

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended June 30, 2017

or

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

For the transition period from _____ to _____

Commission File Number: 000-29089

Agenus Inc.

(exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

06-1562417
(I.R.S. Employer
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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulations S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 | <input type="checkbox"/> | Accelerated filer | <input checked="" type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> (Do not check if a smaller reporting company) | Smaller reporting company | <input type="checkbox"/> |
| Emerging growth company | <input type="checkbox"/> | | |

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 July 31, 2017: 99,712,305 shares

Agenus Inc.
Six Months Ended June 30, 2017
Table of Contents

| | <u>Page</u> | |
|----------------|---|----|
| PART I | | |
| ITEM 1. | <u>Financial Statements:</u> | 2 |
| | <u>Condensed Consolidated Balance Sheets as of June 30, 2017 (Unaudited) and December 31, 2016</u> | 2 |
| | <u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2017 and 2016 (Unaudited)</u> | 3 |
| | <u>Condensed Consolidated Statements of Cash Flows for the three and six months ended June 30, 2017 and 2016 (Unaudited)</u> | 4 |
| | <u>Notes to Unaudited Condensed Consolidated Financial Statements</u> | 5 |
| ITEM 2. | <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 14 |
| ITEM 3. | <u>Quantitative and Qualitative Disclosures About Market Risk</u> | 19 |
| ITEM 4. | <u>Controls and Procedures</u> | 20 |
| PART II | | |
| ITEM 1A. | <u>Risk Factors</u> | 21 |
| ITEM 5. | <u>Other Information</u> | 44 |
| ITEM 6. | <u>Exhibits</u> | 44 |
| | <u>Signatures</u> | 45 |

Item 1. *Financial Statements*

AGENUS INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

| | June 30, 2017 | December 31, 2016 |
|--|-----------------------|-----------------------|
| ASSETS | | |
| Cash and cash equivalents | \$ 81,829,729 | \$ 71,448,016 |
| Short-term investments | 14,936,047 | 4,988,751 |
| Inventories | 87,000 | 88,200 |
| Accounts Receivable | 3,943,904 | 11,352,022 |
| Prepaid expenses | 8,943,072 | 2,596,675 |
| Other current assets | 950,615 | 838,538 |
| Total current assets | <u>110,690,367</u> | <u>91,312,202</u> |
| Property, plant and equipment, net of accumulated amortization and depreciation of \$33,096,539 and \$31,243,967 at June 30, 2017 and December 31, 2016, respectively | 25,575,340 | 25,633,985 |
| Goodwill | 23,351,728 | 22,392,411 |
| Acquired intangible assets, net of accumulated amortization of \$4,420,834 and \$3,193,092 at June 30, 2017 and December 31, 2016, respectively | 15,590,903 | 16,364,726 |
| Other long-term assets | 1,282,662 | 1,282,662 |
| Total assets | <u>\$ 176,491,000</u> | <u>\$ 156,985,986</u> |
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| Current portion, long-term debt | \$ 146,061 | \$ 146,061 |
| Current portion, deferred revenue | 2,645,302 | 2,610,719 |
| Accounts payable | 4,571,916 | 5,428,452 |
| Accrued liabilities | 20,569,516 | 27,874,703 |
| Other current liabilities | 4,979,607 | 4,791,265 |
| Total current liabilities | <u>32,912,402</u> | <u>40,851,200</u> |
| Long-term debt, net of current portion | 138,530,646 | 130,542,424 |
| Deferred revenue, net of current portion | 11,192,448 | 12,344,782 |
| Contingent purchase price considerations | 6,500,000 | 7,561,000 |
| Other long-term liabilities | 4,836,323 | 4,812,846 |
| Commitments and contingencies | | |
| STOCKHOLDERS' DEFICIT | | |
| Preferred stock, par value \$0.01 per share; 5,000,000 shares authorized: | | |
| Series A-1 convertible preferred stock; 31,620 shares designated, issued, and outstanding at June 30, 2017 and December 31, 2016; liquidation value of \$32,522,287 at June 30, 2017 | 316 | 316 |
| Common stock, par value \$0.01 per share; 240,000,000 shares authorized; 99,602,582 and 87,794,933 shares issued at June 30, 2017 and December 31, 2016, respectively | 996,026 | 877,949 |
| Additional paid-in capital | 938,412,195 | 866,854,348 |
| Accumulated other comprehensive loss | (2,289,854) | (1,529,559) |
| Accumulated deficit | (954,599,502) | (905,329,320) |
| Total stockholders' deficit | <u>(17,480,819)</u> | <u>(39,126,266)</u> |
| Total liabilities and stockholders' deficit | <u>\$ 176,491,000</u> | <u>\$ 156,985,986</u> |

