

AGENUS INC
Form 10-Q
November 09, 2016

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, 2016

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

Agenuus 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 November 2, 2016: 87,126,180 shares

Agenus Inc.

Nine Months Ended September 30, 2016

Table of Contents

	Page
PART I	
ITEM 1. <u>Financial Statements:</u>	2
<u>Condensed Consolidated Balance Sheets as of September 30, 2016 (Unaudited) and December 31, 2015</u>	2
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2016 and 2015 (Unaudited)</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015 (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>	13
ITEM 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	18
ITEM 4. <u>Controls and Procedures</u>	18
PART II	
ITEM <u>Risk Factors</u>	
1A.	20
ITEM 6. <u>Exhibits</u>	42
<u>Signatures</u>	43

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30, 2016	December 31, 2015
ASSETS		
Cash and cash equivalents	\$75,438,489	\$136,702,873
Short-term investments	19,960,567	34,964,730
Inventories	88,200	88,200
Accounts Receivable	10,284,267	9,800,342
Prepaid expenses	3,029,182	1,956,941
Other current assets	725,519	582,280
Total current assets	109,526,224	184,095,366
Property, plant and equipment, net of accumulated amortization and depreciation of \$31,359,385 and \$29,488,793 at September 30, 2016 and December 31, 2015, respectively	23,508,290	15,310,623
Goodwill	23,165,457	22,792,778
Acquired intangible assets, net of accumulated amortization of \$2,705,219 and \$987,394 at September 30, 2016 and December 31, 2015, respectively	17,218,224	18,759,662
Other long-term assets	1,423,690	1,270,055
Total assets	\$174,841,885	\$242,228,484
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current portion, long-term debt	\$146,061	\$146,061
Current portion, deferred revenue	2,610,729	3,829,371
Accounts payable	3,267,788	4,488,561
Accrued liabilities	21,533,583	14,165,816
Other current liabilities	7,290,750	6,304,281
Total current liabilities	34,848,911	28,934,090
Long-term debt, net of current portion	126,263,126	114,326,489
Deferred revenue, net of current portion	12,997,414	15,065,754
Contingent purchase price considerations	16,962,000	5,608,000
Other long-term liabilities	4,809,858	7,566,601
Commitments and contingencies		
STOCKHOLDERS' (DEFICIT) 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 outstanding at September 30, 2016 and December 31, 2015; liquidation value of \$32,368,496 at September 30, 2016	316	316
	871,155	863,907

Edgar Filing: AGENUS INC - Form 10-Q

Common stock, par value \$0.01 per share; 240,000,000 and 140,000,000 shares authorized at September 30, 2016 and December 31, 2015, respectively; 87,115,524 and 86,390,697 shares issued at September 30, 2016 and December 31, 2015, respectively

Additional paid-in capital	858,854,694	851,103,934
Accumulated other comprehensive loss	(1,559,541)	(2,053,143)
Accumulated deficit	(879,206,048)	(779,187,464)
Total stockholders' (deficit) equity	(21,039,424)	70,727,550
Total liabilities and stockholders' (deficit) equity	\$174,841,885	\$242,228,484

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,	
	2016	2015	2016	2015
Revenue:				
Service	\$—	\$—	\$147,456	\$—
Research and development	4,446,171	6,848,194	16,849,876	17,178,191
Total revenues	4,446,171	6,848,194	16,997,332	17,178,191
Operating expenses:				
Research and development	(21,588,026)	(18,502,063)	(68,988,290)	(52,495,316)
General and administrative	(8,107,262)	(6,407,902)	(24,456,016)	(19,910,650)
Contingent purchase price consideration fair value adjustment	(10,975,000)	6,994,000	(11,354,000)	(7,326,700)
Operating loss	(36,224,117)	(11,067,771)	(87,800,974)	(62,554,475)
Other expense:				
Non-operating expense	(139,636)	(653,376)	(325,347)	(7,356,139)
Interest expense, net	(4,409,767)	(1,401,102)	(12,745,581)	(2,363,484)
Net loss	(40,773,520)	(13,122,249)	(100,871,902)	(72,274,098)
Dividends on Series A-1 convertible preferred stock	(51,102)	(50,780)	(153,064)	(152,099)
Net loss attributable to common stockholders	\$(40,824,622)	\$(13,173,029)	\$(101,024,966)	\$(72,426,197)
Per common share data:				
Basic and diluted net loss attributable to common stockholders	\$(0.47)	\$(0.16)	\$(1.16)	\$(0.95)
Weighted average number of common shares outstanding:				
Basic and diluted	87,206,685	84,569,118	86,954,060	75,935,985
Other comprehensive income (loss):				
Foreign currency translation gain (loss)	\$98,514	\$(680,993)	\$493,602	\$625,132
Unrealized gain on investments	-	7,760	-	13,650
Other comprehensive gain (loss)	98,514	(673,233)	493,602	638,782
Comprehensive loss	\$(40,726,108)	\$(13,846,262)	\$(100,531,364)	\$(71,787,415)

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,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$(100,871,902)	\$(72,274,098)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,658,483	1,403,324
Share-based compensation	8,701,292	5,218,479
Non-cash interest expense	12,193,674	1,643,417
In-process research and development purchase	—	12,245,230
Change in fair value of contingent obligations	11,354,000	14,190,000
Loss on extinguishment of debt	—	154,117
Changes in operating assets and liabilities:		
Accounts receivable	(480,833)	(7,232,669)
Inventories	—	7,500
Prepaid expenses	(1,067,534)	(693,981)
Accounts payable	(1,272,690)	1,266,219
Deferred revenue	(3,286,987)	18,465,694
Accrued liabilities and other current liabilities	6,340,539	8,390,007
Other operating assets and liabilities	887,383	(10,367,586)
Net cash used in operating activities	(63,844,575)	(27,584,347)
Cash flows from investing activities:		
Purchases of plant and equipment	(8,191,515)	(2,818,429)
Purchases of held-to-maturity securities	(54,884,101)	(15,006,730)
Proceeds from securities held-to-maturity	70,000,000	14,534,486
Net cash provided by (used in) investing activities	6,924,384	(3,290,673)
Cash flows from financing activities:		
Net proceeds from sale of equity	—	109,669,980
Proceeds from employee stock purchases and option exercises	1,092,722	1,963,738
Purchase of treasury shares to satisfy tax withholdings	(667,050)	—
Proceeds from issuance of long-term debt	—	109,000,000
Debt issuance costs	—	(1,774,323)
Payments of debt	—	(1,111,112)
Payment of contingent purchase price consideration	—	(8,380,483)
Payment under a purchase agreement for in-process research and development	(5,000,000)	—
Payment of contingent royalty obligation	—	(20,000,000)
Payment of capital lease obligation	(72,330)	—
Net cash (used in) provided by financing activities	(4,646,658)	189,367,800
Effect of exchange rate changes on cash	302,465	(68,339)
Net (decrease) increase in cash and cash equivalents	(61,264,384)	158,424,441
Cash and cash equivalents, beginning of period	136,702,873	25,714,519
Cash and cash equivalents, end of period	\$75,438,489	\$184,138,960
Supplemental cash flow information:		

