

AGENUS INC  
Form 10-Q  
November 07, 2018

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, 2018

or

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

For the transition period from to

Commission File Number: 000-29089

Agenus Inc.

(exact name of registrant as specified in its charter)

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

incorporation or organization) Identification No.)

3 Forbes Road, Lexington, Massachusetts 02421

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code:

(781) 674-4400

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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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2018: 119,982,965 shares

Agenus Inc.

Nine Months Ended September 30, 2018

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## PART I - FINANCIAL INFORMATION

## Item 1. Financial Statements

## AGENUS INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30, 2018	December 31, 2017
<b>ASSETS</b>		
Cash and cash equivalents	\$46,169,404	\$60,186,617
Inventories	55,491	79,491
Accounts receivable	6,068,854	1,134,493
Prepaid expenses	14,530,053	11,070,960
Other current assets	811,925	1,081,993
Total current assets	67,635,727	73,553,554
Property, plant and equipment, net of accumulated amortization and depreciation of		
\$37,108,300 and \$34,029,085 at September 30, 2018 and December 31, 2017, respectively	25,838,782	26,178,622
Goodwill	22,959,112	23,048,804
Acquired intangible assets, net of accumulated amortization of \$6,998,903 and		
\$5,461,834 at September 30, 2018 and December 31, 2017, respectively	12,827,224	14,406,650
Other long-term assets	1,214,394	1,214,394
Total assets	\$130,475,239	\$138,402,024
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current portion, long-term debt	\$146,061	\$20,639,735
Current portion, liability related to sale of future royalties and milestones	23,920,667	—
Current portion, deferred revenue	843,150	4,484,882
Accounts payable	11,146,451	8,086,992
Accrued liabilities	21,665,078	21,569,449
Other current liabilities	468,978	1,657,063
Total current liabilities	58,190,385	56,438,121
Long-term debt, net of current portion	13,053,895	142,385,024
Liability related to sale of future royalties and milestones, net of current portion	183,322,966	—
Deferred revenue, net of current portion	1,469,131	7,748,284
Contingent purchase price considerations	2,917,000	4,373,000
Other long-term liabilities	2,914,480	3,273,387
Commitments and contingencies		
<b>STOCKHOLDERS' DEFICIT</b>		
Preferred stock, par value \$0.01 per share; 5,000,000 shares authorized:		
Series A-1 convertible preferred stock; 31,620 shares designated, issued, and	316	316
outstanding at September 30, 2018 and December 31, 2017; liquidation value		

of \$32,780,230 at September 30, 2018

Common stock, par value \$0.01 per share; 240,000,000 shares authorized;  
118,352,706

and 101,706,117 shares issued at September 30, 2018 and December 31, 2017,

respectively	1,183,527	1,017,061
Additional paid-in capital	999,580,589	951,811,958
Accumulated other comprehensive loss	(1,615,893 )	(2,169,354 )
Accumulated deficit	(1,129,556,515)	(1,026,475,773)
Total stockholders' deficit attributable to Agenus Inc.	(130,407,976 )	(75,815,792 )
Non-controlling interest	(984,642 )	—
Total stockholders' deficit	(131,392,618 )	(75,815,792 )
Total liabilities and stockholders' deficit	\$ 130,475,239	\$ 138,402,024

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,	
	2018	2017	2018	2017
<b>Revenue:</b>				
Research and development	\$6,276,136	\$3,359,399	\$18,385,111	\$34,522,815
Non-cash royalty revenue related to the sale of future royalties	6,526,291	—	11,947,982	—
Total revenues	12,802,427	3,359,399	30,333,093	34,522,815
<b>Operating expenses:</b>				
Research and development	(29,854,310 )	(25,788,707 )	(88,569,123 )	(84,253,129 )
General and administrative	(9,203,406 )	(8,050,783 )	(27,616,079 )	(23,956,543 )
Contingent purchase price consideration fair value adjustment	180,000	(1,184,000 )	1,456,000	(123,000 )
Operating loss	(26,075,289 )	(31,664,091 )	(84,396,109 )	(73,809,857 )
<b>Other expense:</b>				
Loss on early extinguishment of debt	—	—	(10,766,625 )	—
Non-operating (expense) income	(117,172 )	(472,745 )	(1,489,835 )	1,917,200
Interest expense, net	(7,538,096 )	(4,704,871 )	(16,542,911 )	(13,765,271 )
Net loss	(33,730,557 )	(36,841,707 )	(113,195,480 )	(85,657,928 )
Dividends on Series A-1 convertible preferred stock	(51,752 )	(51,426 )	(155,011 )	(154,034 )
Less: net loss attributable to non-controlling interest	(604,887 )	—	(1,258,242 )	—
Net loss attributable to Agenus Inc. common stockholders	\$(33,177,422 )	\$(36,893,133 )	\$(112,092,249 )	\$(85,811,962 )
<b>Per common share data:</b>				
Basic and diluted net loss attributable to Agenus Inc. common stockholders	\$(0.29 )	\$(0.37 )	\$(1.04 )	\$(0.88 )
<b>Weighted average number of Agenus Inc. common shares outstanding:</b>				
Basic and diluted	114,977,416	99,891,980	107,601,000	97,557,409
<b>Other comprehensive loss:</b>				
Foreign currency translation (loss) gain	\$(38,276 )	\$231,177	\$553,461	\$(529,118 )
Other comprehensive (loss) income	(38,276 )	231,177	553,461	(529,118 )
Comprehensive loss	\$(33,215,698 )	\$(36,661,956 )	\$(111,538,788 )	\$(86,341,080 )

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,	
	2018	2017
<b>Cash flows from operating activities:</b>		
Net loss	\$(113,195,480)	\$(85,657,928)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	4,744,672	4,561,815
Share-based compensation	5,694,829	7,083,948
Non-cash royalty revenue	(11,947,982 )	—
Non-cash interest expense	16,063,404	13,360,630
Loss (gain) on disposal of assets	117,817	(19,822 )
Gain on issuance of stock for settlement of milestone obligation	—	(14,063 )
Change in fair value of contingent obligations	(1,456,000 )	123,000
Loss on extinguishment of debt	10,766,625	—
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(4,934,361 )	9,160,979
Inventories	24,000	7,959
Prepaid expenses	(3,469,828 )	(8,178,360 )
Accounts payable	2,882,184	1,006,808
Deferred revenue	(1,064,391 )	(2,006,858 )
Accrued liabilities and other current liabilities	222,462	(5,962,198 )
Other operating assets and liabilities	269,216	(1,823,880 )
Net cash used in operating activities	(95,282,833 )	(68,357,970)
<b>Cash flows from investing activities:</b>		
Proceeds from sale of plant and equipment	6,187	120,000
Purchases of plant and equipment	(2,995,572 )	(2,366,429 )
Purchases of held-to-maturity securities	—	(14,936,047)
Proceeds from securities held-to-maturity	—	15,000,000
Net cash used in investing activities	(2,989,385 )	(2,182,476 )
<b>Cash flows from financing activities:</b>		
Net proceeds from sale of equity	41,279,969	63,677,302
Proceeds from employee stock purchases and option exercises	1,233,900	833,982
Purchase of treasury shares to satisfy tax withholdings	—	(527,223 )
Proceeds from sale of future royalties	204,878,400	—
Transaction costs from sale of future royalties and milestones	(494,394 )	—
Repayments of debt	(161,847,220)	—
Payment of capital lease obligation	(193,164 )	(216,982 )
Net cash provided by financing activities	84,857,491	63,767,079
Effect of exchange rate changes on cash	(602,486 )	400,708
Net (decrease) increase in cash and cash equivalents	(14,017,213 )	(6,372,659 )
Cash and cash equivalents, beginning of period	60,186,617	71,448,016
Cash and cash equivalents, end of period	\$46,169,404	\$65,075,357
<b>Supplemental cash flow information:</b>		



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Cash paid for interest	\$837,699	\$837,699
Supplemental disclosures - non-cash activities:		
Purchases of plant and equipment in accounts payable and		
accrued liabilities	122,038	222,203
Issuance of common stock, \$0.01 par value, issued in connection with the		
settlement of milestone obligation	—	1,485,937

See accompanying notes to unaudited condensed consolidated financial statements.

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## AGENUS INC. AND SUBSIDIARIES

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2018

## 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 a clinical-stage immuno-oncology (“I-O”) company dedicated to becoming a leader in the discovery and development of innovative combination therapies and committed to bringing effective medicines to patients with cancer. Our business is designed to drive success in I-O through speed, innovation, and effective combination therapies. We have assembled fully integrated capabilities from novel target discovery, antibody generation, cell line development, and good manufacturing practice (“GMP”) manufacturing together with a comprehensive portfolio consisting of antibody-based therapeutics, adjuvants, cancer vaccine platforms, and cell therapy (through our subsidiary, AgenTus Therapeutics, Inc. (“AgenTus Therapeutics”)). We leverage our immune biology platforms to identify effective combination therapies for development and have developed productive partnerships to advance our innovation.

We are developing a comprehensive I-O 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™, SECAN® yeast display, and phage display technologies designed to drive the discovery of future CPM antibody candidates;
- our antibody candidate programs, including our CPM programs;
- our vaccine programs, including Prophage™, AutoSynVax™ and PhosPhoSynVax™;
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon® adjuvant, or QS-21 Stimulon; and
- our cell therapy subsidiary, AgenTus Therapeutics, which is designed to drive the discovery of future adoptive cell therapy, or “living drugs” (CAR-T and TCR) programs.

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 and cash equivalents at September 30, 2018 were \$46.2 million, a decrease of \$14.0 million from December 31, 2017.

The following table outlines our quarter end cash and cash equivalents balances and the changes therein (in millions).

	Quarter Ended		
	March	June	September
	31,	30,	30, 2018
	2018	2018	
Cash and cash equivalents	\$52.3	\$43.2	\$ 46.2
(Decrease) increase in cash and cash equivalents	\$(7.8 )	\$(9.2 )	\$ 3.0
Cash used in operating activities	\$(40.2)	\$(30.5)	\$ (24.6 )



equity securities. We believe the execution of one or more of these transactions will enable us to fund our planned operations for at least one year from when these financial statements were issued. Our ability to address our liquidity needs will largely be determined by the success of our product candidates and key development and regulatory events and our decisions in the future as well as the execution of one or more of the aforementioned contemplated transactions.

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, 2018, are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. 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, 2017 filed with the Securities and Exchange Commission (the “SEC”) on March 16, 2018.

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.

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.

#### Note B - Summary of Significant Accounting Policies

Except as detailed below, there have been no material changes to our significant accounting policies during the nine months ended September 30, 2018, as compared to the significant accounting policies disclosed in Note 2 of the Consolidated Financial Statements in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017.

##### Revenue

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes existing revenue recognition guidance. We adopted ASU 2014-09 and its related amendments (collectively known as “ASC 606”) on January 1, 2018 using the modified retrospective method- i.e., by recognizing the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of equity at January 1, 2018. The reported results for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition (“ASC 605”). The adoption of ASC 606 represents a change in accounting principle that will more closely align revenue recognition with the delivery of our goods and services and will provide financial statement readers with enhanced disclosures. The details of the significant changes and quantitative impact of the changes are disclosed in Note J.

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for these goods and services. To achieve this core principle, we apply the following five steps:

1) Identify the contract with the customer

A contract with a customer exists when (i) the Company enters into an enforceable contract with a customer that defines each party's rights regarding the goods or services to be transferred and identifies the related payment terms, (ii) the contract has commercial substance, and (iii) the Company determines that collection of substantially all consideration for goods and services that are transferred is probable based on the customer's intent and ability to pay the promised consideration. The Company applies judgment in determining the customer's intent and ability to pay, which is based on a variety of factors including the customer's historical payment experience, or in the case of a new customer, published credit and financial information pertaining to the customer.

2) Identify the performance obligations in the contract

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Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct, whereby the customer can benefit from the good or service either on its own or together with other available resources, and are distinct in the context of the contract, whereby the transfer of the good or service is separately identifiable from other promises in the contract. To the extent a contract includes multiple promised goods and services, the Company must apply judgment to determine whether promised goods and services are capable of being distinct and are distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation.

### 3) Determine the transaction price

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method depending on the nature of the variable consideration. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes. Determining the transaction price requires significant judgment, which is discussed in further detail for each of the Company's contracts with customers in Note J.