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 June 30, | | Six Months Ended June 30, | |
|--|-----------------------------|------------------------|---------------------------|------------------------|
| | 2017 | 2016 | 2017 | 2016 |
| Revenue: | | | | |
| Service | \$ — | \$ — | \$ — | \$ 147,456 |
| Research and development | 4,207,573 | 6,592,285 | 31,163,416 | 12,403,705 |
| Total revenues | 4,207,573 | 6,592,285 | 31,163,416 | 12,551,161 |
| Operating expenses: | | | | |
| Research and development | (25,824,431) | (22,361,786) | (58,464,422) | (47,400,264) |
| General and administrative | (8,136,252) | (7,117,232) | (15,905,760) | (16,348,753) |
| Contingent purchase price consideration fair value adjustment | 865,000 | (721,000) | 1,061,000 | (379,000) |
| Operating loss | (28,888,110) | (23,607,733) | (42,145,766) | (51,576,856) |
| Other expense: | | | | |
| Non-operating income | 1,649,811 | (508,794) | 2,389,946 | (185,711) |
| Interest expense, net | (4,474,743) | (4,203,352) | (9,060,400) | (8,335,815) |
| Net loss | (31,713,042) | (28,319,879) | (48,816,220) | (60,098,382) |
| Dividends on Series A-1 convertible preferred stock | (51,344) | (51,021) | (102,608) | (101,962) |
| Net loss attributable to common stockholders | <u>\$ (31,764,386)</u> | <u>\$ (28,370,900)</u> | <u>\$ (48,918,828)</u> | <u>\$ (60,200,344)</u> |
| Per common share data: | | | | |
| Basic and diluted net loss attributable to common stockholders | \$ (0.32) | \$ (0.33) | \$ (0.51) | \$ (0.69) |
| Weighted average number of common shares outstanding: | | | | |
| Basic and diluted | 99,201,975 | 86,964,777 | 96,370,777 | 86,825,646 |
| Other comprehensive (loss) income: | | | | |
| Foreign currency translation (loss) gain | \$ (628,456) | \$ (143,543) | \$ (760,295) | \$ 395,088 |
| Other comprehensive (loss) gain | (628,456) | (143,543) | (760,295) | 395,088 |
| Comprehensive loss | <u>\$ (32,392,842)</u> | <u>\$ (28,514,443)</u> | <u>\$ (49,679,123)</u> | <u>\$ (59,805,256)</u> |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Six Months Ended June 30, | |
|--|---------------------------|----------------------|
| | 2017 | 2016 |
| Cash flows from operating activities: | | |
| Net loss | \$ (48,816,220) | \$ (60,098,382) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 3,057,142 | 2,519,873 |
| Share-based compensation | 5,129,035 | 6,317,596 |
| Non-cash interest expense | 8,783,464 | 7,983,749 |
| Loss on disposal of assets | 9,209 | — |
| Gain on issuance of stock for settlement of milestone obligation | (14,063) | — |
| Change in fair value of contingent obligations | (1,061,000) | 379,000 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 7,408,118 | 434,257 |
| Prepaid expenses | (6,330,969) | (802,505) |
| Accounts payable | (1,225,694) | 474,526 |
| Deferred revenue | (1,117,884) | (2,629,753) |
| Accrued liabilities and other current liabilities | (6,032,357) | 5,385,328 |
| Other operating assets and liabilities | (2,000,691) | 11,452 |
| Net cash used in operating activities | (42,211,910) | (40,024,859) |
| Cash flows from investing activities: | | |
| Proceeds from sale of plant and equipment | 120,000 | — |
| Purchases of plant and equipment | (1,405,932) | (3,164,423) |
| Purchases of held-to-maturity securities | (14,936,047) | (49,895,350) |
| Proceeds from securities held-to-maturity | 5,000,000 | 35,000,000 |
| Net cash used in investing activities | (11,221,979) | (18,059,773) |
| Cash flows from financing activities: | | |
| Net proceeds from sale of equity | 63,677,302 | — |
| Proceeds from employee stock purchases and option exercises | 342,476 | 471,357 |
| Purchase of treasury shares to satisfy tax withholdings | (527,223) | (667,050) |
| Payment under a purchase agreement for in-process research and development | — | (5,000,000) |
| Payment of capital lease obligation | (133,300) | (24,110) |
| Net cash provided by (used in) financing activities | 63,359,255 | (5,219,803) |
| Effect of exchange rate changes on cash | 456,347 | (696) |
| Net increase (decrease) in cash and cash equivalents | 10,381,713 | (63,305,131) |
| Cash and cash equivalents, beginning of period | 71,448,016 | 136,702,873 |
| Cash and cash equivalents, end of period | \$ 81,829,729 | \$ 73,397,742 |
| Supplemental cash flow information: | | |
| Cash paid for interest | \$ 555,397 | \$ 555,397 |
| Supplemental disclosures - non-cash activities: | | |
| Purchases of plant and equipment in accounts payable and accrued liabilities | 355,814 | 62,219 |
| 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.