Edgar Filing: AGENUS INC - Form 10-Q

Cash paid for interest	\$837,699	\$770,538
Supplemental disclosures - non-cash activities:		
Purchases of plant and equipment in accounts payable and		
accrued liabilities	1,000,101	111,903
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, in connection with		
the acquisition of the SECANT yeast display technology	—	3,000,000
Issuance of common stock, \$0.01 par value, in connection with		
payment of the contingent purchase price obligation	—	344,500

See accompanying notes to unaudited condensed consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2016

Note A - Business, Liquidity and Basis of Presentation

Agenus Inc. (including its subsidiaries, collectively referred to as “Agenus,” the “Company,” “we,” “us,” and “our”) is an immuno-oncology company focused on the discovery and development of new treatments that engage the body’s immune system to benefit patients suffering from cancer. We are developing a comprehensive immuno-oncology portfolio driven by the following platforms and programs, which we intend to utilize individually and in combination:

- our antibody discovery platforms, including our Retrocyte Display™, SECANT™ yeast display, and phage display technologies designed to produce quality human antibodies;
- our antibody candidate programs, including our checkpoint modulator (“CPM”) programs;
 - our vaccine programs, including Prophage™, AutoSynVax™ and PhosphoSynVax™; and
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon® adjuvant (“QS-21 Stimulon”).

We have a portfolio of programs in various stages of development, including a series of antibodies in discovery and pre-clinical and clinical development, our Prophage vaccine, a Heat Shock Protein (“HSP”)-based autologous vaccine candidate for a form of brain cancer that has successfully completed Phase 2 trials, and a number of advanced QS-21 Stimulon-containing vaccine candidates in late stage development by our licensee, GlaxoSmithKline (“GSK”).

Our core antibody technologies include our antibody discovery platforms that are designed to effectively discover and produce quality human antibodies against antigens of interest. We and our partners currently have programs targeting GITR, OX40, CTLA-4, LAG-3, TIM-3, PD-1, CEACAM1 and other undisclosed targets.

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.

Our cash, cash equivalents, and short-term investments at September 30, 2016 were \$95.4 million, a decrease of \$76.3 million from December 31, 2015.

The following table outlines our quarter end cash, cash equivalents and short-term investments balances and the changes therein.

	Quarter ended		
	March	June	September
	31,	30,	30, 2016
	2016	2016	
	(in millions)		
Cash, cash equivalents and short-term investments	\$ 148.2	\$ 123.3	\$ 95.4
Decrease in cash, cash equivalents and short-term	\$ 23.5	\$ 24.9	\$ 27.9

investments

Cash used in operating activities	\$21.5	\$18.5	\$ 23.8
-----------------------------------	--------	--------	---------

Reported net loss	\$31.8	\$28.3	\$ 40.8
-------------------	--------	--------	---------

We have incurred significant losses since our inception. As of September 30, 2016, we had an accumulated deficit of \$879.2 million. Since our inception, we have financed our operations primarily through the sale of equity and convertible and other notes, and interest income earned on cash, cash equivalents, and short-term investments balances. We believe that, based on our current plans and activities, our cash, cash equivalents and short-term investments balance of \$95.4 million as of September 30, 2016 will be sufficient to satisfy our liquidity requirements through the first half of 2017. We expect to raise additional funds in advance of depleting our current funds. 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, if necessary.

Edgar Filing: AGENUS INC - Form 10-Q

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) for interim financial information and with the instructions to Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete annual consolidated financial statements. In the opinion of our management, the condensed consolidated financial statements include all normal and recurring adjustments considered necessary for a fair presentation of our financial position and operating results. All significant intercompany transactions and accounts have been eliminated in consolidation. Operating results for the nine months ended September 30, 2016, are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. 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, 2015 filed with the Securities and Exchange Commission (the “SEC”) on March 15, 2016.

Effective June 14, 2016, our certificate of incorporation was amended to increase the number of authorized shares of common stock from 140,000,000 to 240,000,000.

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’ (deficit) 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 income per common share is calculated by dividing net income attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our DDCP) plus the dilutive effect of outstanding instruments such as warrants, stock options, nonvested shares, convertible preferred stock, and convertible notes. Because we reported a net loss attributable to common stockholders for all periods presented, diluted loss per common share is the same as basic loss per common share, as the effect of utilizing the fully diluted share count would have reduced the net loss per common share. Therefore, the following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as of September 30, 2016 and 2015, as they would be anti-dilutive:

Nine Months Ended
September 30,

Edgar Filing: AGENUS INC - Form 10-Q

	2016	2015
Warrants	4,351,450	4,351,450
Stock options	11,761,554	8,226,791
Nonvested shares	1,937,023	1,734,821
Convertible preferred stock	333,333	333,333

Note C - Investments

Cash equivalents and short-term investments consisted of the following as of September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016		December 31, 2015	
	Estimated		Estimated	
	Cost	Fair Value	Cost	Fair Value
Institutional money market funds	\$28,284	\$ 28,284	\$106,370	\$106,370
U.S. Treasury Bills	44,941	44,941	54,945	54,961
Total	\$73,225	\$ 73,225	\$161,315	\$161,331

Edgar Filing: AGENUS INC - Form 10-Q

For the nine months ended September 30, 2016, we received proceeds of approximately \$100.0 million from the maturity of U.S. Treasury Bills classified as cash equivalents and \$70.0 million Treasury Bills classified as short-term investments. As a result of the short-term nature of our investments, there were minimal unrealized holding gains or losses for the three and nine months ended September 30, 2016 and 2015.

Of the investments listed above, \$53.3 million and \$126.4 million have been classified as cash equivalents and \$19.9 million and \$35.0 million as short-term investments on our condensed consolidated balance sheets as of September 30, 2016 and December 31, 2015, 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, 2016 (in thousands):

Balance, December 31, 2015	\$22,793
Foreign currency translation adjustment	372
Balance, September 30, 2016	\$23,165

Acquired intangible assets consisted of the following as of September 30, 2016 and December 31, 2015 (in thousands):

As of September 30, 2016

Amortization

	period	Gross carrying	Accumulated	Net carrying
	(years)	amount	amortization	amount
Intellectual property	7-15 years	\$ 16,578	\$ (1,958)	\$ 14,620
Trademarks	4.5 years	832	(486)	346
Other	2-6 years	571	(261)	310
In-process research and development	Indefinite	1,942	-	1,942
Total		\$ 19,923	\$ (2,705)	\$ 17,218

As of December 31, 2015

Amortization

	period	Gross carrying	Accumulated	Net carrying
	(years)	amount	amortization	amount
Intellectual property	7-15 years	\$ 16,472	\$ (541)	\$ 15,931
Trademarks	4.5 years	812	(339)	473

Edgar Filing: AGENUS INC - Form 10-Q

Other	2-6 years	567	(107)	460
In-process research and development	Indefinite	1,896	—	1,896
Total		\$ 19,747	\$ (987)	\$ 18,760

The weighted average amortization period of our finite-lived intangible assets is 9 years. Amortization expense related to acquired intangibles is estimated at \$800,000 for the remainder of 2016, \$2.2 million for the year ending December 31, 2017, \$2.1 million for the year ending December 31, 2018 and \$1.9 million for each of the years ending December 31, 2019 and 2020.