### 4) Allocate the transaction price to performance obligations in the contract

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation on a relative stand-alone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. The consideration to be received is allocated among the separate performance obligations based on relative stand-alone selling prices. Determining the amount of the transaction price to allocate to each separate performance obligation requires significant judgement, which is discussed in further detail for each of the Company's contracts with customers in Note J.

### 5) Recognize revenue when or as the Company satisfies a performance obligation

The Company satisfies performance obligations either over time or at a point in time. Revenue is recognized over time if either 1) the customer simultaneously receives and consumes the benefits provided by the entity's performance, 2) the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced, or 3) the entity's performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date. If the entity does not satisfy a performance obligation over time, the related performance obligation is satisfied at a point in time by transferring the control of a promised good or service to a customer. Examples of control are using the asset to produce goods or services, enhance the value of other assets, settle liabilities, and holding or selling the asset. ASC 606 requires the Company to select a single revenue recognition method for the performance obligation that faithfully depicts the Company's performance in transferring control of the goods and services. The guidance allows entities to choose between two methods to measure progress toward complete satisfaction of a performance obligation:

1. Output methods - recognize revenue on the basis of direct measurements of the value to the customer of the goods or services transferred to date relative to the remaining goods or services promised under the contract (e.g. surveys of performance completed to date, appraisals of results achieved, milestones reached, time elapsed, and units of produced or units delivered); and

2. Input methods - recognize revenue on the basis of the entity's efforts or inputs to the satisfaction of a performance obligation (e.g., resources consumed, labor hours expended, costs incurred, or time elapsed) relative to the total expected inputs to the satisfaction of that performance obligation.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

**Milestone payments:** At the inception of each arrangement that includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. ASC 606 suggests two alternatives to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used, it should be consistently applied throughout the life of the contract; however, it is not necessary for the Company to use the same approach for all contracts. The Company uses the most likely amount method for development and regulatory milestone payments. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability or achievement of each such milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

**Royalties:** For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

**Up-front Fees:** Depending on the nature of the agreement, up-front payments and fees may be recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

#### Impact of Adopting ASC 606 on Financial Statements

We adopted ASC 606 using the modified retrospective method. The cumulative effect of applying the new guidance to all contracts with customers that were not completed as of January 1, 2018 was recorded as an adjustment to accumulated deficit as of the adoption date. We elected to apply a practical expedient to reflect the aggregate effect of all modifications that occurred before January 1, 2018 when identifying the satisfied and unsatisfied performance obligations, determining the transaction price, and allocating the transaction price to the satisfied and unsatisfied performance obligations. The estimated effect of applying this practical expedient results in a slower recognition of the transaction price, as more consideration is allocated to performance obligations originally identified as a material right at contract inception. As a result of applying the modified retrospective method to adopt the new revenue guidance, the following adjustments were made to the consolidated balance sheet as of January 1, 2018 (in thousands):

	As Reported December 31, 2017	ASC 606 Adjustment	Adjusted January 1, 2018
<b>Consolidated Balance Sheet Data:</b>			
Current portion, deferred revenue	\$4,485	\$ (2,986 )	\$1,499
Deferred revenue, net of current portion	7,748	(5,870 )	1,878
Accumulated deficit	\$(1,026,476)	\$ 8,856	\$(1,017,620)



Impact of ASC 606 on Financial Statements

In accordance with Topic 606, the disclosure of the impact of adoption to our condensed consolidated statements of income and balance sheets was as follows (in thousands):

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	Nine months ended September 30, 2018			
	As Reported Under ASC 606	Adjustments	Notes	Balances without Adoption of ASC 606
<b>Consolidated Balance Sheet Data:</b>				
Accounts receivable	\$6,069	\$ (5,000 )	(1 )	\$1,069
Current portion, deferred revenue	843	1,045	(2 )	1,888
Deferred revenue, net of current portion	1,469	4,863	(2 )	6,332
Accumulated deficit	(1,129,557)	(10,908 )	(3 )	(1,140,465)
<b>Consolidated Statement of Operations Data:</b>				
Research and development revenue	\$18,385	\$ (2,051 )	(4 )	\$16,334

	Three months ended September 30, 2018			
<b>Consolidated Statement of Operations Data:</b>				
Research and development revenue	\$6,276	\$ (790 )	(4 )	\$5,486

- (1) Adjustment to accounts receivable to reflect a milestone recognized under ASC 606 and included in accounts receivable on September 30, 2018.
- (2) Adjustment to deferred revenue to reflect recognition of revenue under ASC 605 primarily attributable to the change in the timing of revenue recognition for amounts received under the Incyte Collaboration Agreement, see Note J.
- (3) Adjustment to accumulated deficit to reflect the reversal of the cumulative transition adjustment and the difference in revenue from ASC 606 to ASC 605, see Note J.
- (4) Adjustment to reflect the difference in revenue recognition from ASC 606 to ASC 605 primarily attributable to the timing of milestone recognition and the change in recognition of an upfront fee related to the GSK License and Amended Supply Agreements, see Note J.

Note C - 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, non-vested 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, 2018 and 2017, as they would be anti-dilutive:

	Three and Nine Months Ended September 30,	
	2018	2017
Warrants	2,900,000	4,351,450
Stock options	16,917,576	14,749,924
Non-vested shares	2,221,795	1,915,991
Convertible preferred stock	333,333	333,333

Note D - Investments

Cash equivalents consisted of the following as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018		December 31, 2017	
	Estimated		Estimated	
	Cost	Fair Value	Cost	Fair Value
Institutional money market funds	\$25,372	\$ 25,372	\$57,036	\$ 57,036

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, 2018 and 2017.

## Note E - 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, 2018 (in thousands):

Balance, December 31, 2017	\$23,049
Foreign currency translation adjustment	(90 )
Balance, September 30, 2018	\$22,959

Acquired intangible assets consisted of the following as of September 30, 2018 and December 31, 2017 (in thousands):

As of September 30, 2018				
Amortization				
	period	Gross carrying	Accumulated	Net carrying
	(years)	amount	amortization	amount
Intellectual property	7-15 years	\$ 16,520	\$ (5,684 )	\$ 10,836
Trademarks	4.5 years	821	(821 )	-
Other	2-6 years	569	(494 )	75
In-process research and development	Indefinite	1,916	—	1,916
Total		\$ 19,826	\$ (6,999 )	\$ 12,827

As of December 31, 2017				
Amortization				
	period	Gross carrying	Accumulated	Net carrying
	(years)	amount	amortization	amount
Intellectual property	7-15 years	\$ 16,545	\$ (4,290 )	\$ 12,255
Trademarks	4.5 years	826	(711 )	115
Other	2-6 years	570	(461 )	109
In-process research and development	Indefinite	1,928	—	1,928
Total		\$ 19,869	\$ (5,462 )	\$ 14,407

The weighted average amortization period of our finite-lived intangible assets is 9 years. Amortization expense related to acquired intangibles is estimated at \$0.5 million for the remainder of 2018 and \$1.9 million for each of the years ending December 31, 2019, 2020, 2021 and 2022.



## Note F - Debt

Debt obligations consisted of the following as of September 30, 2018 and December 31, 2017 (in thousands):

Debt instrument	Principal at		Unamortized		Balance at
	September 30, 2018	Non-cash Interest	Debt Issuance Costs	Unamortized Debt Discount	
<b>Current Portion:</b>					
Debt instrument	\$ 146	\$ —	\$ —	\$ —	\$ 146
<b>Long-term Portion:</b>					
2015 Subordinated Notes	14,000	—	—	(946 )	13,054
<b>Total</b>	<b>\$ 14,146</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ (946 )</b>	<b>\$ 13,200</b>

  

Debt instrument	Principal at		Unamortized		Balance at
	December 31, 2017	Non-cash Interest	Debt Issuance Costs	Unamortized Debt Discount	
<b>Current Portion:</b>					
Debt instrument	\$ 146	\$ —	\$ —	\$ —	\$ 146
Note Purchase Agreement	15,000	5,494	—	—	20,494
<b>Total current</b>	<b>15,146</b>	<b>5,494</b>	<b>—</b>	<b>—</b>	<b>20,640</b>
<b>Long-term Portion:</b>					
2015 Subordinated Notes	14,000	—	—	(1,375 )	12,625
Note Purchase Agreement	100,000	31,323	(1,362 )	(201 )	129,760
<b>Total long-term</b>	<b>114,000</b>	<b>31,323</b>	<b>(1,362 )</b>	<b>(1,576 )</b>	<b>142,385</b>
<b>Total</b>	<b>\$ 129,146</b>	<b>\$ 36,817</b>	<b>\$ (1,362 )</b>	<b>\$ (1,576 )</b>	<b>\$ 163,025</b>

We have capital lease agreements that expire in 2020 for equipment with a carrying value of approximately \$950,000, which is included in property, plant and equipment, net on our condensed consolidated balance sheet. Under the terms of the capital lease agreements, we will remit payments to the lessors of \$94,000 for the remainder of 2018, \$375,000 for the year ending December 31, 2019 and \$165,000 for the year ending December 31, 2020. As of September 30, 2018, our remaining obligation under the capital lease agreements is approximately \$550,000, of which \$360,000 and \$180,000 are classified as other current and other long-term liabilities, respectively, on our condensed consolidated balance sheet.

In January 2018, we, through our wholly-owned subsidiary, Antigenics LLC (“Antigenics”), entered into a Royalty Purchase Agreement (the “HCR Royalty Purchase Agreement”) with Healthcare Royalty Partners III, L.P., and certain of its affiliates (collectively “HCR”), whereby we received gross proceeds of \$190.0 million (refer to Note G). Concurrently with the closing of the HCR Royalty Purchase Agreement, we used \$161.9 million of these proceeds to redeem Antigenics’ \$115.0 million principal amount of notes issued pursuant to the Note Purchase Agreement dated September 4, 2015 with Oberland Capital SA Zermatt LLC and the purchasers named therein (the “Note Purchase

Agreement”), as well as the associated accrued and unpaid interest, and the Note Purchase Agreement and the notes issued thereunder were redeemed in full and terminated. In connection with this redemption, we recorded a \$10.8 million loss on early extinguishment of debt which primarily reflects the payment of premiums to fully redeem the notes and the write-off of unamortized debt issuance costs and discounts.

Note G – Liability Related to the Sale of Future Royalties and Milestones

The following table shows the activity within the liability account in the nine months ended September 30, 2018 (in thousands):

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	Nine months ended September 30, 2018
Liability related to sale of future royalties and milestones - beginning balance	\$ —
Proceeds from sale of future royalties and milestones	205,000
Non-cash royalty revenue	(11,948 )
Non-cash interest expense recognized	14,741
Liability related to sale of future royalties and milestones - ending balance	207,793
Less: unamortized transaction costs	(549 )
Liability related to sale of future royalties and milestones, net	\$ 207,244

### Healthcare Royalty Partners

On January 6, 2018, we, through Antigenics, entered into the HCR Royalty Purchase Agreement with HCR, which closed on January 19, 2018. Pursuant to the terms of the HCR Royalty Purchase Agreement, we sold to HCR 100% of Antigenics' worldwide rights to receive royalties from GlaxoSmithKline ("GSK") on sales of GSK's vaccines containing our QS-21 Stimulon adjuvant. At closing, we received gross proceeds of \$190.0 million from HCR. As part of the transaction, we reimbursed HCR for transaction costs of \$100,000 and incurred approximately \$500,000 in transaction costs of our own, which are presented net of the liability in the consolidated balance sheet and will be amortized to interest expense over the estimated life of the HCR Royalty Purchase Agreement. Although we sold all of our rights to receive royalties on sales of GSK's vaccines containing QS-21, as a result of our obligation to HCR, we are required to account for these royalties as revenue when earned, and we recorded the \$190.0 million in proceeds from this transaction as a liability on our condensed consolidated balance sheet that will be amortized using the interest method over the estimated life of the HCR Royalty Purchase Agreement. The liability is classified between the current and non-current portion of liability related to sale of future royalties and milestones in the consolidated balance sheets based on the estimated recognition of the royalty payments to be received by HCR in the next 12 months from the financial statement reporting date.

During the nine months ended September 30, 2018, we recognized \$11.9 million of non-cash royalty revenue, and we recorded \$14.7 million of related non-cash interest expense related to the HCR Royalty Purchase Agreement.

