by third-party payors, including government health authorities and private health insurers. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors, and coverage and reimbursement for products can differ significantly from payor to payor. If coverage and reimbursement are not available, or reimbursement is available only to limited levels, we or our collaborators may not be able to successfully commercialize our product candidates.

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 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.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technology. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to duplicate or surpass our technological achievements, eroding our competitive position in the market. Our patent applications may not result in issued patents, and, even if issued, the patents may be challenged and invalidated. Moreover, our patents and patent applications may not be sufficiently broad to prevent others from practicing our technologies or developing competing products. We also face the risk that others may independently develop similar or alternative technologies or may design around our proprietary property.

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.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. 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. For example, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product candidates under patent protection could be reduced.

Our strategy depends on our ability to identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we and our current or future licensors 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. It is also possible that we or our current licensors, or any future licensors or licensees, may not identify patentable aspects of inventions made in the course of development and commercialization activities in time to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc. If we or our current licensors, or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. 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. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

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 impact our freedom to operate in relation to our technology platforms, including Retrocyte Display and SECANT, 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 50 issued United States patents and approximately 120 issued foreign patents. We also have ownership of or exclusive rights to approximately 30 pending United States patent applications and approximately 40 pending foreign patent applications. However, our patents may not protect us against our competitors. Our patent positions, and those of other biopharmaceutical, 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.

Through our acquisitions of 4-AB and certain assets of Celexion, LLC, we 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 such entities' 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 2031. We also own patents and patent applications relating to the SECANT platform, a platform used for the generation of novel monoclonal antibodies and efficient integration of drug targets such as CPMs. This patent family is projected to expire between 2028 and 2029. 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 acquired along with 4-AB, will have commercial value, or that any of our existing or future patent applications, including the patent applications that were acquired with 4-AB, will result in the issuance of valid and enforceable patents.

The issued patents that cover the Prophage vaccine expire at various dates between 2015 and 2024. 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.

The patent position of biopharmaceutical, 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 biopharmaceutical, 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 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.

Third parties may infringe or misappropriate our intellectual property, including our existing patents, patents that may issue to us in the future, or the patents of our licensors to which we have a license. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Further, we may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidates is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent.

In addition, within and outside of the United States, there has been a substantial amount of litigation and administrative proceedings, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions, regarding patent and other intellectual property rights in the biopharmaceutical industry. Recently, the AIA introduced new procedures, including inter partes review and post grant review. These procedures may be used by competitors to challenge the scope and/or validity of our patents, including those that patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges.

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. An adverse outcome may also put our pending patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administrative panel to affect the validity or enforceability of a claim, for example, if a priority claim is found to be improper. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our relevant product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, during the course of litigation or administrative proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Any of these occurrences could adversely affect our competitive business position, business prospects, and financial condition.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage. 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 the patent landscape around the discovery, development, manufacture and commercial use of our pre-clinical CPM antibody programs and therapeutic antibodies is crowded.

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 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 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 biopharmaceutical, 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.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or the American Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents,

even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We may have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biopharmaceutical, biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights

may be adversely affected by unforeseen changes in foreign intellectual property laws.

Risks Related to Litigation

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

From time to time we 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 and/or negligent 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, transparency, and/or data privacy and security 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; to promote transparency; and to protect the privacy and security of patient data. 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.

While we have adopted a corporate compliance program, we may not be able to protect against all potential issues of noncompliance. Efforts to ensure that our business complies with all applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable laws and regulations.

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

Product liability and other claims against us may reduce demand for our products and/or result in substantial damages.

We face an inherent risk of product liability exposure related to testing our product candidates in human clinical trials and may face even greater risks if we ever sell products 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:

- regulatory investigations;
- injury to our reputation;
- withdrawal of clinical trial volunteers;
- costs of related litigation; and
- substantial monetary awards to plaintiffs; and
- decreased demand for any future products.

We manufacture the Prophage 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 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.

43

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

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.

For the period from our initial public offering on February 4, 2000 to September 30, 2015, and for the nine months ended September 30, 2015, the closing price of our common stock has fluctuated between \$1.80 (or \$0.30 pre-reverse stock split) and \$315.78 (or \$52.63 pre-reverse stock split) per share and \$3.91 and \$9.78 per share, respectively. The average daily trading volume for the nine months ended September 30, 2015 was approximately 1,770,623 shares while the average daily trading volume for the year ended December 31, 2014 was approximately 728,000. 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 or delays in any such announcements;
- results of our pre-clinical studies and clinical trials or delays in anticipated timing;
- delays in our regulatory filings or those of our partners, such as our planned IND filings for product candidates;
- announcements of new collaboration agreements with strategic partners or developments by our existing collaboration partners;
- announcements of acquisitions;
 - 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 acquisitions;
- 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 biopharmaceutical, biotechnology and pharmaceutical industries generally;
- 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 biopharmaceutical, biotechnology and pharmaceutical companies generally experience significant stock price volatility.