Note E - Debt

Debt obligations consisted of the following as of September 30, 2016 and December 31, 2015 (in thousands):

	Principal at		Unamortized		Balance at
	September	Non-cash	Debt	Unamortized	September
	30,	Interest	Issuance	Debt	30,
Debt instrument	2016		Costs	Discount	2016
Current Portion:					
Debentures	\$ 146	\$ —	\$ —	\$ —	\$ 146
Long-term Portion:					
2015 Subordinated Notes	14,000	—	—	(1,570)	12,430
Note Purchase Agreement	100,000	15,438	(1,378)	(227)	113,833
Total long-term	\$ 114,000	\$ 15,438	\$ (1,378)	\$ (1,797)	\$ 126,263
Total	\$ 114,146	\$ 15,438	\$ (1,378)	\$ (1,797)	\$ 126,409

	Principal at		Unamortized		Balance at
	December	Non-cash	Debt	Unamortized	December
	31,	Interest	Issuance	Debt	31,
Debt instrument	2015		Costs	Discount	2015
Current Portion:					
Debentures	\$ 146	\$ —	\$ —	\$ —	\$ 146
Long-term Portion:					
2015 Subordinated Notes	14,000	—	—	(2,292)	11,708
Note Purchase Agreement	100,000	4,342	(1,481)	(243)	102,618
Total long-term	\$ 114,000	\$ 4,342	\$ (1,481)	\$ (2,535)	\$ 114,326
Total	\$ 114,146	\$ 4,342	\$ (1,481)	\$ (2,535)	\$ 114,472

In June 2016, we executed a capital lease agreement that expires in June 2020 for equipment with a carrying value of approximately \$1.0 million, which is included in property, plant and equipment, net on our condensed consolidated balance sheets as of September 30, 2016. Under the terms of the capital lease agreement, we will remit payments to the lessor of \$72,000 for the remainder of 2016, \$288,000 for each of the years 2017 through 2019 and \$144,000 for the year ending December 31, 2020. As of September 30, 2016, our remaining obligations under the capital lease agreement are approximately \$1.0 million, of which \$300,000 and \$665,000 are classified as other current and other long-term liabilities, respectively, on our condensed consolidated balance sheets.

Note F - Accrued and Other Current Liabilities

Accrued liabilities consisted of the following as of September 30, 2016 and December 31, 2015 (in thousands):

Edgar Filing: AGENUS INC - Form 10-Q

	September 30,	December
	2016	31, 2015
Payroll	\$ 5,218	\$ 4,600
Professional fees	4,431	3,343
Contract manufacturing costs	7,531	3,886
Other	4,354	2,337
Total	\$ 21,534	\$ 14,166

Other current liabilities consisted of the following as of September 30, 2016 and December 31, 2015 (in thousands):

	September 30,	December
	2016	31, 2015
Current portion of deferred purchase price	\$ 4,895	\$ 5,906
Other	2,396	398
Total	\$ 7,291	\$ 6,304

Note G - Fair Value Measurements

We measure our cash equivalents and short-term investments and contingent purchase price considerations at fair value. Our cash equivalents and 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.

Edgar Filing: AGENUS INC - Form 10-Q

The fair values of our contingent purchase price considerations, \$17.0 million, are based on significant inputs not observable in the market, which require it to be reported as Level 3 liabilities within the fair value hierarchy. The valuation of these liabilities use assumptions we believe would be made by a market participant and are based on estimates from a Monte Carlo simulation of our market capitalization and share price, and other factors impacting the probability of triggering the milestone payments. Market capitalization and share price were evolved using a geometric brownian motion, calculated daily for the life of the contingent purchase price considerations.

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

Description	September 30, 2016	Quoted Prices in	Significant	
		Active	Other	Significant
		Markets for	Observable	Unobservable
		Identical Assets	Inputs	Inputs
		(Level 1)	(Level 2)	(Level 3)
Assets:				
Cash equivalents	\$ 24,980	\$ 24,980	\$ —	\$ —
Short-term investments	19,961	19,961	—	—
Total	\$ 44,941	\$ 44,941	\$ —	\$ —
Liabilities:				
Contingent purchase price considerations	\$ 16,962	\$ —	\$ —	\$ 16,962

Description	December 31, 2015	Quoted Prices in	Significant	
		Active	Other	Significant
		Markets for	Observable	Unobservable
		Identical Assets	Inputs	Inputs
		(Level 1)	(Level 2)	(Level 3)
Assets:				
Cash equivalents	\$ 19,996	\$ 19,996	\$ —	\$ —
Short-term investments	34,965	34,965	—	—
Total	\$ 54,961	\$ 54,961	\$ —	\$ —
Liabilities:				
Contingent purchase price considerations	\$ 5,608	\$ —	\$ —	\$ 5,608

The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3), as of September 30, 2016 (in thousands):

Balance, December 31, 2015	\$5,608
Change in fair value of contingent purchase price considerations	11,354

during the period	
Balance, September 30, 2016	\$16,962

The estimated fair values of all of our financial instruments, excluding our outstanding debt, approximate their carrying amounts in our condensed consolidated balance sheets.

The fair value of our outstanding debt balance at September 30, 2016 and December 31, 2015 was \$125.7 million and \$115.9 million, respectively, based on the Level 2 valuation hierarchy of the fair value measurements standard using a present value methodology that 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 principal amount of our outstanding debt balance at September 30, 2016 and December 31, 2015 was \$129.6 million, inclusive of \$15.4 million of accrued interest, and \$118.5 million, inclusive of \$4.3 million of accrued interest, respectively.

Note H - 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, 2016 is presented below:

		Weighted		
		Average		
		Weighted	Remaining	
		Average	Contractual	Aggregate
		Exercise	Term	Intrinsic
	Options	Price	(in years)	Value
Outstanding at December 31, 2015	8,345,835	\$ 4.77		
Granted	4,252,739	4.26		
Exercised	(198,636)	3.31		
Forfeited	(452,604)	5.03		
Expired	(185,780)	8.75		
Outstanding at September 30, 2016	11,761,554	\$ 4.53	7.70	\$32,843,626
Vested or expected to vest at September 30, 2016	10,599,495	\$ 4.55	7.57	\$29,971,443
Exercisable at September 30, 2016	5,624,490	\$ 4.68	6.23	\$15,941,877

The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2016 and 2015 were \$2.38 and \$3.85, respectively.

As of September 30, 2016, \$11.4 million of total unrecognized compensation cost related to stock options granted to employees and directors is expected to be recognized over a weighted average period of 2.4 years.

As of September 30, 2016, 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 \$308,000. 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, 2016 is presented below:

	Weighted	
	Average	
	Nonvested	Grant Date
	Shares	Fair Value
Outstanding at December 31, 2015	1,730,604	\$ 8.55

Edgar Filing: AGENUS INC - Form 10-Q

Granted	935,438	2.91
Vested	(570,037)	8.52
Forfeited	(158,982)	8.05
Outstanding at September 30, 2016	1,937,023	\$ 6.51

As of September 30, 2016, there was approximately \$10.4 million of unrecognized share-based compensation expense related to these nonvested shares awarded to employees which pertained primarily to performance based awards for which, if all milestones are achieved, will be recognized over a 1.6 year period. The total intrinsic value of shares vested during the nine months ended September 30, 2016, was \$2.4 million.