As royalties are remitted to HCR from GSK, the balance of the recorded liability will be effectively repaid over the life of the HCR Royalty Purchase Agreement. To determine the amortization of the recorded liability, we are required to estimate the total amount of future royalty payments to be received by HCR. The sum of these amounts less the \$190.0 million proceeds we received will be recorded as interest expense over the life of the HCR Royalty Purchase Agreement. Periodically, we assess the estimated royalty payments to be paid to HCR from GSK, and to the extent the amount or timing of the payments is materially different from our original estimates, we will prospectively adjust the amortization of the liability. During the three months ended September 30, 2018, our estimate of the effective annual interest rate over the life of the agreement increased to 14.6%, which results in a prospective interest rate of 14.0%.

There are a number of factors that could materially affect the amount and timing of royalty payments from GSK, all of which are not within our control. Such factors include, but are not limited to, changing standards of care, the introduction of competing products, manufacturing or other delays, biosimilar competition, patent protection, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates, and other events or circumstances that could result in reduced royalty payments from GSK, all of which would result in a reduction of non-cash royalty revenues and the non-cash interest expense over the life of the HCR Royalty Purchase Agreement. Conversely, if sales of GSK's vaccines containing QS-21 are more than expected, the non-cash royalty revenues and the non-cash interest expense recorded by us would be greater



over the life of the HCR Royalty Purchase Agreement.

Pursuant to the HCR Royalty Purchase Agreement, we will also be entitled to receive up to \$40.4 million in milestone payments based on sales of GSK's vaccines as follows: (i) \$15.1 million upon reaching \$2.0 billion last-twelve-months net sales any time prior to 2024 and (ii) \$25.3 million upon reaching \$2.75 billion last-twelve-months net sales any time prior to 2026.

Additionally, pursuant to the HCR Royalty Purchase Agreement, we would owe approximately \$25.9 million to HCR in 2021 (the "Rebate Payment") if neither of the following sales milestones are achieved: (i) 2019 sales exceed \$1.0 billion or (ii) 2020 sales exceed \$1.75 billion. As part of the transaction, we provided a guaranty for the potential Rebate Payment and secured the obligation with substantially all of our assets pursuant to a security agreement, subject to certain customary exceptions and excluding all assets necessary for AgenTus Therapeutics.

XOMA

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On September 20, 2018, we, through our wholly-owned subsidiary, Agenus Royalty Fund, LLC, entered into a Royalty Purchase Agreement (the “XOMA Royalty Purchase Agreement”) with XOMA (US) LLC (“XOMA”). Pursuant to the terms of the XOMA Royalty Purchase Agreement, XOMA paid us \$15.0 million at closing in exchange for the right to receive 33% of the future royalties and 10% of the future milestones that we are entitled to receive from Incyte Corporation (“Incyte”) and Merck Sharpe & Dohme (“Merck”) under our agreements with each party (see Note J), net of certain of our obligations to a third party and excluding the \$5.0 million milestone from Incyte that we recognized in the quarter ended September 30, 2018. We retained 90% of the future milestones and 67% of the future royalties under our agreements with Incyte and Merck. Although we sold our rights to receive 33% of future royalties and 10% of future milestones, as a result of our significant continued involvement in the generation of the potential royalties and milestones, we are required to account for the full amount of these royalties and milestones as revenue when earned, and we recorded the \$15.0 million in proceeds from this transaction as a liability on our condensed consolidated balance sheet. Under the terms of the XOMA Royalty Purchase Agreement, should the percentage of milestones and royalties ultimately received by XOMA fail to repay the amount received by us at closing we would have no further obligation to XOMA.

#### Note H - Accrued Liabilities

Accrued liabilities consisted of the following as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Payroll	\$ 5,364	\$ 7,790
Professional fees	2,790	2,021
Contract manufacturing costs	5,883	5,528
Research services	6,260	4,663
Other	1,368	1,567
Total	\$ 21,665	\$ 21,569

#### Note I - Fair Value Measurements

We measure our contingent purchase price considerations at fair value.

The fair values of our contingent purchase price considerations, \$2.9 million, are based on significant inputs not observable in the market, which require them 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.

Liabilities measured at fair value are summarized below (in thousands):

Description	Quoted Prices in	Significant	Significant
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	September 30, 2018	Active Markets for Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
<b>Liabilities:</b>				
Contingent purchase price considerations	\$ 2,917	\$ —	\$ —	\$ 2,917
<b>Total</b>	<b>\$ 2,917</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 2,917</b>

	December 31, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Liabilities:</b>				
Contingent purchase price consideration	\$ 4,373	\$ —	\$ —	\$ 4,373
<b>Total</b>	<b>\$ 4,373</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 4,373</b>

The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3), as of September 30, 2018 (in thousands):

Balance, December 31, 2017	\$4,373
Change in fair value of contingent purchase price considerations	
during the period	(1,456)
Balance, September 30, 2018	\$2,917

The estimated fair values of all of our financial instruments, excluding our outstanding debt as of December 31, 2017, approximate their carrying amounts in our condensed consolidated balance sheets.

The fair value of our outstanding debt balance at September 30, 2018 and December 31, 2017 was \$14.2 million and \$205.9 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, 2018 and December 31, 2017 was \$14.1 million and \$129.1 million, respectively.

#### Note J - Revenue from Contracts with Customers

##### GSK License and Amended GSK Supply Agreements

In July 2006, we entered into a license agreement and a supply agreement with GSK for the use of QS-21 Stimulon (the “GSK License Agreement” and the “GSK Supply Agreement”, respectively). In January 2009, we entered into an Amended and Restated Manufacturing Technology Transfer and Supply Agreement (the “Amended GSK Supply Agreement”) under which GSK has the right to manufacture all of its requirements of commercial grade QS-21 Stimulon. GSK is obligated to supply us (or our affiliates, licensees, or customers) certain quantities of commercial grade QS-21 Stimulon for a stated period of time. Under these agreements, GSK paid an upfront license fee of \$3.0 million and agreed to pay aggregate milestones of \$5.0 million. In July 2007, the Amended GSK Supply Agreement was further amended, and we were paid an additional fixed fee of \$7.3 million. In March 2012 we entered into a First Right to Negotiate and Amendment Agreement amending the GSK License Agreement and the Amended GSK Supply Agreement to clarify and include additional rights for the use of our QS-21 Stimulon (the “GSK First Right to Negotiate Agreement”). In addition, we granted GSK the first right to negotiate for the purchase of the Company or certain of our assets, which such rights expired in March 2017. As consideration for entering into the GSK First Right to Negotiate Agreement, GSK paid us an upfront, non-refundable payment of \$9.0 million, \$2.5 million of which is creditable toward future royalty payments. As of December 31, 2017, we had received all of the potential \$24.3 million in upfront and milestone payments related to the GSK Agreements. We were also generally entitled to receive 2% royalties on net sales of prophylactic vaccines for a period of 10 years after the first commercial sale of a resulting GSK product, but we sold these royalty rights to HCR in January 2018 pursuant to the HCR Royalty Purchase Agreement (See Note G). The GSK License and Amended GSK Supply Agreements may be terminated by either party upon a material breach if the breach is not cured within the time specified in the respective agreement. The termination or expiration of the GSK License Agreement does not relieve either party from any obligation which accrued prior to the termination or expiration. Among other provisions, the license rights granted to GSK survive expiration of the GSK License Agreement. The license rights and payment obligations of GSK under the Amended GSK Supply Agreement survive termination or expiration, except that GSK's license rights and future royalty obligations do not survive if we terminate due to GSK's material breach unless we elect otherwise.

We assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, GSK, is a customer. We identified the following performance obligations under the contract: (1) an exclusive license to QS-21 in the specified field and related technology transfer; and (2) an exclusive license to QS-21 in an additional field.

We determined that the fixed payments of \$19.3 million constituted all of the consideration to be included in the transaction price and to be allocated to the performance obligations based on their relative stand-alone selling prices. The fixed upfront consideration is recognized under ASC 606 based on when control of the combined performance obligation is transferred to the customer, which corresponds with the service period (through December 2014). At contract inception, the milestones of \$5.0 million had been excluded from the transaction price, as we could not conclude that it was probable a significant reversal would not occur. Event driven milestones are a form of variable consideration as the payments are variable based on the occurrence of future events. As part of its estimation of the amount, we considered numerous factors, including that receipt of the milestones is outside of our control and contingent upon success in future clinical trials and the licensee's efforts. Recognition of event driven milestones should be recognized when the variable consideration is able to be estimated. As of December 31, 2017, all milestones had been received, and therefore recognized.

Any consideration related to royalties will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to GSK and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

For the three and nine months ended September 30, 2018, we recognized \$6.5 million and \$11.9 million, respectively, in non-cash royalty revenue from GSK. For both the three and nine months ended September 30, 2017 we did not recognize any revenue from GSK.

The cumulative impact of changing the timing of revenue recognition for the GSK License and Amended GSK Supply Agreements as of January 1, 2018 was a decrease to stockholders' deficit of approximately \$2.5 million and a corresponding decrease in deferred revenue of \$2.5 million for the portion of the upfront fee creditable toward future royalties, as described above. This amount was included in the transition adjustment, as under ASC 606 it would have been recognized as revenue in March 2012, at the time of the amendment.

#### Merck Collaboration and License Agreement

During the quarter ended June 30, 2014, we entered into a collaboration and license agreement with Merck to discover and optimize fully-human antibodies against two undisclosed cancer targets using the Retrocyte Display<sup>®</sup>. Under this agreement, Merck is responsible for the clinical development and commercialization of antibodies generated under the collaboration. There are no unsatisfied performance obligations relating to this contract. Pursuant to the XOMA Royalty Purchase Agreement, we sold to XOMA 33% of the future royalties and 10% of the future milestones that we are entitled to receive from Merck, and we remain eligible to receive from Merck approximately \$85.5 million in potential payments associated with the completion of certain clinical, regulatory and commercial milestones, as well as 67% of all future royalties on worldwide product sales.

For the three months ended September 30, 2018, we did not recognize any revenue from this agreement. For the nine months ended September 30, 2018, we recognized \$4.0 million in research and development revenue related to the achievement of a milestone. For both the three and nine months ended September 30, 2017, we did not recognize any revenue from this agreement.

The adoption of ASC 606 did not have an impact on the Merck collaboration and license agreement.

#### Incyte Collaboration Agreement

On January 9, 2015 and effective February 19, 2015, we entered into a global license, development and commercialization agreement (the "Collaboration Agreement") with Incyte pursuant to which the parties plan to develop and commercialize novel immuno-therapeutics using our antibody discovery platforms. The Collaboration Agreement was initially focused on four checkpoint modulator programs directed at GITR, OX40, LAG-3 and TIM-3. In addition to the four identified antibody programs, the parties have an option to jointly nominate and pursue the development and commercialization of antibodies against additional targets during a five-year discovery period which, upon mutual agreement of the parties for no additional consideration, can be extended for an additional three years. In November 2015, we and Incyte jointly nominated and agreed to pursue the development and commercialization of three additional CPM targets. In February 2017, we amended the Collaboration Agreement by entering into a First Amendment to License, Development and Commercialization Agreement (the "Amendment"). See "Amendment" section below.

On January 9, 2015, we also entered into the Stock Purchase Agreement with Incyte Corporation whereby, for an aggregate purchase price of \$35.0 million, Incyte purchased approximately 7.76 million shares of our common stock.

#### Agreement Structure

Under the terms of the Collaboration Agreement, we received non-creditable, nonrefundable upfront payments totaling \$25.0 million. In addition, until the Amendment, the parties shared all costs and profits for the GITR, OX40 and two of the additional antibody programs on a 50:50 basis (profit-share products), and we were eligible to receive up to \$20.0 million in future contingent development milestones under these programs. Incyte is obligated to reimburse us for all development costs that we incur in connection with the TIM-3, LAG-3 and one of the additional antibody programs (royalty-bearing products) and we are eligible to receive (i) up to \$155.0 million in future contingent development, regulatory, and commercialization milestone payments and (ii) tiered royalties on global net sales at rates generally ranging from 6% to 12%. For each royalty-bearing product, we will also have the right to elect to co-fund 30% of development costs incurred following initiation of pivotal clinical trials in return for an increase in royalty rates. Additionally, we had the option to retain co-promotion participation rights in the United States on any profit-share product. Through the direction of a joint steering committee, until the Amendment, the parties anticipated that, for each program, we would serve as the lead for pre-clinical development activities through investigational new drug (“IND”) application filing, and Incyte would serve as the lead for clinical development activities. The parties initiated the first clinical trials of antibodies arising from these

programs in 2016. For each additional program beyond GITR, OX40, TIM-3 and LAG-3 that the parties elect to bring into the collaboration, we will have the option to designate it as a profit-share product or a royalty-bearing product.