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

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

The sale by us or the resale by stockholders of a significant number of shares of our common stock could cause the market price of our common stock to decline. As of September 30, 2015, we had 84,646,215 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. As of September 30, 2015, we had 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'

45

Deferred Compensation Plan, to permit the sale of approximately 10,248,000 shares of common stock pursuant to various private placement agreements (including 1,400,000 shares of common stock issuable upon the exercise of certain warrants that we issued in February 2015) and to permit the sale of approximately 10,000,000 shares of our common stock pursuant to our At Market Issuance Sales Agreement. As of September 30, 2015, an aggregate of approximately 23 million of these shares remain available for sale. We also intend to file one or more registration statements to register an additional 4,000,000 shares for issuance under our equity incentive plan and an additional 100,000 shares for issuance under our Directors' Deferred Compensation Plan, both of which were approved by our stockholders at our annual stockholder meeting on June 24, 2015 as well as an additional 150,000 shares that were issued to our Chief Financial Officer in June 2015 as an inducement grant in accordance with NASDAQ Listing Rule 5635(c)(4). In connection with our acquisition of 4-AB in February 2014, we are obligated to make contingent milestone payments to the former shareholders of 4-AB, payable in cash or shares of our common stock at our option, as follows (i) \$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 (ii) \$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. In addition, as additional consideration for assets that we purchased from Celexion, we agreed to pay to Celexion \$4.0 million on each of the 12-month and 24-month anniversaries of the Closing Date payable at our discretion in cash, shares of our common stock, or any combination thereof. We intend to file one or more registration statements covering the resale of shares of our common stock held by certain of our stockholders or investors in 2015. We are also obligated to file registration statements covering any additional shares that may be issued to Celexion in the future pursuant to the terms of our agreement with Celexion.

As of September 30, 2015, warrants to purchase approximately 4,351,450 shares of our common stock with a weighted average exercise price per share of \$9.01 were outstanding.

As of September 30, 2015, options to purchase 8,226,791 shares of our common stock with a weighted average exercise price per share of \$4.75 were outstanding. These options are subject to vesting that occurs over a period of up to four years following the date of grant. As of September 30, 2015 we had 1,734,821 nonvested shares outstanding.

As of September 30, 2015, our outstanding shares of Series A-1 Convertible Preferred Stock were convertible into 333,333 shares of our common stock.

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

We do not intend to pay dividends on our common stock and, consequently your ability to obtain a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or maintain their current value.

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, 2014, 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

AGENUS INC.

SIGNATURES

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

Date: November 4, 2015 AGENUS INC.

/s/ C. Evan Ballantyne
C. Evan Ballantyne

Chief Financial Officer

48

Exhibit Index

Exhibit No. Description

- 4.1 Note Purchase Agreement, by and among Antigenics LLC, the guarantors named therein, Oberland Capital SA Zermatt LLC, as collateral agent (“Oberland”), an affiliate of Oberland as the lead purchaser and the other purchasers, dated September 4, 2015. Filed as Exhibit 4.1 to our Current Report on Form 8-K/A (File No. 000-29089) filed on September 11, 2015 and incorporated herein by reference.
- 4.2 Form of Limited Recourse Note under the Note Purchase Agreement, by and among Antigenics LLC, the guarantors named therein, Oberland Capital SA Zermatt LLC, as collateral agent (“Oberland”), an affiliate of Oberland as the lead purchaser and the other purchasers, dated September 4, 2015. Filed as Exhibit 4.2 to our Current Report on Form 8-K/A (File No. 000-29089) filed on September 11, 2015 and incorporated herein by reference.
- 4.3 Revenue Interest Assignment and Termination Agreement, by and among Agenus Inc., Antigenics LLC, Ingalls & Snyder Value Partners, L.P. and Arthur Koenig, dated September 4, 2015. Filed as Exhibit 4.3 to our Current Report on Form 8-K/A (File No. 000-29089) filed on September 11, 2015 and incorporated herein by reference.
- 31.1 Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith.
- 31.2 Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith.
- 32.1 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
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB XBRL Label Linkbase Document
- 101.PRE XBRL Taxonomy Presentation Linkbase Document