During the nine months ended September 30, 2016, 121,228 shares were issued under the 2009 Employee Stock Purchase Plan, 570,037 shares were issued as a result of the vesting of nonvested stock and 198,636 shares were issued as a result of stock option exercises.

Edgar Filing: AGENUS INC - Form 10-Q

The impact on our results of operations from share-based compensation for the three and nine months ended September 30, 2016 and 2015, was as follows (in thousands):

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
Research and development	\$818	\$453	\$3,689	\$1,695
General and administrative	1,565	320	5,012	3,523
Total share-based compensation expense	\$2,383	\$773	\$8,701	\$5,218

Note I - Benefit Plans

We maintain a multiple employer benefit plan that covers 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, 2016, we contributed approximately \$41,000 and \$119,000, respectively and for the three and nine months ended September 30, 2015 we contributed approximately \$26,000 and \$80,000, respectively, to our international multiple employer benefit plan. For the remainder of the year ending December 31, 2016, we expect to contribute approximately \$28,000 to our international multiple employer benefit plan.

Note J - 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. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. These ASUs are effective for interim and annual periods beginning after December 15, 2017. We are currently evaluating the potential impact these ASUs 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 February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) (“ASU 2016-02”), which supersedes Topic 840, Leases. ASU2016-02 requires lessees to recognize a right-of-use asset and a lease liability on their balance sheets for all leases with terms greater than twelve months. Based on certain criteria, leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The modified retrospective approach includes a number of optional practical expedients primarily focused on leases that commenced before the effective date of Topic 842, including continuing to account for leases that commence before the effective date in accordance with previous guidance, unless the lease is modified. We are evaluating the impact of the adoption of the standard on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, (“ASU 2016-09”). ASU 2016-09 provides for the simplification of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 applies to all entities and is effective for the annual effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for any entity in any interim or annual period. We are currently evaluating the potential impact that ASU 2016-09 may have on our financial position and results of operations.

No other new accounting pronouncement issued or effective during the fiscal year had or is expected to have a material impact on our consolidated financial statements or disclosures.

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.

ASV™, AutoSynVax™, Oncophage™, PSV™, PhosphoSynVax™, Prophage™, Retrocyte Display™, SECANT™, Stimulon® are trademarks of Agenus Inc. and its subsidiaries. All rights reserved.

Overview

We are an immuno-oncology company focused on the discovery and development of new treatments that engage the body's immune system to benefit patients suffering from cancer. By combining multiple platforms, we have established a highly integrated approach to target identification and validation, and for the discovery, development and manufacturing of monoclonal antibodies. Our broad portfolio of checkpoint modulator ("CPM") and other monoclonal antibodies, vaccines and adjuvants provide the opportunity to create best-in-class therapeutic regimens. Our heat shock protein-based autologous vaccine, Prophage, has successfully completed Phase 2 clinical trials in newly-diagnosed glioblastoma multiforme ("ndGBM"), and we expect to initiate Phase 1 clinical trials of our heat shock protein-based synthetic vaccine, AutoSynVax, within the next six months.

We are developing a comprehensive immuno-oncology portfolio driven by the following platforms and programs, which we intend to utilize individually and in combination:

- our antibody discovery platforms, including our Retrocyte Display, SECANT yeast display, and phage display technologies designed to produce quality human antibodies;
- our antibody candidate programs, including our CPM programs;
 - our vaccine programs, including Prophage, AutoSynVax and PhosphoSynVax; and
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon adjuvant ("QS-21 Stimulon").

We assess development, commercialization and partnering strategies for each of our product candidates periodically based on several factors, including pre-clinical and clinical trial results, competitive positioning and funding requirements and resources. We have formed collaborations with companies such as Incyte Corporation (“Incyte”), Merck Sharpe & Dohme and Recepta Biopharma SA (“Recepta”). Through these alliances, as well as our own internal programs, we currently have over a dozen antibody programs, including our anti-CTLA-4 (partnered with Recepta for certain South America territories) and anti-GITR (partnered with Incyte) antibody candidates that each commenced Phase 1 trials in 2016.

We are also advancing a series of Heat Shock Protein (“HSP”) peptide-based vaccines to treat cancer. In July 2014, we reported positive results from a Phase 2 clinical trial with our Prophage vaccine, which showed that patients with ndGBM, 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, each as compared to historical control data. We are currently advancing our Prophage vaccine program via third party sponsored clinical trials in which Agenus provides product supply and does not hold the IND. We also reported

positive results in June 2014 from a Phase 2 clinical trial of our synthetic HerpV vaccine candidate for genital herpes. Although we determined not to move forward with this product candidate in herpes, based on our findings, we launched our AutoSynVax (“ASV”), synthetic neo-antigen cancer vaccine program in 2015, and we plan to initiate our first Phase 1 clinical trial for this program in the next six months.

Our QS-21 Stimulon adjuvant is partnered with GlaxoSmithKline (“GSK”), and is a key component in multiple GSK vaccine programs that target prophylactic or therapeutic impact in a variety of infectious diseases. These programs are in various stages, with the most advanced being GSK’s shingles and malaria programs, which GSK first announced positive Phase 3 results for in December 2014 and October 2013, respectively. 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 (“NPA”) and received net proceeds of approximately \$78.2 million. In October 2016, GSK filed for regulatory approval of its shingles vaccine candidate in the United States and reported that it was on track to file applications for marketing approval in the European Union and Canada by the end of 2016.

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.

Historical Results of Operations

Three months ended September 30, 2016 compared to the three months ended September 30, 2015

Revenue: We recognized revenue of approximately \$4.4 million and \$6.8 million during the three months ended September 30, 2016 and 2015, respectively. Revenues in 2016 and 2015 primarily included fees earned under our license agreements, including approximately \$3.8 million and \$3.9 million for the three months ended September 30, 2016 and 2015, respectively, related to the reimbursement of development costs under our Collaboration Agreement, dated February 19, 2015, with Incyte (the “Collaboration Agreement”). During the three months ended September 30, 2016 and 2015, we recorded revenue of \$657,000 and \$2.7 million, respectively, from the amortization of deferred revenue.

Research and development: Research and development expenses include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, costs of consultants, and administrative costs. Research and development expense increased 17% to \$21.6 million for the three months ended September 30, 2016 from \$18.5 million for the three months ended September 30, 2015. Increased expenses in 2016 relate primarily to a \$2.9 million increase in payroll related expenses due mainly to increases in headcount and a \$1.4 million increase in facility related expenses including amortization and depreciation both primarily as a result of our acquisition of an antibody manufacturing facility from XOMA Corporation in December 2015 offset by decreased other costs of \$1.2 million primarily due to one-time technology license fees incurred during the three months ended September 30, 2015.

General and administrative: General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 27% to \$8.1 million for the three months ended September 30, 2016 from \$6.4 million for the three months September 30, 2015. Increased general and administrative expenses in 2016 primarily relate to a \$300,000 increase in professional fees related to our corporate activities and a \$1.2 million increase in share-based compensation expense primarily related to the increase in the fair value of awards period over period.