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

#### Amendment

Pursuant to the terms of the Amendment, the GITR and OX40 programs immediately converted from profit-share programs to royalty-bearing programs and we became eligible to receive a flat 15% royalty on global net sales should any candidates from either of these two programs be approved. Incyte is now responsible for global development and commercialization and all associated costs for these programs. In addition, the profit-share programs relating to TIGIT and one undisclosed target were removed from the collaboration, with the undisclosed target reverting to Incyte and TIGIT to Agenus. Should any of those programs be successfully developed by a party, the other party will be eligible to receive the same milestone payments as the royalty-bearing programs and royalties at a 15% rate on global net sales. The terms for the remaining three royalty-bearing programs targeting TIM-3, LAG-3 and one undisclosed target remain unchanged, with Incyte being responsible for global development and commercialization and all associated costs. The Amendment gives Incyte exclusive rights and all decision-making authority for manufacturing, development, and commercialization with respect to all royalty-bearing programs.

In connection with the Amendment, Incyte paid us \$20.0 million in accelerated milestones related to the clinical development of the antibody candidates targeting GITR and OX40.

In February 2017, we also entered into a Stock Purchase Agreement with Incyte, pursuant to which Incyte purchased 10 million shares of our common stock at a purchase price of \$6.00 per share.

Pursuant to the XOMA Royalty Purchase Agreement, we sold to XOMA 33% of the future royalties and 10% of the future milestones that we were entitled to receive from Incyte, excluding the \$5.0 million milestone that we recognized in the three months ended September 30, 2018. As of September 30, 2018, we remain eligible to receive up to \$450.0 million in future potential development, regulatory and commercial milestones across all programs in the collaboration, as well as 67% of all future royalties on worldwide product sales.

#### Collaboration Revenue

We identified the following performance obligations under the Incyte Collaboration Agreement, as amended: (1) combined license and related research and development ("R&D") services to a GITR antibody, (2) combined license and related R&D services to an OX40 antibody, (3) combined license and related R&D services to a TIM-3 antibody, (4) combined license and related R&D services to a LAG-3 antibody, (5) combined license and related R&D services to a TIGIT antibody, (6) combined license and related R&D services to a first undisclosed target, (7) combined license and related R&D services to a second undisclosed target, and (8) the option to license certain other mutually agreed-upon antibodies combined with related R&D Services ("Assumed Project Options Development"). Each of these performance obligations consists of a license or option to a license and related R&D services through the filing of an IND for each antibody candidate.

We concluded that the licenses could be used with other readily available resources if the know-how was also transferred with the license; however, our knowledge and experience is necessary for further development of the licensed antibodies. Therefore, we determined that each of the licensed antibodies and the related developmental R&D



services should be treated as a combined performance obligation. We also evaluated whether the Assumed Project Options Development was a material right. At contract inception Incyte paid us a nonrefundable access fee for the ability to exercise the option and bring additional targets into the program. Both we and Incyte have the ability to explore targets and, if mutually agreed upon, convert those targets into assumed projects for no additional license fee. We concluded that Assumed Project Options Development represents a material right and is therefore a performance obligation.

We determined that there were no significant financing components, noncash consideration, or amounts that may be refunded to the customer, and as such the total upfront fixed consideration of the \$10.0 million license fee and \$15.0 million project access fee would be included in the total transaction price of \$25.0 million. This amount was then allocated to the performance obligations on a relative stand-alone selling price basis.

The estimated variable consideration to be recognized for developmental R&D services and related reimbursable expenses (“Development Costs”) was determined based on the forecasted amounts in the research plan that had been approved by the both parties via the joint steering committee (“JSC”). Under the Agreement, Development Costs related to Profit-Sharing products are split equally between us and Incyte. Therefore, our expected revenue is 50% of the costs of these programs. Based on review of the budgets presented at the JSC meetings, as well as costs of previous R&D projects, we expected the total development costs over the term of the contract would be \$43.4 million. This amount was allocated entirely to the distinct R&D services that forms part of each performance obligation.

We determined that the transaction price of the Collaboration Agreement was \$78.7 million as of September 30, 2018, an increase of \$10.3 million from the transaction price of \$68.4 million as of December 31, 2017. In order to determine the transaction price, we evaluated all the payments to be received during the duration of the contract. We determined that the fixed upfront license fee and project access fee of \$10.0 million and \$15.0 million, respectively, and the \$53.7 million of actual and estimated variable consideration for development costs (including R&D services) and milestones constituted consideration to be included in the transaction price, which is allocated among the performance obligations.

For payments made to Incyte related to their work performed on profit-sharing programs, we considered that we will receive a benefit through the performance of a series of distinct R&D services by Incyte. Additionally, the R&D services are being provided by Incyte at fair value. Therefore, the amount paid to Incyte represents the fair value of the services performed, and no excess will be allocated as a reduction of the transaction price. We will record the consideration paid to Incyte in the same manner that we would purchases for other vendors, classified as R&D expense.

In summary, each of the performance obligations includes a license or option to a license, and respective R&D services that will be performed over time from program initiation through the filing of an IND with respect to each antibody candidate. We have determined that the combined performance obligation is satisfied over time, and that the input method should be applied for all performance obligations that have consideration allocated to them. The cost-cost measure will be applied based on the percentage of completion of R&D services provided during the period compared to the respective budget. We believe this is the best measure of progress because other measures do not reflect how we transfer our performance obligation to Incyte. We will recognize the fixed consideration allocated to each performance obligation over time as the related R&D services are being performed using the input of R&D costs incurred over total R&D costs expected to be incurred through IND filing, beginning on the date a license is granted. A cost-based input method of revenue recognition requires management to make estimates of costs to complete our performance obligations. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete our performance obligations will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

We considered the nature of the arrangement between Incyte and us in evaluating the classification of the payments to be received under the cost-sharing arrangement. We do not currently have any commercial products available for sale. Our primary operations to date have included research and development activities, licensing intellectual property and performing R&D services for external parties. Accordingly, arrangements such as this Collaboration Agreement represent our ongoing business operations. Therefore, we have concluded that payments received from Incyte under the cost-sharing arrangement represent payments made to us as part of our on-going operations and should be classified as revenue as such amounts are earned.

For the three months ended September 30, 2018, we recognized approximately \$6.3 million of research and development revenue. This amount included \$0.3 million of the transaction price for the Collaboration Agreement recognized based on proportional performance, \$5.0 million for the achievement of a milestone and \$1.0 million for research and development services. For the three months ended September 30, 2017, we recognized approximately

\$3.2 million of research and development revenue.

For the nine months ended September 30, 2018, we recognized approximately \$14.4 million of license and collaboration revenue. This amount included \$1.1 million of the transaction price for the Collaboration Agreement recognized based on proportional performance, \$10.0 million for the achievement of milestones and \$3.3 million for research and development services. For the nine months ended September 30, 2017, we recognized approximately \$34.0 million of research and development revenue.

We expect to recognize deferred research and development revenue of \$0.3 million, \$0.8 million, and \$1.2 million for the remainder of 2018, 2019, and 2020, respectively, related to performance obligations that are unsatisfied or partially unsatisfied as of September 30, 2018. These amounts exclude amounts (milestones, R&D services and royalties) where we have a right to invoice the customer in the amount that corresponds directly with the value of the performance completed to date.

The cumulative impact of the adoption of ASC 606 for the Incyte Collaboration Agreement as of January 1, 2018 was a decrease to stockholders' deficit of approximately \$6.4 million and a corresponding decrease in deferred revenue of \$6.4 million.

## Disaggregation of Revenue

The following table presents revenue (in thousands) for the three and nine months ended September 30, 2018 disaggregated by geographic region and revenue type. Revenue by geographic region is allocated based on the domicile of our respective business operations.

	Three months ended September 30, 2018		
	United States	Europe	Total
Revenue Type			
Research and development services	\$1,014	\$—	\$1,014
License and collaboration milestones	5,000	—	5,000
Recognition of deferred revenue	262	—	262
Non-cash royalty revenue	6,526	—	6,526
	\$12,802	\$—	\$12,802
	Nine months ended September 30, 2018		
Revenue Type			
Research and development services	\$3,321	\$—	\$3,321
License and collaboration milestones	10,000	4,000	14,000
Recognition of deferred revenue	1,064	—	1,064
Non-cash royalty revenue	11,948	—	11,948
	\$26,333	\$4,000	\$30,333

## Contract Balances

Contract assets primarily relate to our rights to consideration for work completed in relation to our R&D services performed but not billed at the reporting date. The contract assets are transferred to the receivables when the rights become unconditional. Currently, we do not have any contract assets which have not transferred to a receivable. We had no asset impairment charges related to contract assets in the period. The contract liabilities primarily relate to contracts where we received payments but have not yet satisfied the related performance obligations. The advance consideration received from customers for R&D services or licenses bundled with other promises is a contract liability until the underlying performance obligations are transferred to the customer.

The following table provides information about contract assets and contract liabilities from contracts with customers (in thousands):

Nine months ended September 30, 2018	Balance at beginning of period	Additions	Deductions	Balance at end of period
Contract assets:				
Unbilled receivables from collaboration partners	\$ -	\$ -	\$ -	\$ -
Contract liabilities:				
Deferred revenue	\$ 3,376	\$ -	\$ (1,064 )	\$2,312

The change in contract liabilities is primarily related to the recognition of \$1.1 million of revenue during the nine months ended September 30, 2018. Deferred revenue related to our Collaboration Agreement with Incyte of \$2.3 million as of September 30, 2018, which was comprised of the \$25.0 million upfront payment, less \$22.7 million of license and collaboration revenue recognized from the effective date of the contract, will be recognized as the combined performance obligation is satisfied.

We also recorded a \$6.1 million receivable as of September 30, 2018 that consisted of \$1.1 million for R&D services provided and \$5.0 million for the achievement of a milestone.

During the three and nine months ended September 30, 2018, we did not recognize any revenue from amounts included in the contract asset or the contract liability balances from performance obligations satisfied in previous periods. None of the costs to obtain or fulfill a contract were capitalized.

## Note K - 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.

A summary of option activity for the nine months ended September 30, 2018 is presented below:

	Options	Price	Weighted Average Exercise Term (in years)	Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2017	14,366,787	\$ 4.22			
Granted	4,101,113	5.21			
Exercised	(272,493 )	3.41			
Forfeited	(770,115 )	4.18			
Expired	(507,716 )	5.65			
Outstanding at September 30, 2018	16,917,576	\$ 4.43	7.26		\$ 25,088
Vested or expected to vest at September 30, 2018	16,917,576	\$ 4.43	7.26		\$ 25,088
Exercisable at September 30, 2018	9,928,173	\$ 4.26	6.08		\$ 801

The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2018 and 2017 were \$1.28 and \$1.96, respectively.

As of September 30, 2018, \$8.7 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 2.3 years.

As of September 30, 2018, 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 \$0.9 million. 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 non-vested stock. The fair value of non-vested market-based awards is calculated based on a Monte Carlo simulation as of the date of issuance. The fair value of other non-vested stock is calculated based on the closing sale price of our common stock on the date of issuance.

A summary of non-vested stock activity for the nine months ended September 30, 2018 is presented below:

	Weighted Average	
	Non-vested	Grant Date
	Shares	Fair Value
Outstanding at December 31, 2017	1,313,550	\$ 2.91
Granted	1,014,109	3.74
Vested	(53,050 )	3.77
Forfeited	(52,814 )	4.26
Outstanding at September 30, 2018	2,221,795	\$ 3.23

As of September 30, 2018, there was approximately \$3.5 million of unrecognized share-based compensation expense related to these non-vested shares for which, if all milestones are achieved, will be recognized over a period of 2.5 years. The total intrinsic value of shares vested during the nine months ended September 30, 2018, was \$0.2 million.

During the nine months ended September 30, 2018, 140,313 shares were issued under the 2009 Employee Stock Purchase Plan, 53,050 shares were issued as a result of the vesting of non-vested stock and 272,493 shares were issued as a result of stock option exercises.

The impact on our results of operations from share-based compensation for the three and nine months ended September 30, 2018 and 2017, was as follows (in thousands):

	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2017	
Research and development	\$895	\$969	\$2,535	\$3,368
General and administrative	1,010	986	3,160	3,716
Total share-based compensation expense	\$1,905	\$1,955	\$5,695	\$7,084

#### Note L - Benefit Plans

Previously, we maintained a multiple employer benefit plan that covered certain international employees. During the year ended December 31, 2017, in connection with the closure of our facility in Basel, Switzerland, we ended our participation in the plan.