AGENUS INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2017

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 company focused on the discovery and development of therapies that engage the body’s immune system to fight cancer. Our approach to cancer immunotherapy involves a diverse portfolio of antibody-based therapeutics, adjuvants and cancer vaccine platforms. We, in collaboration with our partners, are developing a number of immuno-modulatory antibodies against important nodes of immune regulation. These include antibodies targeting CTLA-4, GITR, OX40 and PD-1 that are in clinical development. Our discovery pipeline consists of a number of proprietary checkpoint modulating (“CPM”) antibodies against innovative targets such as TIGIT and 4-1BB (also known as CD137). We believe that tailored combination therapies are essential to combat some of the most resistant cancers. Accordingly, our immune education strategy focuses on pursuing antibodies as well as vaccine candidates in conjunction with adjuvants. We are developing a comprehensive immuno-oncology portfolio driven by the following platforms and programs, which we intend to utilize individually and in combination:

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

Our business activities have included product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development activities, and support of our collaborations. Our product candidates require clinical trials and approvals from regulatory agencies, as well as acceptance in the marketplace. Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing arrangements with academic and corporate collaborators and licensees and by entering into new collaborations.

Our cash, cash equivalents, and short-term investments at June 30, 2017 were \$96.8 million, an increase of \$20.3 million from December 31, 2016.

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

| | Quarter Ended | |
|--|-----------------------|----------------------|
| | March 31, 2017 | June 30, 2017 |
| Cash, cash equivalents and short-term investments | \$ 123.8 | \$ 96.8 |
| Increase (decrease) in cash, cash equivalents and short-term investments | \$ 47.4 | \$ (27.0) |
| Cash used in operating activities | \$ 14.8 | \$ 27.4 |
| Reported net loss | \$ 17.3 | \$ 31.7 |

As of December 31, 2016, we along with all public companies, adopted the provisions of Accounting Standards Update 2014-15 (“ASU 2014-15”), Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern which requires management to assess the Company’s ability to continue as a going concern for twelve months after the date each periodic financial statement is issued. This disclosure is a result of and in accordance with the provisions of this standard. We have incurred significant losses since our inception. As of June 30, 2017, we had an accumulated deficit of \$954.6 million. Since our inception, we have successfully financed our operations primarily through the sale of equity and convertible and other notes, corporate partnerships, and interest income earned on cash, cash equivalents, and short-term investments balances. Based on our current plans and activities, our cash, cash equivalents and short-term investments balance of \$96.8 million as of June 30, 2017 would only be sufficient to satisfy our liquidity requirements through the first quarter of 2018 without any additional funding before that time, which we anticipate. Regardless of this anticipated funding, in accordance with ASU 2014-15 this is deemed to be a condition which raises substantial doubt regarding our ability to continue as a going concern for at least one year from when these financial statements were issued. In order to continue as a going concern, we expect to raise additional funding from currently contemplated transactions before year end. We also continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be feasible, restrict capital expenditures and/or reduce the scale of our operations, if necessary.