Contingent purchase price consideration fair value adjustment: Contingent purchase price considerations fair value adjustment in 2016 represents the increase in the fair value of our purchase price considerations which resulted from our increased market capitalization and share price and changes in the credit spread at quarter end compared to these values at June 30, 2016. The fair value of our contingent purchase price considerations decreased in 2015 due to a decline in these values. The fair value of our contingent purchase price considerations is based on estimates from a Monte Carlo simulation of our market capitalization and share price.

Non-operating expense: Non-operating expense for the three months ended September 30, 2016 includes our foreign currency loss and other expense. Non-operating expense for the three months ended September 30, 2015 represents the fair value adjustment of our then outstanding contingent royalty obligation as well as our foreign currency loss.

Interest expense, net: Interest expense, net increased to approximately \$4.4 million for the three months ended September 30, 2016 from \$1.4 million for the three months ended September 30, 2015 due to the issuance of notes pursuant to the NPA in September 2015.

Nine months ended September 30, 2016 compared to the nine months ended September 30, 2015

Revenue: We recognized revenue of approximately \$17.0 million and \$17.2 million during the nine months ended September 30, 2016 and 2015, respectively. Revenues in 2016 and 2015 primarily included fees earned under our license agreements, including approximately \$11.3 million and \$9.6 million for the nine months ended September 30, 2016 and 2015, respectively, related to the reimbursement of development costs under our Collaboration Agreement with Incyte, which have increased due to the stage of programs under the collaboration. During the nine months ended September 30, 2016 and 2015, we recorded revenue of \$3.3 million and \$6.7 million, respectively, from the amortization of deferred revenue.

Research and development: Research and development expenses include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, costs of consultants, and administrative costs. Research and development expense increased 31% to \$69.0 million for the nine months ended September 30, 2016 from \$52.5 million for the nine months ended September 30, 2015. Increased expenses in 2016 primarily relate to an increase in third-party services and other related expenses of \$16.0 million primarily relating to the advancement of our antibody programs, a \$10.7 million increase in payroll related expenses due primarily to increases in headcount, a \$4.1 million increase in facility related expenses including amortization and depreciation both primarily as a result of our acquisition of an antibody manufacturing facility from XOMA Corporation in December 2015 and a \$2.0 million increase in share-based compensation expense primarily related to performance awards. Included in our 2015 expenses was a one-time \$13.2 million charge related to our asset acquisition which was expensed as in-process research and development and \$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 \$24.5 million for the nine months ended September 30, 2016 from \$19.9 million for the nine months ended September 30, 2015. Increased general and administrative expenses in 2016 primarily relate to a \$1.2 million increase in professional fees related to our corporate activities, \$1.1 million increase in payroll related expenses as the result of increased headcount and a \$1.5 million increase in share-based compensation, which is related to the increase in the fair value of awards period over period and outstanding performance awards.

Contingent purchase price consideration fair value adjustment: Contingent purchase price considerations fair value adjustment represents, in each period, the increase in the fair value of our purchase price considerations, which resulted from changes in our market capitalization and share price and changes in the credit spread since each year end. The fair value of our contingent purchase price considerations is based on estimates from a Monte Carlo simulation of our market capitalization and share price.

Non-operating expense: Non-operating expense for the nine months ended September 30, 2016 includes our foreign currency loss and other expense. Non-operating expense for the nine months ended September 30, 2015 represents the change in the fair value of our then outstanding contingent royalty obligation, a foreign currency loss as well as the loss on extinguishment of senior subordinated notes that we originally issued in 2013.

Interest expense, net: Interest expense, net increased to approximately \$12.7 million for the nine months ended September 30, 2016 from \$2.4 million for the nine months ended September 30, 2015 due to the issuance of new senior subordinated notes in February 2015 and the issuance of notes under our NPA in September 2015.

Research and Development Programs

Edgar Filing: AGENUS INC - Form 10-Q

For the nine months ended September 30, 2016, our research and development programs consisted largely of our antibody programs as indicated in the following table (in thousands).

		Nine months ended September 30,	Year Ended December 31,				Prior to
Research and Development Program	Product	2016	2015	2014	2013	2013	Total
Heat shock proteins for cancer	Prophage						
	Vaccines	\$ 7,960	\$5,508	\$6,153	\$5,882	\$297,646	\$323,149
Antibody programs*		58,285	63,290	13,422	—	—	134,997
Heat shock proteins for infectious diseases	HerpV	11	293	2,443	6,358	23,950	33,055
Vaccine adjuvant	QS-21						
	Stimulon	73	142	321	753	12,583	13,872
Other research and development programs		2,659	1,211	10	12	33,544	37,436
Total research and development expenses		\$ 68,988	\$70,444	\$22,349	\$13,005	\$367,723	\$542,509

15

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

Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions and our review of the status of each program. Our product candidates are in various stages of development and significant additional expenditures will be required if we start new clinical trials, encounter delays in our programs, apply for regulatory approvals, continue development of our technologies, expand our operations, and/or bring our product candidates to market. The total cost of any particular clinical trial is dependent on a number of factors such as trial design, length of the trial, number of clinical sites, number of patients, and trial sponsorship. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because our antibody programs are pre-clinical and early stage or just recently in the clinic, and because further development of our vaccine candidates is dependent on pre-clinical testing and clinical trial results, 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 material cash inflows from operations are likely to commence, if ever. Active programs involving QS-21 Stimulon depend on our licensee 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 \$879.2 million as of September 30, 2016. We expect to incur significant losses over the next several years as we continue to develop 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, 2016, we have raised aggregate net proceeds of approximately \$840.0 million through the sale of common and preferred stock, the exercise of stock options and warrants, proceeds from our Employee Stock Purchase Plan, and the issuance of convertible and other notes.

We 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. As of September 30, 2016, \$70.3 million remained available under the Shelf Registration Statement. The Shelf Registration Statement also includes a prospectus covering the offer, issuance and sale of up to 10 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, 2016, we had 10 million shares available for sale under the Sales Agreement.

As of September 30, 2016, we had debt outstanding of \$129.6 million in principal including \$15.4 million in accrued interest. In February 2015, we exchanged our 2013 senior subordinated notes in the aggregate principal amount of \$5.0 million 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. The 2015 Subordinated Notes are due in February 2018. In addition, we also issued to the holders of the 2015 Subordinated Notes five year warrants to purchase 1.4 million shares of our common stock at an exercise price of \$5.10 per share. In September 2015, we and our wholly-owned subsidiary Antigenics LLC

(“Antigenics”) entered into the NPA with certain purchasers 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, 2016 were \$95.4 million, a decrease of \$76.3 million from December 31, 2015. We believe that, based on our current plans and activities, our cash, cash equivalents, and short-term investments of \$95.4 million as of September 30, 2016 will be sufficient to satisfy our liquidity requirements through the first half of 2017. 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, if necessary.

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, antibody programs, HSP-based vaccines, and vaccines containing QS-21 Stimulon under development by our licensees. Our long-term success will also depend on the successful identification, development and commercialization of other potential 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 and trials. 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 \$101.9 million over the term of the related activities. Through September 30, 2016, we have expensed \$88.8 million as research and development expenses and \$79.2 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 \$8.2 million, of which \$7.0 million have been paid as of September 30, 2016. 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 antibodies against certain targets is managed by a joint steering committee with equal representation from Agenus and Incyte. We also have an agreement with GSK that allows the use of our QS-21 Stimulon adjuvant in numerous vaccines, which grants exclusive worldwide rights in some fields of use and co-exclusive or non-exclusive rights in others. This agreement generally calls for royalties to be paid on future sales of licensed products that result from this agreement, which may or may not be achieved. As noted above, in September 2015 we monetized a portion of the anticipated royalties related to GSK’s shingles and malaria vaccines through our NPA.