We made no contributions to the plan during the three and nine months ended September 30, 2018, and no future contributions are expected. For the three and nine months ended September 30, 2017, we contributed approximately \$39,000 and \$124,000 to our international multiple employer benefit plan.

#### Note M – Equity

##### At the Market Offerings

During the nine months ended September 30, 2018, we received net proceeds of approximately \$8.5 million from the sale of approximately 1.9 million shares of our common stock at an average price per share of approximately \$4.56 in at-the-market offerings under our Controlled Equity Offering<sup>SM</sup> sales agreement with Cantor Fitzgerald & Co. We terminated our Controlled Equity Offering<sup>SM</sup> sales agreement with Cantor Fitzgerald & Co. in May 2018.

In May 2018 we entered into an At Market Issuance Sales Agreement with B. Riley FBR, Inc. with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, up to 20,000,000 shares of our common stock through B. Riley FBR, Inc. as our sales agent. During the nine months ended September 30, 2018, we received net proceeds of approximately \$32.8 million from the sale of approximately 14.3 million shares of our common stock at an average price per share of approximately \$2.37 in at-the-market offerings under our At Market Issuance Sales Agreement with B. Riley FBR, Inc.



Note N - Recent Accounting Pronouncements

Recently Issued and Adopted

In May 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers, (Topic 606) (“ASU 2014-09”). ASU 2014-09 amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB subsequently issued additional, clarifying standards to address issues arising from the implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards require an entity to recognize revenue when control of promised goods or services is transferred to the customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted this new standard on January 1, 2018, by using the modified-retrospective method. See Note B and Note J.

In January 2017, the FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business (“ASU 2017-01”), which provides guidance regarding the definition of a business, with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. We adopted ASU 2017-01 on January 1, 2018 and will apply it prospectively. The impact on our consolidated financial statements in future periods will depend on the specific facts and circumstances of future transactions.

In May 2017, the FASB issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718) Scope of Modification Accounting (“ASU 2017-09”). The amendments in ASU 2017-09 provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. We adopted ASU 2017-09 on January 1, 2018. The guidance will be applied prospectively to awards modified on or after the adoption date. The adoption of ASU 2017-09 did not have any impact on our consolidated financial statements.

Recently Issued, Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) (“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 2016-2 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. In July 2018, the FASB issued ASU 2018-11, which provides companies an additional, optional, transition method. This optional method allows companies to initially apply the standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Note 15 in our Annual Report on Form 10-K for the year ended December 31, 2017 provides details on our current lease arrangements. While we continue to evaluate the provisions of ASC 842 to determine how it will be affected, the primary effect of adopting the new standard will be to record assets and obligations for current operating leases. Upon adoption, based on leases in place as of December 31, 2017, we expect to recognize assets and liabilities of approximately \$8.2 million related to our operating leases. The adoption of ASC 842 is not expected to have a material impact on our results of operations or cash flows.

In January 2017, the FASB issued ASU 2017-04, Intangibles – Goodwill and Other (Topic 350) (“ASU 2017-04”) that will eliminate the requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Instead, an impairment charge will be based on the excess of a reporting unit’s carrying amount over its fair value. The guidance is effective for the Company in the first quarter of fiscal 2020. Early adoption is permitted. We do not anticipate the adoption of this guidance to have a material impact on our consolidated financial statements, absent any goodwill impairment.

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting (“ASU 2018-07”). The amendments in ASU 2018-07 simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The standard will be effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of adoption of ASU 2018-07 on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement (“ASU 2018-13”). The amendments in ASU 2018-13 modify the disclosure requirements of fair value measurements. The standard will be effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, with early adoption permitted. Certain disclosures are required to be applied on a retrospective basis and others on a prospective basis. We are currently evaluating the impact of adoption of ASU 2018-13 on our financial statement disclosures.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract ("ASU 2018-15"). The amendments in ASU 2018-15 align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The standard will be effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, with early adoption permitted. ASU 2018-15 is required to be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. We are currently evaluating the impact of adoption of ASU 2018-07 on our consolidated financial statements.

No other new accounting pronouncement issued or effective during the nine months ended September 30, 2018 had or is expected to have a material impact on our consolidated financial statements or disclosures.

#### Note O - Subsequent Events

##### At the Market Offerings

On October 3 & 4, 2018, we received aggregate net proceeds of approximately \$3.6 million from the sale of approximately 1.6 million shares of our common stock at an average price per share of approximately \$2.32 in at-the-market offerings under our At Market Issuance Sales Agreement with B. Riley FBR, Inc. As of November 07, 2018, approximately 4.1 million shares remain available for sale under this agreement.

Stock Purchase Agreement

On October 10, 2018, we entered into a Stock Purchase Agreement with certain institutional investors (the “Purchasers”), pursuant to which we issued and sold an aggregate of 18,459 shares of Series C-1 Convertible Preferred Stock (the “Preferred Shares”), at a purchase price of \$2,167 per share. Each Preferred Share is convertible into 1,000 shares of our common stock (the “Common Stock”) at a conversion price of \$2.167 per share of Common Stock, subject to adjustment. The aggregate purchase price paid by the Purchasers for the Preferred Shares was approximately \$40.0 million and we received net proceeds of approximately \$39.9 million, after offering expenses. The transaction closed on October 11, 2018.

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 relate to, among other things, our business strategy, our research and development, our product development efforts, our ability to commercialize our product candidates, the activities of our licensees, our prospects for initiating partnerships or collaborations, the timing of the introduction of products, the effect of new accounting pronouncements, uncertainty regarding our future operating results and our profitability, anticipated sources of funds as well as our plans, objectives, expectations, and intentions.

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

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Overview

We are a clinical-stage immuno-oncology (“I-O”) company dedicated to becoming a leader in the discovery and development of innovative combination therapies and committed to bringing effective medicines to patients with cancer. Our business is designed to drive success in I-O through speed, innovation, and effective combination therapies. We have assembled fully integrated capabilities from novel target discovery, antibody generation, cell line development, and good manufacturing practice (“GMP”) manufacturing together with a comprehensive portfolio consisting of antibody-based therapeutics, adjuvants, cancer vaccine platforms, and cell therapy (through our subsidiary, AgenTus Therapeutics, Inc. (“AgenTus Therapeutics”)). We leverage our immune biology platforms to identify effective combination therapies for development and have developed productive partnerships to advance our innovation.

We are developing a comprehensive I-O 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 drive the discovery of future CPM antibody candidates;
- our antibody candidate programs, including our CPM programs;
- our vaccine programs, including Prophage™, AutoSynVax™ and PhosPhoSynVax™;
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon® adjuvant, or QS-21 Stimulon; and
-

our cell therapy subsidiary, AgenTus Therapeutics, which is designed to drive the discovery of future adoptive cell therapy, or “living drugs” (CAR-T and TCR) programs.

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. As such, we have recently shifted our strategy for first approval from lung cancer to cervical cancer based on increasing competition and recent data that would have hindered our ability to pursue accelerated pathways for approval. We are currently advancing our own combination of CTLA-4 and PD-1 antibodies in second line cervical cancer.

We have formed collaborations with companies such as Incyte Corporation (“Incyte”), Merck Sharpe & Dohme (“Merck”) and Recepta Biopharma SA (“Recepta”). Through these alliances, as well as our own internal programs, we currently have more than a dozen antibody programs in pre-clinical or early phase development, including our anti-CTLA-4 and anti-PD-1 antibody programs

(both partnered with Recepta for certain South America territories) and anti-GITR and anti-OX40 antibody programs (both partnered with Incyte). In February 2017, we amended our collaboration agreement with Incyte to, among other things, convert the GITR and OX40 programs from profit-share to royalty-bearing programs, and there are no longer any profit-share programs remaining under the collaboration. Pursuant to the amended agreement, we received accelerated milestone payments of \$20.0 million from Incyte related to the clinical development of INCAGN1876 (anti-GITR agonist) and INCAGN1949 (anti-OX40 agonist). Concurrent with the execution of the amendment, we and Incyte also entered into the Stock Purchase Agreement whereby Incyte purchased an additional 10 million shares of our common stock at \$6.00 per share, resulting in additional proceeds of \$60.0 million to us. On September 20, 2018, we, through our wholly-owned subsidiary, Agenus Royalty Fund, LLC, entered into a Royalty Purchase Agreement (the “XOMA Royalty Purchase Agreement”) with XOMA (US) LLC (“XOMA”). Pursuant to the terms of the XOMA Royalty Purchase Agreement, XOMA paid us \$15.0 million at closing in exchange for the right to receive 33% of the future royalties and 10% of the future milestones that we are entitled to receive from Incyte and Merck, net of certain of our obligations to a third party and excluding the next milestone that we expect to receive from Incyte. After taking into account our obligations under the XOMA Royalty Purchase Agreement, as of September 30, 2018, we remain eligible to receive up to \$450.0 million and \$85.5 million in potential development, regulatory and commercial milestones from Incyte and MDS, respectively.

In addition to our antibody platforms and CPM programs, we are also advancing a series of vaccine programs to treat cancer. In January 2017, we announced a clinical trial collaboration with the National Cancer Institute (“NCI”), which is a double-blind, randomized controlled Phase 2 trial that is evaluating the effect of our autologous vaccine candidate, Prophage, in combination with pembrolizumab (Keytruda®, Merck & Co., Inc. (“Merck”)) in patients with newly diagnosed glioblastoma. Under this collaboration, we are supplying Prophage, Merck is supplying pembrolizumab and the NCI and Brain Tumor Trials Collaborative member sites are recruiting patients and conducting the trial.

Our QS-21 Stimulon adjuvant is also partnered with GlaxoSmithKline (“GSK”) and is a key component in multiple GSK vaccine programs. These programs are in various stages, with the most advanced being GSK’s shingles program. In 2015, we monetized a portion of the future royalties we were 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 million. In October 2017, GSK’s shingles vaccine was approved in the United States by the FDA and granted marketing authorization in Canada by Health Canada, and in November 2017, we exercised our option to issue the \$15.0 million in additional notes in accordance with the terms of the NPA. In January 2018, we entered into a Royalty Purchase Agreement with Healthcare Royalty Partners III, L.P. and certain of its affiliates (together, “HCR”), pursuant to which HCR purchased 100% of our worldwide rights to receive royalties from GSK on GSK’s sales of vaccines containing our QS-21 Stimulon adjuvant. We used the majority of the upfront proceeds from HCR to redeem all of the notes issued pursuant to the NPA, resulting in net proceeds to us of approximately \$28.0 million at closing. We do not incur clinical development costs for products partnered with GSK.

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.

In October 2017, we announced the launch of a subsidiary that is advancing our cell therapy business, AgenTus Therapeutics. The subsidiary is focused on the discovery, development, and commercialization of breakthrough “living drugs” to advance cures for cancer patients. AgenTus Therapeutics licenses intellectual property assets from Agenus and has its own management and governance.

## Historical Results of Operations

Three months ended September 30, 2018 compared to the three months ended September 30, 2017

Research and development revenue

We recognized Research and Development (“R&D”) revenue of approximately \$6.3 million and \$3.4 million during the three months ended September 30, 2018 and 2017, respectively. R&D revenues in the third quarter of 2018 primarily consisted of fees earned under our Collaboration Agreement with Incyte, including \$5.0 million related to the recognition of a milestone and \$1.0 million related to the reimbursement of development costs, which have decreased due to the stage of the programs under the collaboration. R&D revenues in the third quarter of 2017 primarily consisted of fees earned under our Collaboration Agreement with Incyte, including \$2.5 million related to the reimbursement of development costs. During the three months ended September 30, 2018 and 2017, we recorded revenue of \$0.3 million and \$0.9 million, respectively, from the amortization of deferred revenue. See Notes B and J to our Condensed Consolidated Financial Statements for additional discussion of our revenues, including the adoption of ASC 606 during the first quarter of 2018.

Non-cash royalty revenue related to the sale of future royalties



In January 2018, we sold 100% of our worldwide rights to receive royalties from GSK on sales of GSK's vaccines containing our QS-21 Stimulon adjuvant to HCR. As described in Note G to our Condensed Consolidated Financial Statements, this transaction has been recorded as a liability that amortizes over the estimated life of our Royalty Purchase Agreement with HCR. As a result of this liability accounting, even though the royalties are remitted directly to HCR, we record these royalties from GSK as revenue. During the three months ended September 30, 2018, we recognized approximately \$6.5 million in non-cash royalty revenue related to our agreement with GSK.