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. We anticipate raising additional funding by: (1) pursuing collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities. 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 six months ended June 30, 2017, are not necessarily indicative of the results that may be expected for the year ending December 31, 2017. 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, 2016 filed with the Securities and Exchange Commission (the “SEC”) on March 16, 2017.

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 - Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our Directors’ Deferred Compensation Plan, or “DDCP”). Diluted income per common share is calculated by dividing net income attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our DDCP) plus the dilutive effect of outstanding instruments such as warrants, stock options, nonvested shares, convertible preferred stock, and convertible notes. Because we reported a net loss attributable to common stockholders for all periods presented, diluted loss per common share is the same as basic loss per common share, as the effect of utilizing the fully diluted share count would have reduced the net loss per common share. Therefore, the following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as of June 30, 2017 and 2016, as they would be anti-dilutive:

| | Six Months Ended June 30, | |
|-----------------------------|---------------------------|------------|
| | 2017 | 2016 |
| Warrants | 4,351,450 | 4,351,450 |
| Stock options | 15,287,781 | 11,659,125 |
| Nonvested shares | 2,022,324 | 1,999,294 |
| Convertible preferred stock | 333,333 | 333,333 |

Note C - Investments

Cash equivalents and short-term investments consisted of the following as of June 30, 2017 and December 31, 2016 (in thousands):

| | June 30, 2017 | | December 31, 2016 | |
|----------------------------------|------------------|----------------------|-------------------|----------------------|
| | Cost | Estimated Fair Value | Cost | Estimated Fair Value |
| Institutional money market funds | \$ 60,669 | \$ 60,669 | \$ 38,913 | \$ 38,913 |
| U.S. Treasury Bills | 34,890 | 34,890 | 14,978 | 14,978 |
| Total | <u>\$ 95,559</u> | <u>\$ 95,559</u> | <u>\$ 53,891</u> | <u>\$ 53,891</u> |

For the six months ended June 30, 2017, we received proceeds of approximately \$5.0 million from the maturity of U.S. Treasury Bills classified as short-term investments. As a result of the short-term nature of our investments, there were minimal unrealized holding gains or losses for the three and six months ended June 30, 2017 and 2016.

Of the investments listed above, \$80.6 million and \$48.9 million have been classified as cash equivalents and \$14.9 million and \$5.0 million as short-term investments on our condensed consolidated balance sheets as of June 30, 2017 and December 31, 2016, respectively.

Note D - Goodwill and Acquired Intangible Assets

The following table sets forth the changes in the carrying amount of goodwill for the six months ended June 30, 2017 (in thousands):

| | |
|---|------------------|
| Balance, December 31, 2016 | \$ 22,392 |
| Foreign currency translation adjustment | 960 |
| Balance, June 30, 2017 | <u>\$ 23,352</u> |

Acquired intangible assets consisted of the following as of June 30, 2017 and December 31, 2016 (in thousands):

| | As of June 30, 2017 | | | |
|-------------------------------------|-----------------------------------|--------------------------|-----------------------------|------------------------|
| | Amortization period (years) | Gross carrying amount | Accumulated amortization | Net carrying amount |
| Intellectual property | 7-15 years | \$ 16,630 | \$ (3,374) | \$ 13,256 |
| Trademarks | 4.5 years | 842 | (631) | 211 |
| Other | 2-6 years | 575 | (416) | 159 |
| In-process research and development | Indefinite | 1,965 | — | 1,965 |
| Total | | <u>\$ 20,012</u> | <u>\$ (4,421)</u> | <u>\$ 15,591</u> |

| | As of December 31, 2016 | | | |
|-------------------------------------|-----------------------------------|--------------------------|-----------------------------|------------------------|
| | Amortization period (years) | Gross carrying amount | Accumulated amortization | Net carrying amount |
| Intellectual property | 7-15 years | \$ 16,358 | \$ (2,384) | \$ 13,973 |
| Trademarks | 4.5 years | 791 | (505) | 286 |
| Other | 2-6 years | 563 | (303) | 260 |
| In-process research and development | Indefinite | 1,846 | — | 1,846 |
| Total | | <u>\$ 19,558</u> | <u>\$ (3,193)</u> | <u>\$ 16,365</u> |

The weighted average amortization period of our finite-lived intangible assets is 9 years. Amortization expense related to acquired intangibles is estimated at \$1.1 million for the remainder of 2017, \$2.0 million for the year ending December 31, 2018, \$1.9 million for the year ending December 31, 2019 and \$1.9 million for each of the years ending December 31, 2020 and 2021.