Net cash used in operating activities for the nine months ended September 30, 2016 and 2015 was \$63.9 million and \$27.6 million, respectively. Subject to regulatory submission and approval, the first products containing QS-21 Stimulon are anticipated to be launched in 2018. We are generally entitled to royalties on sales by GSK of vaccines using QS-21 Stimulon for at least ten years after commercial launch, with some exceptions. In September 2015, we entered into the NPA 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 GITR and OX40 programs as well as two of the additional undisclosed programs nominated for development during 2015; 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. 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 and the risks highlighted under Part I, Item 1A. “Risk Factors” of this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of September 30, 2016.

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. In March 2016, ASU No. 2016-08 was issued which clarifies the implementation guidance on principal versus agent considerations. These ASUs are effective for interim and annual periods beginning after December 15, 2017 for public entities. We are currently evaluating the potential impact these ASUs 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 February 2016, ASU 2016-02 which supersedes Topic 840, Leases. ASU 2016-02 requires lessees to recognize a right-of-use asset and a lease liability on their balance sheets for all leases with terms greater than twelve months. Based on certain criteria, leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The modified retrospective approach includes a number of optional practical expedients primarily focused on leases that commenced before the effective date of Topic 842, including continuing to account for leases that commence before the effective date in accordance with previous guidance, unless the lease is modified. We are evaluating the impact of the adoption of the standard on our consolidated financial statements.

In March 2016, ASU 2016-09 was issued which provides for the simplification of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 applies to all entities and is effective for the annual effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for any entity in any interim or annual period. We are currently evaluating the potential impact that ASU 2016-09 may have on our financial position and results of operations.

No other new accounting pronouncement issued or effective during the fiscal year had or is expected to have a material impact on our consolidated financial statements or disclosures.

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 9% and 4% of our cash used in operations for the nine months ended September 30, 2016 and the year ended December 31, 2015, respectively, was from a foreign subsidiary. 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 Swiss Franc and British Pound, in large part due to our wholly-owned subsidiaries, 4-Antibody AG, a company with operations in Switzerland, and Agenesis UK Limited, with operations in England. 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, 2015.

We had cash, cash equivalents and short-term investments at September 30, 2016 of \$95.4 million, which are exposed to the impact of interest rate changes, and our interest income fluctuates as interest rates change. Additionally, in the normal course of business, we are exposed to fluctuations in interest rates as we seek debt financing and invest excess cash. 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, 2016.

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, 2016 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, 2016.

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, 2015, 2014, and 2013, were \$87.9 million, \$42.5 million, and \$30.1 million, respectively. During the nine months ended September 30, 2016, we generated a net loss of \$100.9 million. We expect to incur additional losses over the next several years as we continue to research and develop 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 antibody programs and platforms (including those partnered with Incyte), our vaccine programs, and our saponin-based vaccine adjuvants.

On September 30, 2016, we had \$95.4 million in cash, cash equivalents, and short-term investments. We believe that, based on our current plans and activities, our working capital resources September 30, 2016, will be sufficient to satisfy our liquidity requirements through the first half of 2017. We expect to attempt to secure additional funds before our current funds are depleted although additional funding may not be available on favorable terms, or at all.

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 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;
- the scope, progress, results and costs of researching and developing our future product candidates and conducting pre-clinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our and our licensees' product candidates;
- the cost of manufacturing;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such 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 ("GSK"), 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 an Note Purchase Agreement ("NPA") with Oberland Capital SA Zermatt LLC ("Oberland"), 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 GSK's shingles vaccine, HZ/su, by the Food and Drug Administration ("FDA"), 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"): \$100.0 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, 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 circumstances 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 NPA 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 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 (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 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 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 a joint steering committee that oversees and manages worldwide regulatory, development, manufacturing, and commercialization activities for our antibody product candidates pursuant to the collaboration agreement with equal representation from both parties. For each program, we serve as the lead for pre-clinical development activities through the filing of an investigational new drug application (“IND”) and Incyte serves 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 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 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.

Each program in the collaboration falls under either (i) a cost sharing model, in which we share all costs and profits on a 50:50 basis with Incyte and we are eligible for potential milestones, or (ii) a royalty-bearing model, in which Incyte funds 100% of the costs, and we are eligible for potential milestones and royalties. Incyte has far greater resources than us, and it may be difficult for us to meet our obligation to fund 50% of all costs for the cost-sharing programs, including the G1TR and OX40 programs and two of the additional antibody programs. Moreover, clinical programs under the collaboration could be accelerated due to better than expected clinical outcomes, thus requiring us to spend more money than anticipated on a given program and in a shorter period of time. We can elect to cease sharing costs 50:50 and convert the arrangements to royalty-bearing on twelve months prior written notice. If we fail to meet this notice obligation and do not meet our funding commitments, we would be in breach of our obligations under the

agreement.

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

- 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 antibody 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 antibody 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 antibody product candidates.

Our antibody programs are in early stage development, and there is no guarantee that we will be successful in advancing antibody product candidates through clinical development.

Our antibody programs are currently in early stage development, and many of our antibody programs are pre-clinical. Even if our pre-clinical studies or Phase 1 trials 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 or Phase 1 trials, 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 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 October 1, 2016, our headcount has increased from 70 to 224, in part through various acquisitions and the expansion of our research and development activities both nationally and internationally to California, Virginia, Switzerland and the United Kingdom. We previously conducted discovery research operations in Germany, but as part of our efforts to optimize efficiency across our organization, we closed our Jena office and consolidated these operations in the United Kingdom and Switzerland. 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 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 our third party licensee, GSK, to develop, test, market and manufacture vaccines that utilize our QS-21 Stimulon adjuvant. Our other previous licensee, Janssen Science Ireland UC, terminated their license for use of QS-21 Stimulon in May 2016.

GSK manages its product development process, and we cannot predict its requirements for QS-21 Stimulon in the future or to what extent, if any, they will develop and commercialize vaccines that use QS-21 Stimulon as an adjuvant. GSK may initiate or terminate programs containing QS-21 Stimulon at any time. In addition, even if GSK successfully completes 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 have a successful commercial launch or generate any future milestones or royalty payments. In September 2015, we entered into the NPA and monetized a portion of 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. However, there is no guarantee that GSK's shingles and malaria vaccines will be approved in any territories for which they seek regulatory approval. Even if GSK's shingles and/or malaria vaccines are approved, there is no guarantee that GSK will have a successful commercial launch of either product or generate any revenues from sales to help satisfy our obligations under the NPA. 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 synthetic Heat Shock Protein (“HSP”) peptide-based platform 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 HerpV™, a vaccine candidate for genital herpes from our synthetic HSP peptide-based platform. While the HerpV Phase 2 trial met its formal endpoints, subjects were not followed long enough to determine whether 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 expect to advance this program into a Phase 3 trial, but we have initiated our AutoSynVax™ (“ASV”) synthetic cancer vaccine program based on our prior findings with this platform. Although we are targeting to initiate a clinical trial for our first AutoSynVax product candidate in the next six months, there is no guarantee that we will be able to do so. There is no guarantee that a product candidate will progress from this platform at all or that results of any potential future clinical trials will be positive. Furthermore, it is possible that research and discoveries by others will render any product candidate from this platform as obsolete or noncompetitive.