#### Research and development expense

Research and development expense includes the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, manufacturing costs, costs of consultants, and administrative costs. Research and development expense increased 16% to \$29.9 million for the three months ended September 30, 2018 from \$25.8 million for the three months ended September 30, 2017. Increased expenses in the three months ended September 30, 2018 primarily relate to a \$2.6 million increase in third-party services and other related expenses largely relating to the advancement of our antibody programs, a \$2.3 million increase in expenses attributable to the activities of our subsidiary, AgenTus Therapeutics, which began operations in the quarter ended September 30, 2017, and a \$0.5 million license payment in the quarter ended September 30, 2018 for which there was no corresponding payment in the quarter ended September 30, 2017. These increases were partially offset by a \$1.3 million decrease in expenses for our foreign subsidiaries mainly attributable to the closure of our facility in Basel, Switzerland in 2017.

#### General and administrative expense

General and administrative expense consists primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 14% to \$9.2 million for the three months ended September 30, 2018 from \$8.1 million for the three months ended September 30, 2017. Increased expenses in the three months ended September 30, 2018 primarily relate to a \$0.6 million increase in professional fees, a \$0.3 million increase in personnel related expenses, primarily due to increased headcount and a \$0.3 million increase in expenses attributable to the activities of our subsidiary, AgenTus Therapeutics, which began operations in the quarter ended September 30, 2017.

#### Contingent purchase price consideration fair value adjustment

Contingent purchase price consideration fair value adjustment represents the change 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 income (expense)

Non-operating income (expense) includes our foreign currency translation adjustment and other income or expense. Non-operating expense decreased \$0.4 million for the three months ended September 30, 2018, from expense of \$0.5 million for the three months ended September 30, 2017 to an expense of \$0.1 million for the three months ended September 30, 2018, primarily due to our decreased foreign currency exchange losses in the third quarter of 2018 compared to the third quarter of 2017.

#### Interest expense, net

Interest expense, net increased to approximately \$7.5 million for the three months ended September 30, 2018 from \$4.7 million for the three months ended September 30, 2017 due to the January 2018 closing of the Royalty Purchase Agreement with HCR and the resulting increase in non-cash interest expense compared to the amount recorded for our

Note Purchase Agreement, which was outstanding in the three months ended September 30, 2017, and fully redeemed and terminated simultaneously with the closing of the Royalty Purchase Agreement.

Nine months ended September 30, 2018 compared to the nine months ended September 30, 2017

#### Research and development revenue

We recognized research and development revenue of approximately \$18.4 million and \$34.5 million during the nine months ended September 30, 2018 and 2017, respectively. R&D revenues in the nine months ended September 30, 2018 primarily consisted of \$4.0 million related to the recognition of a milestone under our license agreement with Merck and fees earned under our Collaboration Agreement with Incyte, including \$10.0 million related to the recognition of milestones and \$3.3 million related to the reimbursement of development costs, which have decreased due to the stage of the programs under the collaboration. R&D revenues in the nine months ended September 30, 2017 primarily consisted of fees earned under our Collaboration Agreement with Incyte, including \$20.0 million related to the acceleration of milestone payments and \$12.0 million related to the reimbursement of development costs. During the nine months ended September 30, 2018 and 2017, we recorded revenue of \$1.1 million and \$2.4 million, respectively, from the amortization of deferred revenue. See Notes B and J to our Condensed Consolidated Financial Statements for additional discussion of our revenues, including the adoption of ASC 606 during the first quarter of 2018.

#### Non-cash royalty revenue related to the sale of future royalties

In January 2018, we sold 100% of our worldwide rights to receive royalties from GSK on sales of GSK's vaccines containing our QS-21 Stimulon adjuvant to HCR. As described in Note G to our Condensed Consolidated Financial Statements, this transaction has been recorded as a liability that amortizes over the estimated life of our Royalty Purchase Agreement with HCR. As a result of this liability accounting, even though the royalties are remitted directly to HCR, we record these royalties from GSK as revenue. During the nine months ended September 30, 2018, we recognized approximately \$11.9 million in non-cash royalty revenue related to our agreement with GSK.

#### Research and development expense

Research and development expense includes the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, manufacturing costs, costs of consultants, and administrative costs. Research and development expense increased 5% to \$88.6 million for the nine months ended September 30, 2018 from \$84.3 million for the nine months ended September 30, 2017. Increased expenses in the nine months ended September 30, 2018 primarily relate to a \$5.8 million increase in third-party services and other related expenses largely relating to the advancement of our antibody programs and a \$4.4 million increase in expenses attributable to the activities of our subsidiary, AgenTus Therapeutics, which began operations in the quarter ended September 30, 2017. These increases were partially offset by a \$0.5 million decrease in personnel related expenses and a \$5.4 million decrease in expenses for our foreign subsidiaries due to the closure of our facility in Basel, Switzerland in 2017, which decrease was partially offset by increased expenses attributable to our wholly-owned subsidiary in the United Kingdom, Agenus UK Limited.

#### General and administrative expense

General and administrative expense consists primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 15% to \$27.6 million for the nine months ended September 30, 2018 from \$24.0 million for the nine months ended September 30, 2017. Increased expenses in the nine months ended September 30, 2018 primarily relate to a \$1.2 million increase in personnel related expenses, primarily due to increased headcount, a \$1.3 million increase in professional fees, a \$0.2 million increase in repair and maintenance expense and a \$0.9 million increase in expenses attributable to the activities of our subsidiary, AgenTus Therapeutics, which began operations in the quarter ended September 30, 2017.

#### Contingent purchase price consideration fair value adjustment

Contingent purchase price consideration fair value adjustment represents the change 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.

#### Loss on early extinguishment of debt

Loss on early extinguishment of debt of \$10.8 million for the nine months ended September 30, 2018 represents the payment of premiums and the write-off of unamortized debt issuance costs and discounts incurred in connection with the full redemption and termination of Antigenics' \$115.0 million principal amount of notes issued pursuant to the Note Purchase Agreement dated September 4, 2015 with Oberland Capital SA Zermatt LLC and the purchasers named therein.

#### Non-operating income (expense)

Non-operating income (expense) includes our foreign currency translation adjustment and other income or expense. Non-operating expense increased \$3.4 million for the nine months ended September 30, 2018, from income of \$1.9 million for the nine months ended September 30, 2017 to an expense of \$1.5 million for the nine months ended September 30, 2018, primarily due to our increased foreign currency exchange losses in the nine months ended September 30, 2018 compared to gains in the nine months ended September 30, 2017.

Interest expense, net:

Interest expense, net increased to approximately \$16.5 million for the nine months ended September 30, 2018 from \$13.8 million for the nine months ended September 30, 2017 due to the January 2018 closing of the Royalty Purchase Agreement with HCR and the resulting increase in non-cash interest expense compared to the amount recorded for our Note Purchase Agreement, which was outstanding in the nine months ended September 30, 2017, and fully redeemed and terminated simultaneously with the closing of the Royalty Purchase Agreement.

## Research and Development Programs

For the nine months ended September 30, 2018, our research and development programs consisted largely of our antibody programs as indicated in the following table (in thousands).

Research and		Nine Months Ended September 30,	Year Ended December 31,				Prior to	
Development Program	Product	2018	2017	2016	2015	2015	Total	
Heat shock proteins for cancer	Prophage and ASV	\$ 8,713	\$12,499	\$8,202	\$5,508	\$309,681	\$344,603	
Antibody programs*	Various	69,282	95,656	83,919	63,290	13,422	325,569	
Vaccine adjuvant	QS-21 Stimulon	157	222	77	142	13,657	14,255	
Other research and development programs		10,417	7,748	2,772	1,504	66,318	88,759	
Total research and development expenses		\$ 88,569	\$116,125	\$94,970	\$70,444	\$403,078	\$773,186	

\*Prior to 2014, costs were incurred by 4-AB, which we acquired in February 2014.

Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions and our review of the status of each program. Our product candidates are in various stages of development and significant additional expenditures will be required if we start new clinical trials, encounter delays in our programs, apply for regulatory approvals, continue development of our technologies, expand our operations, and/or bring our product candidates to market. The total cost of any particular clinical trial is dependent on a number of factors such as trial design, length of the trial, number of clinical sites, number of patients, and trial sponsorship. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because our CPM antibody programs are early stage, and because further development of HSP-based vaccines is dependent on 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, if ever, material cash inflows are likely to commence. 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 \$1.1 billion as of September 30, 2018. 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, 2018, we have raised aggregate net proceeds of approximately \$1.17 billion through the sale of common and preferred stock, the exercise of stock options and warrants, proceeds from our Employee Stock Purchase Plan, royalty monetization transactions, and the issuance of convertible and other notes.

We maintain an effective registration statement (the “Registration Statement”), covering the offering of up to \$250 million of common stock, preferred stock, warrants, debt securities and units. The Registration Statement includes a prospectus covering the offer, issuance and sale of up to 20 million shares of our common stock from time to time in “at-the-market offerings” pursuant to an At Market Issuance Sales Agreement (the “Sales Agreement”) with B. Riley FBR, Inc. as our sales agent. We sold approximately 14.3 million and 1.6 million shares of our common stock pursuant to the Sales Agreement during the nine months ended September 30, 2018 and the month of October 2018, respectively, and received aggregate net proceeds totaling \$36.4 million. Accordingly, as of November 7, 2018, approximately 4.1 million shares remain available for sale under the Sales Agreement.

As of September 30, 2018, we had debt outstanding of \$14.1 million in principal. In February 2015, we issued subordinated notes in the aggregate principal amount of \$14.0 million with annual interest at 8% (the “2015 Subordinated Notes”). The 2015 Subordinated Notes are due in February 2020. We and Antigenics entered into the Note Purchase Agreement 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, which we exercised in November

2017. The limited recourse notes were due on the earlier of (i) the 10<sup>th</sup> anniversary of the first commercial sale of GSK's shingles or malaria vaccines and (ii) September 8, 2030. In January 2018, we entered into a Royalty Purchase Agreement with HCR whereby we received proceeds of \$190.0 million. We used \$161.9 million of these proceeds to redeem all of the notes issued pursuant to the NPA.

Our cash, cash equivalents, and short-term investments at September 30, 2018 were \$46.2 million, a decrease of \$14.0 million from December 31, 2017. Based on our current plans, including the additional funding we received during October 2018 (see Note O), and funding we anticipate from other sources, including out-licensing and/or partnering opportunities, we believe that our cash resources of \$46.2 million as of September 30, 2018 will be sufficient to satisfy our liquidity requirements into the second quarter of 2019. We also continue to monitor the likelihood of success of our key initiatives and can discontinue funding of such activities if they do not prove to be successful, restrict capital expenditures and/or reduce the scale of our operations if necessary. In spite of these anticipated sources of funding and our ability to control our cash burn, in accordance with the requirements of ASU 2014-15, we are required to disclose the existence of a substantial doubt regarding our ability to continue as a going concern for twelve months from when these financial statements were issued.

Our future liquidity needs will be determined primarily by the success of our operations with respect to the progression of our product candidates and key development and regulatory events in the future. Potential sources of additional funding include: (1) pursuing collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities. Satisfying long-term liquidity needs may require the successful commercialization and/or substantial out-licensing or partnering arrangements for our antibody discovery platforms, CPM antibody programs, and HSP-based vaccines. Our long-term success will also be dependent on the successful identification, development and commercialization of potential other product candidates, each of which will require additional capital with no certainty of timing or probability of success. If we incur operating losses for longer than we expect, and/or we are unable to raise additional capital, we may become insolvent and be unable to continue our operations.

Our future cash requirements include, but are not limited to, supporting clinical trial and regulatory efforts and continuing our other research and development programs. Since inception, we have entered into various agreements with contract manufacturers, institutions, and clinical research organizations (collectively "third party providers") to perform pre-clinical activities and to conduct and monitor our clinical studies 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 \$228.7 million over the term of the related activities. Through September 30, 2018, we have expensed \$161.4 million as research and development expenses and \$160.5 million has been paid under these agreements. The timing of expense recognition and future payments related to these agreements is subject to the enrollment of patients and performance by the applicable third-party provider. We have also entered into sponsored research agreements related to our product candidates that required payments of \$9.6 million, of which \$8.5 million have been paid as of September 30, 2018. We plan to enter into additional agreements with third party providers as well as sponsored research agreements, and we anticipate significant additional expenditures will be required to initiate and advance our various programs.

Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing collaboration arrangements with academic and collaboration partners and licensees and by entering into new collaborations. As a result of our collaboration agreements, we will not completely control the efforts to attempt to bring those product candidates to market. For example, our collaboration with Incyte for the development, manufacture and commercialization of CPM antibodies against certain targets is managed by a joint steering committee, which is controlled by Incyte.

Net cash used in operating activities for the nine months ended September 30, 2018 and 2017 was \$95.3 million and \$68.4 million, respectively. 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. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Forward Looking Statements” in Part I, Item 2, and the risks highlighted under Part II, 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, 2018.

#### 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 1% and 18% of our cash used in operations for the nine months ended September 30, 2018 and the year ended December 31, 2017, respectively, was from our foreign



subsidiaries. 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 formally with operations in Switzerland, and Agenus 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, 2017.

We had cash and cash equivalents at September 30, 2018 of \$46.2 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, our carrying value approximates the fair value of these investments at September 30, 2018.

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 three months ended September 30, 2018 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, 2018 filed with the SEC on August 9, 2018.

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, 2017, 2016, and 2015, were \$120.7 million, \$127.0 million, and \$87.9 million, respectively. During the nine months ended September 30, 2018, we generated a net loss of \$113.2 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, our vaccine programs, and our saponin-based vaccine adjuvants.

On September 30, 2018, we had \$46.2 million in cash and cash equivalents and short-term investments. We believe that, based on our current plans, including the additional funding we received during October 2018 (see Note O), and funding we anticipate from other sources, including out-licensing and/or partnering opportunities, our cash resources at September 30, 2018, will be sufficient to satisfy our liquidity requirements into the second quarter of 2019. We also continue to monitor the likelihood of success of our key initiatives and can discontinue funding of such activities if they do not prove to be successful, restrict capital expenditures and/or reduce the scale of our operations if necessary.

To date, we have financed our operations primarily through the sale of equity and debt securities. In order to finance future operations, we will be required to raise additional funds in the capital markets, through arrangements with 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 and our partners' ability to successfully develop, manufacture, and commercialize product candidates;

- 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.

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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 obligations to HCR and the holders of our 2015 Subordinated Notes could materially and adversely affect our liquidity.

In January 2018, we and our wholly-owned subsidiary, Antigenics LLC (“Antigenics”), entered into a Royalty Purchase Agreement with HCR, pursuant to which HCR purchased 100% of Antigenics’ worldwide rights to receive royalties from GSK on sales of GSK’s vaccines containing our QS-21 Stimulon adjuvant. As consideration for the purchase of the royalty rights, HCR paid \$190.0 million at closing, less certain transaction expenses. Of the closing proceeds, approximately \$161.9 million was used to redeem Antigenics’ \$115.0 million principal amount of notes issued pursuant to the Note Purchase Agreement with Oberland Capital SA Zermatt LLC, and we retained approximately \$28.0 million of net proceeds. Antigenics is also entitled to receive up to \$40.35 million in milestone payments based on sales of GSK’s vaccines as follows: (i) \$15.1 million upon reaching \$2.0 billion last-twelve-months net sales any time prior to 2024 and (ii) \$25.25 million upon reaching \$2.75 billion last-twelve-months net sales any time prior to 2026. Antigenics will owe approximately \$25.9 million to HCR in 2021 if neither of the following sales milestones are achieved: (i) 2019 sales of GSK’s vaccines exceed \$1.0 billion or (ii) 2020 sales GSK’s vaccines exceed \$1.75 billion (the “Rebate Payment”). As part of the transaction, we provided a guaranty for the potential Rebate Payment and secured the obligation with substantially all of our assets pursuant to a security agreement. If GSK’s sales do not achieve either of the relevant milestones and we are obligated to make the Rebate Payment, our liquidity could be materially and adversely affected.

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 were originally due February 2018, and in March 2017, we amended the 2015 Subordinate Notes to extend the maturity date to February 2020. The 2015 Subordinated Notes 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 the Rebate 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 could be significantly reduced, the development and/or commercialization of these antibodies

may be terminated or substantially delayed, and our business could be adversely affected.

In February 2017, we amended the terms of our collaboration agreement with Incyte to, among other things, convert the GTR and OX40 programs from profit-share programs, where we and Incyte shared all costs and profits on a 50:50 basis, to royalty-bearing programs, where Incyte funds 100% of the costs and we are eligible for potential milestones and royalties. In addition, the profit-share programs relating to TIGIT and one undisclosed target were removed from the collaboration, with TIGIT reverting to Agenus and the undisclosed target reverting to Incyte, each with a potential 15% royalty to the other party on any global net sales. The remaining three royalty-bearing programs in the collaboration targeting TIM-3, LAG-3 and one undisclosed target remain unchanged, and there are no more profit-share programs under the collaboration. For each program in the collaboration, we serve as the lead for pre-clinical

development activities through the filing of an IND, and Incyte has exclusive rights and all decision-making authority for manufacturing, clinical development and commercialization. Accordingly, the timely and successful completion by Incyte of clinical development and commercialization activities will significantly affect the timing and amount of any royalties or milestones we may receive under the collaboration agreement. In addition, in March 2017 we transferred manufacturing responsibilities to Incyte for antibodies under that collaboration. Any delays or weaknesses in the ability of Incyte to successfully manufacture could have an adverse impact on those programs. 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. There can be no assurance that any of the development, regulatory or sales milestones will be achieved, or that we will receive any future milestone or royalty payments under the collaboration agreement. In September 2018, we sold to XOMA (US) LLC a portion of the royalties and milestones we are entitled to receive from Incyte.

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;
- Incyte has control over the development of assets in the collaboration;
- 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 may need to raise additional capital and may need to identify and come to agreement with another collaboration partner to advance certain of 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 under the collaboration.

Our antibody programs are in early stage development, and there is no guarantee that we or our partners will be successful in advancing antibody product candidates into and 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 our and/or our partners' clinical trials produce positive results, they may not necessarily be predictive of the results of future clinical trials. 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 earlier clinical 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 and our partners fail to produce positive results in clinical trials of antibodies, our business and financial prospects would be materially adversely affected.

Although we are pursuing indications and combinations that enable rapid paths to a Biologic License Application filing as early as 2020, there is no guarantee that we will be able to do so on that timeline or at all. Earlier this year we shifted our strategy for first approval from lung cancer to cervical cancer, and we have not yet fully evaluated the impact this could have on our previously stated timelines, or our costs. In addition, our timelines are aggressive and subject to various factors outside of our control, including patient accrual rates for our clinical trials. If our trials are unable to accrue patients at the rate we expect, we are unlikely to hit our anticipated timelines and our business and

financial prospects could be materially adversely affected.

Similarly, although we are striving to file a number of INDs to advance novel antibodies, cell therapy candidates, and neoantigen vaccine combinations into the clinic in the next nine to twelve months, there is no guarantee that we will be able to do so on that timeline, if at all. Our stated timelines are aggressive and subject to various risks, including resource constraints. If we are unable to advance novel candidates into the clinic as planned due to resource constraints or otherwise, our business and partnering prospects could be materially adversely affected.



We have undergone significant growth across multiple locations over the past few years, and are focusing on further enhancing core areas and capabilities as we move toward commercialization. In addition, we have consolidated certain sites while expanding others to focus on our core priorities and future needs. We may encounter difficulties in managing these growth and/or consolidation efforts, either of which could disrupt our operations.

Since our acquisition of Agenus Switzerland Inc., formerly known as 4-Antibody AG (“4-AB”) in February 2014, we have more than tripled our headcount, in part through various acquisitions and the expansion of our research and development activities both nationally and internationally. While we have restructured our organization over the past two years, we expect to continue increasing our headcount in certain core areas as we continue to build our development, manufacturing and commercialization capabilities and integrate our acquired technology platforms. To manage these organizational changes, 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.

As part of our efforts to optimize efficiency across our organization, we closed our Jena, Germany office in 2016 and consolidated these operations in the United Kingdom and Switzerland. In 2017, we completed a reduction in force in our Lexington, MA facility, which included certain members of our management, in line with our prioritization efforts, and we closed our office in Basel, Switzerland and transferred our research and development assets and capabilities there to the United Kingdom. If these transition efforts prove to be unsuccessful, or if we identify management or operational gaps in connection with our changes, it could cause delays in discovery timelines and increased costs for certain of our internal and partnered programs, which also could have an 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<sup>TM</sup>, 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. Although we have not advanced this program into a Phase 3 trial, we initiated our ASV synthetic cancer vaccine program based on our prior findings with this platform. We initiated our first clinical trial for our first AutoSynVax product candidate in 2017; however, there is no guarantee that results of this trial or any potential future clinical trials will be positive. Although we are planning to initiate a combination trial with ASV and one or more of our antibodies, the timeline is uncertain and there is no guarantee that we will be able to do so at all. 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 our cancer vaccine candidates or realize any benefits from these programs.

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 16 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, the only marketing approval for Prophage is 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 one government sponsored IND 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, in January 2017, we announced a clinical trial collaboration with the National Cancer Institute (“NCI”), whereby the NCI is conducting a double-blind, randomized controlled Phase 2 trial to evaluate the effect of Prophage vaccine in conjunction with Merck’s pembrolizumab on the overall survival rate of patients with newly diagnosed glioblastoma (“ndGBM”). In addition, the Phase 2 trial of Prophage vaccine in combination with bevacizumab in patients with surgically resectable recurrent glioma that was being conducted under the sponsorship of the Alliance for Clinical Trials in Oncology, a cooperative group of the NCI, has been closed. Our other cancer vaccine programs (ASV and PSV) are in Phase 1 and pre-clinical development, respectively, and there is no guarantee that they will successfully advance in and through the clinic. ASV also utilizes QS-21 Stimulon, and any inability or delay in securing adequate supplies of the adjuvant could have an adverse impact on the program or otherwise delay timelines. 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.

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 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. In 2015, we secured our own antibody manufacturing capabilities with the purchase of a manufacturing pilot plant from XOMA Corporation (“XOMA”), and we 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 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.

To date, we have manufactured 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. 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. 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. Although we have the right to secure certain quantities of QS-21 from GSK and we have some internal supply in-house, we currently do not have an alternative long term supply partner for this adjuvant.

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. 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 routine audits, and minor changes in manufacturing processes may require additional regulatory approvals and audits, either of which could cause us to incur significant additional costs, set-backs or delays and eventual loss of revenue.

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

We currently have research and development operations in the United Kingdom, and 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 and domestic markets, including without limitation any resulting from the United Kingdom's withdrawal from the European Union or our current political regime, and limitations on the flexibility of our operations and costs imposed by local labor laws.

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;
- 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.

The CPM landscape is crowded with several competitors developing assets against a number of targets. Development plans are spread out across various indications and lines of therapy, either alone or in combination with other assets. Competitors range from small cap to large cap companies, with assets in pre-clinical or clinical stages of development. Therefore, the landscape is dynamic and constantly evolving. We and our partners have CPM antibody programs, currently in clinical stage development targeting PD-1, CTLA-4, GITR, OX40, TIM-3 and LAG-3. 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 targets as these programs, including, without limitation, the following: (1) BMS markets ipilimumab, an anti-CTLA-4 antibody, and nivolumab, an anti-PD-1 antibody, and is developing additional antagonists to LAG-3, TIM-3 as well as agonists to GITR and OX-40. BMS also has next generation anti-CTLA-4 antibodies in the clinic, which may be competitive to our next generation anti-CTLA-4 program, (2) Merck has an approved anti-PD-1 antibody, as well as anti-CTLA-4 and LAG-3 antagonists and an anti-GITR agonist in clinical development, (3) Regeneron has an approved anti-PD-1 antibody as well as antibodies targeting CTLA-4, LAG-3 and GITR in clinical development, (4) AstraZeneca has an approved anti PD-L1 antibody, as well as anti-CTLA-4, PD-1, GITR and OX40 targeting antibodies in the clinic, (5) Pfizer has an approved anti-PD-L1 (with Merck KgaA) as well as anti-PD-1, and anti-OX40 antibodies in clinical development, and (6) Roche/Genentech has an approved anti-PD-L1 antibody. We are also aware of other competitors with PD-1/PD-L1 antibodies in clinical development, including but not restricted to AbbVie, Arcus Biosciences, Boehringer Ingelheim, Tesaro, Beigene, Eli Lilly, Jiangsu HengRui Medicine,

Shanghai Junshi, MacroGenics/Incyte, CytomX/BMS, Symphogen, Janssen, CBT Pharmaceuticals, Checkpoint Therapeutics, CStone Pharmaceuticals, Livzon MabPharm Inc, Suzhou Alphamab, Mabspace Biosciences, Henlix Biotech Inc. and Akeso Biopharma. We are also aware of competitors with pre-clinical antibodies against PD-1 or PD-L1. In addition, we are aware of competitors with clinical stage antibodies against GITR, OX40, LAG-3, TIM-3 as well as our earlier stage programs such as TIGIT and CD137. As outlined above, some of these include, but are not limited to, BMS, Pfizer, Novartis, Merck, Tesaro, Eli Lilly, OncoMed, Boehringer Ingelheim, Potenza and Symphogen. Additionally, we are aware of competitors developing preclinical assets and bispecifics against these targets. There is no guarantee that our antibody product candidates will be able to compete with our competitors' antibody products and product candidates.