We may not be able to advance clinical development or commercialize Prophage™ vaccines or realize any benefits from this program.

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. All of our currently planned trials involving Prophage are intended to be sponsored by third parties, and there is no guarantee that they will occur at all. 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, if completed, subsequent Prophage trials would yield useful translational and/or efficacy data.

Our current clinical trial plans with Prophage vaccines entail investigator or government sponsored INDs in which we provide support and product supply. For third-party sponsored trials, we lack the ability to control trial design, timelines, tumor tissue procurement and data availability. For example, the Phase 2 trial of Prophage vaccine in combination with bevacizumab in patients with surgically resectable recurrent glioma is currently enrolling. 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. 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. 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.

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 antibody programs, including those partnered with Incyte, will require substantial manufacturing development and investment to progress. We are currently progressing a portfolio of antibody programs that are at different stages of development. If these 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 recently secured our own antibody manufacturing capabilities with the purchase of a manufacturing pilot plant from XOMA Corporation (“XOMA”) and expect this facility to supply us with antibody drug substance requirements through clinical proof-of-concept studies. We will also need to develop or secure later phase and/or commercial manufacturing capabilities for larger, registrational studies or any commercial supply requirements. For the programs for which we will produce our own drug substance, we will continue to rely on third parties for fill-finish services and other parts of the manufacturing process. These services include the storage and maintenance of our drug substance during all stages of the manufacturing process. While we maintain insurance to cover certain potential losses, there is no guarantee that our insurance coverage will be adequate. Furthermore, we currently still rely on contract manufacturing organizations (“CMOs”) and contract research organizations (“CROs”) to support some of our existing antibody programs. Our dependence on external CMOs for the manufacture of certain antibodies results in intrinsic risks to our performance, timelines, and costs of our accelerated development plans, and which could divert resources away from our antibody programs and/or lead to delays in the development of our product candidates. In the event that our antibody programs require progressively larger production capabilities, our options for qualified CMOs may become more limited.

The long-term success of the antibody pilot plant manufacturing facility and capabilities that we acquired from XOMA will depend, in part, on our ability to realize the anticipated synergies, business opportunities and growth prospects from combining our manufacturing facilities in Lexington, MA with the antibody pilot plant manufacturing

facility in Berkeley, CA. We may never realize these anticipated synergies, business opportunities and growth prospects. Assumptions underlying estimates of expected cost savings as a result of the acquisition of the antibody pilot plant manufacturing facility may be inaccurate. If any of these factors limit our ability to successfully manufacture antibodies to support our planned clinical trials, the expectations of future results of operations, including certain cost savings and synergies expected to result from the acquisition of XOMA's antibody pilot plant manufacturing facility, might not be met.

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 or deficiencies in size or quality of source material could result in production failures. Specific vulnerabilities in the process may exist in tumor types in which quality or quantity of tissue is limited, such as recurrent GBM. 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 licensee, GSK, 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 NPA. 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 product candidates is contingent, in part, upon our own, and our CMOs', 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 all of our product candidates 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 current good manufacturing practices ("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 the United Kingdom, and we previously had discovery and research operations in Germany that were transferred to Switzerland and the United Kingdom. We expect to pursue pathways to develop and commercialize our product candidates in both U.S. and 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, including without limitation any resulting from the United Kingdom's withdrawal from the European Union, 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 and for the treatment cancer. 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 therapeutic vaccines and other 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;

25

- adversely affect our ability to recruit patients for our clinical trials;
 - solidify partnerships or strategic acquisitions that may increase the competitive landscape;
 - develop or 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 antibody programs currently in early stage development targeting, amongst others, 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 OX40; (2) Merck has an approved anti-PD-1 antibody in the United States, is developing an anti-GITR agonist and anti-CEACAM antibodies, and has partnered with GSK on combination studies with OX40; (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) Pfizer has an anti-CTLA-4 antibody, an anti-PD-1 antibody (through Medivation), an anti-CD137, and an OX-40 agonist in development; (6) Tesaro has antibody programs targeting PD-1, TIM-3 and LAG-3, which include both monospecific and dual reactive antibody drug candidates; (7) Novartis has anti-TIM-3 and anti-LAG-3 antibodies in discovery and anti-PD1 antibody and GITR agonist in clinical trials; and (8) Roche/Genentech 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 have autologous vaccine programs in development including our Prophage vaccine in clinical development for GBM and our neo-antigen based AutoSynVax vaccine in preclinical development. We are aware of many companies pursuing cancer vaccines and/or immunotherapies in clinical development, including, without limitation, the following: (1) Neon Therapeutics is developing a personalized neoantigen vaccine; (2) Gritstone Oncology is discovering and developing a novel tumor-specific neo-antigen based immunotherapies, with an initial focus on lung cancer; (3) Aduro Biotech is developing immunotherapy platforms (Listeria, cyclic dinucleotides, and B-select antibodies); (4) Inovio Pharmaceutical Inc. and Medimmune are collaborating on developing DNA-based immunotherapies for cancer and infectious disease; (5) Oncolytics Biotech Inc. is developing oncolytic virus based cancer therapeutics in lung, colorectal and pancreatic cancers; (6) Oncothyreon is developing synthetic vaccines for cancer therapeutics and; (7) Genetech acquired BioNTech's personalized tumor antigen vaccines.

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.

As we develop our vaccines, such as Prophage and ASV, in other indications or in combination with other product candidates, such as available standard of care agents (Avastin®), or with CPMs, they could face additional competition in those indications or in those combinations. In addition, and prior to regulatory approval, if ever, our vaccines and 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.

Failure to realize the anticipated benefits of our strategic acquisitions and licensing transactions could adversely affect our business, operations and financial condition.

An important part of our business strategy has been to identify and advance a pipeline of product candidates by acquiring and in-licensing product candidates, technologies and businesses that we believe are a strategic fit with our existing business. Since we acquired 4-Antibody AG (“4-AB”) in February 2014, we have completed numerous additional strategic acquisitions and licensing transactions. The ultimate success of these strategic transactions entails numerous operational and financial risks, including:

- higher than expected development and integration costs;
- difficulty in combining the technologies, operations and personnel of acquired businesses with our technologies, operations and personnel;
- exposure to unknown liabilities;
- difficulty or inability to form a unified corporate culture across multiple office sites both nationally and internationally;
- inability to retain key employees of acquired businesses;
- disruption of our business and diversion of our management’s time and attention; and
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed product candidates, technologies or businesses.

We have limited resources to integrate acquired and in-licensed product candidates, technologies and businesses into our current infrastructure, and we may fail to realize the anticipated benefits of our strategic transactions. Any such failure could have an adverse effect on our business, operations and financial condition.