We are conducting both single arm and combination trials in second line cervical cancer. We are aware that Merck's PD-1 antagonist, Keytruda, has been approved in advanced cervical cancer. We are also aware of industry sponsored clinical trials, including exploratory studies, that are underway in cervical cancer. Clinical stage competitors include, but are not limited to, Regeneron (anti-PD-1), Ono Pharmaceuticals and BMS (anti-PD-1 alone or in combination with agents against other checkpoint targets), Seattle Genetics and Genmab (antibody drug conjugate targeting Tissue Factor) and Iovance Biotherapeutics (autologous TILs). Additionally, we are aware of other early stage clinical trials testing alternate checkpoint targets in cervical cancer patients. These include, but are not limited to, OX40 +/- CD137 agonists (Pfizer) and anti-PD-1 + anti-ICOS (GSK/Merck), anti-CTLA-4 (treme) and anti-ICOS (GSK/AZ).

We have autologous vaccine programs in development including our Prophage vaccine in clinical development for GBM. We are aware of other therapeutic options in GBM that could compete with our vaccine, including but not restricted to the following: Schering Corporation, a subsidiary of Merck, markets temozolomide for treatment of patients with ndGBM and refractory astrocytoma. Other companies are developing vaccines for the treatment of patients with ndGBM, including, but not limited to, Northwest Biotherapeutics (DC-Vax), Mimivax Inc. (SurVaxM) and Annias Immunotherapeutics (CMV Vaccine). Other companies may begin development programs as well. We are advancing our neoantigen vaccine, AutoSynVax, in solid tumors. There are companies advancing individualized or synthetic vaccine technologies and/or patient-specific medicine techniques that compete with our HSP based vaccines such as: Aduro Biotech, Neon Therapeutics, Gritstone Oncology, Advaxis/Amgen, BioNTech, Moderna/Merck, Genocea Biosciences, Argos Therapeutics, ISA Pharmaceuticals, Nouscom, ImmuneDesign, EpiVax Inc., Achilles Therapeutics, Vaccibody and BrightPath Biotherapeutics.

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.

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 may include, but are not limited to, (1) oligonucleotides, under development by Pfizer, Idera, and Dynavax, (2) MF59, under development by Novartis, (3) IC31, under development by Intercell (now part of Valneva), 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 developed or sold using QS-21 Stimulon.

We are also aware of a third party that manufactures pre-clinical material purporting to be comparable to QS-21 Stimulon. The claims being made by this third party may create marketplace confusion and have an adverse effect on the goodwill generated by us and our partners with respect to QS-21 Stimulon. We are also aware of at least two manufacturers of QS-21. 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.

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-AB in 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;

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• 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 in a timely manner and 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. If we or Incyte fail to perform as expected, the potential for us to generate future revenues under the collaboration could be significantly reduced, the development and/or commercialization of these antibodies may be terminated or substantially delayed, and our business could be adversely affected." 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 in a timely manner or at all, 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.

Because we rely on collaborators and licensees for the development and commercialization of certain 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. If we or Incyte fail to perform as expected, the potential for us to generate future revenues under the collaboration could be significantly reduced, the development and/or commercialization of these antibodies may be terminated or substantially delayed, and our business could be adversely affected." 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 product candidates. Disagreements or the failure of either party to perform satisfactorily could have an adverse impact on these programs.

The Brain Tumor Trials Collaborative, through the NCI, is sponsoring a Phase 2 clinical trial of our Prophage vaccine candidate in combination with Merck's pembrolizumab in patients with glioma. 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.

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. Potential vulnerabilities can also be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents. 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 certain of 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 do not maintain cyber liability insurance, and would therefore have no coverage for any losses resulting from any data security incident.

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 certain members of our management team. In addition, we have limited internal resources and if we fail to recruit and/or retain the services of key employees and external consultants as needed, we may not be able to achieve our strategic and operational objectives.

Garo H. Armen, Ph.D., the Chairman of our Board of Directors and our Chief Executive Officer who co-founded the Company in 1994, is integral to building our company and developing our technology. If Dr. Armen is unable or unwilling to continue his relationship with Agenus, our business may be adversely impacted. We have an employment agreement with Dr. Armen, and he plays an important role in our day-to-day activities. We do not carry a key employee insurance policy for Dr. Armen 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 partners or our growth generally. 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. Moreover, in connection with our 2017 restructuring activities, certain positions on our management team were eliminated and Dr. Robert Stein retired from his role as President of R&D to become a senior R&D advisor to the Company. Any key capability gaps identified following this restructuring could have a material adverse effect on our business, financial condition and results of operations.

We intend to advance our cell therapy business through our subsidiary, AgenTus Therapeutics, eventually with separate funding. Moving intellectual property assets into AgenTus Therapeutics in foreign jurisdictions could have adverse tax consequences, and there is no guarantee that we will be able to attract external funding. Moreover, even if the business is funded, there is no guarantee that it will be successful.

We are currently in the process of pursuing external funding and partnership opportunities to advance AgenTus Therapeutics, but Agenus is currently funding such operations. There is no guarantee that external funding will be available. If funding is available, there is no guarantee that it will be on attractive or acceptable terms, or that it will be adequate to advance the business to an inflection point for additional funding. Similarly, there is no guarantee that partnership opportunities will be available on attractive terms, if at all. If external funding is not available, we may be forced to either retire these programs or continue to use internal resources to advance them. In addition, our cell therapy assets are pre-clinical. Even if adequate funding and partnership opportunities are available, there is no guarantee that we will be successful in advancing one or more product candidates into and through clinical development. In addition, most of the efforts being made on behalf of AgenTus Therapeutics are being led by a separate AgenTus chief executive officer, utilizing Agenus' management team and internal G&A resources. The current structure could distract management and divert Agenus resources from Agenus' own core pipeline and programs.

The cell therapy assets necessary to enable AgenTus Therapeutics are currently owned or controlled by Agenus in the United States and Switzerland. In connection with capitalizing AgenTus Therapeutics, these assets will be transferred or licensed to new legal entities within the United States and Europe and potentially others. Transferring these assets or licensing them on an exclusive basis would require that taxes be paid based on the fair market value of the assets. While we expect to have adequate net operating losses to offset any tax liabilities, there is no guarantee that this will be the case in all relevant jurisdictions. Moreover, we have previously disclosed our interest in potentially issuing a tax-free dividend to Agenus' stockholders in the form of stock of AgenTus Therapeutics. There is no guarantee that any such dividend will be tax-free or that it will be issued at all, or the timing thereof. If we issue a dividend in the form of stock, there could be adverse tax consequences for certain of our stockholders.

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. We own an antibody pilot plant manufacturing facility and lease 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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act" (the "TCJA") that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. Our net deferred tax assets and liabilities were revalued at the newly enacted U.S. corporate rate. We did not recognize any tax expense in the year of enactment as our net deferred tax assets have

a full valuation allowance recorded. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform is uncertain and could be adverse.

#### 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, 2018, we had spent more than 20 years and \$773.2 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 or our partners 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 or our partners 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. Significant legislative changes to the ACA also appear possible in the 115<sup>th</sup> U.S. Congress under the Trump Administration.

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.

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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 biosimilar or 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. 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 25 issued United States patents and approximately 95 issued foreign patents. We also own, co-own or have exclusive rights to approximately 35 pending United States patent applications and approximately 155 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 our 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 are seeking 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 Leahy-Smith America Invents Act, or the American Invents Act (“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 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;

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- 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, 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-inventor-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 the 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;
- 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 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.

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## 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.

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, 2018, and the nine months ended September 30, 2018, the closing price of our common stock has fluctuated between \$1.59 (or \$0.27 pre-reverse stock split) and \$315.78 (or \$52.63 pre-reverse stock split) per share and \$1.59 and \$6.04 per share, respectively. The average daily trading volume for the nine months ended September 30, 2018 was approximately 1,501,240 shares, while the average daily trading volume for the year ended December 31, 2017 was approximately 1,174,002. 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;
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other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;

• changes in accounting principles;

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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 November 2, 2018, we had 119,982,965 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, and to permit the sale of 1,500,000 shares of common stock under our 2015 Inducement Equity Plan. In addition, at our annual shareholder meeting in June 2018, our shareholders approved a resolution to add an additional 9,000,000 shares of common stock to the pool available under our equity incentive plan, which shares have not been registered with the Securities and Exchange Commission (“SEC”) yet. 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 31,100,319 shares of common stock pursuant to various private placement agreements and to permit the sale of up to 20,000,000 shares of our common stock pursuant to our At Market Issuance Sales Agreement. As of the date of filing, an aggregate of approximately 32,100,000 of these shares remained available for sale. In October 2018, we completed a private placement of 18,459 shares of preferred stock that are convertible into 18,459,000 shares of common stock, the resale of which has not been registered with the SEC yet. 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) February 12, 2024, (b) the sale of 4-AB or (c) the sale of Agenus and (ii) \$10.0 million upon our market capitalization exceeding \$1.0 billion for 30 consecutive trading days prior to the earliest of (a) February 12, 2024, (b) the sale of 4-AB or (c) the sale of Agenus. 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 XOMA or the former shareholders of PhosImmune in the future pursuant to the terms of our agreements with XOMA and PhosImmune, respectively. The market price of our common stock may decrease based on the expectation of such sales.

As of September 30, 2018, warrants to purchase approximately 2,900,000 shares of our common stock with a weighted average exercise price per share of \$4.52 were outstanding.

As of September 30, 2018, options to purchase 16,917,576 shares of our common stock with a weighted average exercise price per share of \$4.43 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, 2018, we had 9,928,173 vested options and 2,221,795

non-vested shares outstanding.

As of September 30, 2018, 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.

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We do not intend to pay cash 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.

Our independent auditor's report for the fiscal year ended December 31, 2017 includes an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.

In its report accompanying our audited consolidated financial statements for the year ended December 31, 2017, our independent registered public accounting firm included an explanatory paragraph regarding concerns about our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph may negatively impact the trading price of our common stock and make it more difficult, time consuming or expensive to obtain necessary financing. In the event we are unable to continue our operations, we may have to liquidate our assets and it is likely that investors will lose all or a part of their investment.

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, 2017, 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

Exhibit No. Description

- 3.1 Form of Certificate of Designation of Preferences, Rights and Limitations of Series C-1 Convertible Preferred Stock. Incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on October 11, 2018.
- 4.1 (1) Royalty Purchase Agreement dated September 20, 2018, by and among Agenus Inc., Agenus Royalty Fund, LLC and XOMA (US) LLC. Filed herewith.
- 10.1 Amendment No.1 to Consulting Agreement, effective July 1, 2018, by and between Agenus Inc. and Dr. Robert Stein. Filed herewith.
- 10.2 Consulting Agreement, effective July 1, 2018, as amended, by and between AgenTus Therapeutics, Inc. and Dr. Robert Stein. Filed herewith.
- 10.3 Consulting Agreement dated July 12, 2018, by and between Agenus Inc. and Karen Valentine. Filed herewith.
- 10.4 Stock Purchase Agreement dated October 10, 2018, between the Company and the purchasers listed on Exhibit A thereto. Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 11, 2018.
- 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

(1) Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.





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 7, 2018 AGENUS INC.

/s/ CHRISTIAN CORTIS, PH.D.  
Christian Cortis, Ph.D.

Chief Strategy Officer and Head of Finance, Principal Financial Officer