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 antibody 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 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 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 many 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 many 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 our technology platforms are, in part, contingent upon the participation of institutional and corporate collaborators. For example, in February 2015 we began a broad collaboration with Incyte to pursue the discovery and development of antibodies. See “Risk Factors-Risks Related to our Business—We are dependent upon our collaboration with Incyte to further develop, manufacture and commercialize 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 antibodies may be terminated or substantially delayed, and our business would be severely harmed.” Furthermore, we have a collaboration arrangement with Recepta for CTLA-4 and PD-1, giving Recepta rights to certain South American countries and requiring us to agree upon development plans for these candidates. Disagreements or the failure of either party to perform satisfactorily could have an adverse impact on these programs.

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 partner. Such product candidates depend on our collaborator 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.

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 internal computer systems, or those of our third-party CROs, CMOs, 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 or could subject us to sanctions and penalties that could have a material adverse effect on our reputation or financial condition.

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 use and store customer, vendor, employee and business partner and, in certain instances patient, personally identifiable information in the ordinary course of our business. We are subject to various domestic and international privacy and security regulations, including but not limited to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. Failure to comply with these standards, or a computer security breach or cyber-attack that affects our systems or results in the unauthorized release of proprietary or personally identifiable information, could subject us to criminal penalties and civil sanctions, and our reputation could be materially damaged and our operations could be impaired. We may also be exposed to a risk of loss or litigation and potential liability, which could have a material adverse effect on our business, results of operations and financial condition.

We are highly reliant on our Chief Executive Officer, President of R&D 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 President of R&D who joined the Company in January 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 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.

Calamities, power shortages or power interruptions could disrupt our business and materially adversely affect our operations.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure (such as our manufacturing facility) or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue certain activities, such as for example our manufacturing capabilities, for a substantial period of time. In December 2015, we acquired an antibody pilot plant manufacturing facility and leased additional office space in Berkeley, CA. This location is in an area of seismic activity near active earthquake faults. Any earthquake, terrorist attack, fire, power shortage or other calamity affecting our facilities or those of third parties upon whom we depend may disrupt our business and could have a material adverse effect on our business, results of operations, financial condition and prospects. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses and delays as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Risks Related to Regulation of the Biopharmaceutical Industry

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

Drug development, including non-clinical testing and clinical development, and the process of obtaining regulatory approvals for new therapeutic products, is lengthy, expensive, and uncertain. For example, as of September 30, 2016, we had spent approximately 20 years and \$542.5 million on our research and development programs. The development and regulatory approval processes also can vary substantially based on the therapeutic area, 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. Results of pre-clinical studies do not necessarily predict clinical results, and promising results in early clinical studies might not be confirmed 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 emerging manufacturing or control issues, limitations of pre-clinical assessments, difficulties to enroll a sufficient number of patients, changing therapeutic landscape or failure to prospectively identify the benefit/risk profile of the new product. 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 emerging with products of the same class of drug could require additional studies 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 or mitigating 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 final clinical results. 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 and 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 operate 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 or licensees 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 licensees, 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 licensees, 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 licensees, 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, LAG-3, and CEACAM1. 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, 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 own, co-own or have exclusive rights to approximately 50 issued United States patents and approximately 130 issued foreign patents. We also own, co-own or have exclusive rights to approximately 45 pending United States patent applications and approximately 60 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 (“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, PhosImmune and certain assets of Celexion, we own, co-own, or have exclusive rights to 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. Through our acquisition of PhosImmune, we own, co-own, or have exclusive rights to patents and patent applications directed to various methods and compositions, including a patent directed to methods for identifying phosphorylated proteins using mass spectrometry. This patent is projected to expire in 2023. We also own patents and patent applications relating to the SECANT® platform, a platform used for the generation of novel monoclonal antibodies. 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 we acquired or in-licensed in connection with our acquisitions of 4-AB, PhosImmune and certain assets of Celexion, will have commercial value, or that any of our existing or future patent applications, including the patent applications that we acquired or in-licensed in connection with our acquisitions of 4-AB, PhosImmune and certain assets of Celexion, will result in the issuance of valid and enforceable patents.

Our issued patents covering Prophage vaccine and methods of use thereof, alone or in combination with other agents, expired or will expire at various dates between 2015 and 2024. In particular, our issued U.S. patents covering Prophage composition of matter expired in 2015. In addition, our issued patents covering QS-21 Stimulon composition of matter expired in 2008. 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.

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 or licensees 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 or licensees, 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 or licensees 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 non-exclusive 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 or licensees 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 or licensees 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 or licensees, we or our licensors or licensees 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 (“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, securities, 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 and regulatory investigations consume 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.

If we or our employees fail to comply with laws or regulations, it could adversely impact our reputation, business and stock price.

We are 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 manufacturing antibodies in our Berkeley, CA facility 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.

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 GSK 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 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.

During the period from our initial public offering on February 4, 2000 to September 30, 2016, and the nine months ended September 30, 2016, 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 \$2.72 and \$7.20 per share, respectively. The average daily trading volume for the nine months ended September 30, 2016 was approximately 1,182,107 shares, while the average daily trading volume for the year ended December 31, 2015 was approximately 1,652,962. 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;
- 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, including our average monthly cash used in operating activities;
- 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 many biopharmaceutical, biotechnology and pharmaceutical companies 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, 2016, we had 87,115,524 shares of common stock outstanding. All of these shares are eligible for sale on NASDAQ, although certain of the shares are subject to sales volume and other limitations. We have filed registration statements to permit the sale of approximately 22,200,000

shares of common stock under our equity incentive plans, to permit the sale of 1,500,000 shares of common stock under our 2015 Inducement Equity Plan, and to permit the sale of 150,000 shares of common stock under an inducement grant. 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 325,000 shares of common stock under our Directors' Deferred Compensation Plan, to permit the sale of approximately 19,943,489 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, 2016, an aggregate of approximately 29 million of these shares remained available for sale. 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) \$10.0 million upon our market capitalization exceeding \$750.0 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 Agenesis and (ii) \$10.0 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 Agenesis. In addition, as additional consideration for assets that we purchased from Cellexion, we agreed to pay to Cellexion \$4.0 million on the 24-month anniversary of the Closing Date payable at our discretion in cash, shares of our common stock, or any combination thereof. In connection with our acquisition of PhosImmune in December 2015, we issued 1,631,521 shares of our common stock to the shareholders of PhosImmune and other third parties having a fair market value of approximately \$7.4 million at closing. In addition, we may be obligated in the future to pay certain contingent milestones payments, payable at our election in cash or shares of our common stock of up to \$35.0 million in the aggregate. We are also obligated to file registration statements covering any additional shares that may be issued to Cellexion, XOMA or the former shareholders of PhosImmune in the future pursuant to the terms of our agreements with Cellexion, XOMA and PhosImmune, respectively. The market price of our common stock may decrease based on the expectation of such sales. The market price of our common stock may decrease based on the expectation of such sales.

Edgar Filing: AGENUS INC - Form 10-Q

As of September 30, 2016, 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, 2016, options to purchase 11,761,554 shares of our common stock with a weighted average exercise price per share of \$4.53 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, 2016, we had 10,599,495 vested options and 1,937,023 nonvested shares outstanding.

As of September 30, 2016, 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, 2015, 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.

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 9, 2016 AGENUS INC.

/s/ CHRISTINE M. KLASKIN

Christine M. Klaskin

VP, Finance, Principal Financial Officer, Principal Accounting Officer

Exhibit Index

Exhibit No. Description

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