Note E - Debt

Debt obligations consisted of the following as of June 30, 2017 and December 31, 2016(in thousands):

| <u>Debt instrument</u> | <u>Principal at June 30, 2017</u> | <u>Non-cash Interest</u> | <u>Unamortized Debt Issuance Costs</u> | <u>Unamortized Debt Discount</u> | <u>Balance at June 30, 2017</u> |
|---------------------------|---|------------------------------|--|--------------------------------------|---|
| Current Portion: | | | | | |
| Debentures | \$ 146 | \$ — | \$ — | \$ — | \$ 146 |
| Long-term Portion: | | | | | |
| 2015 Subordinated Notes | 14,000 | — | — | (1,642) | 12,358 |
| Note Purchase Agreement | 100,000 | 27,664 | (1,279) | (212) | 126,173 |
| Total long-term | \$ 114,000 | \$ 27,664 | \$ (1,279) | \$ (1,854) | \$ 138,531 |
| Total | \$ 114,146 | \$ 27,664 | \$ (1,279) | \$ (1,854) | \$ 138,677 |

| <u>Debt instrument</u> | <u>Principal at December 31, 2016</u> | <u>Non-cash Interest</u> | <u>Unamortized Debt Issuance Costs</u> | <u>Unamortized Debt Discount</u> | <u>Balance at December 31, 2016</u> |
|---------------------------|---|------------------------------|--|--------------------------------------|---|
| Current Portion: | | | | | |
| Debentures | \$ 146 | \$ — | \$ — | \$ — | \$ 146 |
| Long-term Portion: | | | | | |
| 2015 Subordinated Notes | 14,000 | — | — | (1,311) | 12,689 |
| Note Purchase Agreement | 100,000 | 19,421 | (1,345) | (222) | 117,853 |
| Total long-term | \$ 114,000 | \$ 19,421 | \$ (1,345) | \$ (1,533) | \$ 130,542 |
| Total | \$ 114,146 | \$ 19,421 | \$ (1,345) | \$ (1,533) | \$ 130,688 |

In June 2016, we executed a capital lease agreement that expires in June 2020 for equipment with a carrying value of approximately \$0.9 million, which is included in property, plant and equipment, net on our condensed consolidated balance sheets as of June 30, 2017. Under the terms of the capital lease agreement, we will remit payments to the lessor of \$144,000 for the remainder of 2017, \$288,000 for each of the years 2018 through 2019 and \$144,000 for the year ending December 31, 2020. As of June 30, 2017, our remaining obligations under the capital lease agreement are approximately \$0.8 million, of which \$290,000 and \$465,000 are classified as other current and other long-term liabilities, respectively, on our condensed consolidated balance sheets.

In March 2017, we and the holders of our subordinated notes issued in February 2015 (the “2015 Subordinated Notes”) entered into an Amendment to Notes and Warrants, pursuant to which the parties (i) extended the term of the 2013 Warrants by two years from April 15, 2017 to April 15, 2019 and (ii) extended the maturity date of the 2015 Notes by two years from February 20, 2018 to February 20, 2020. This resulted in an additional debt discount of \$0.7 million, which will be amortized using the effective interest method over three years, the expected life of the 2015 Subordinated Notes. The 2013 Warrants and 2015 Subordinated Notes are otherwise unchanged.

Note F - Accrued and Other Current Liabilities

Accrued liabilities consisted of the following as of June 30, 2017 and December 31, 2016 (in thousands):

| | <u>June 30, 2017</u> | <u>December 31, 2016</u> |
|------------------------------|----------------------|--------------------------|
| Payroll | \$ 4,757 | \$ 6,504 |
| Professional fees | 3,968 | 2,373 |
| Contract manufacturing costs | 5,270 | 10,492 |
| Research services | 5,224 | 5,639 |
| Leasehold improvements | 10 | 1,280 |
| Other | 1,341 | 1,587 |
| Total | \$ 20,570 | \$ 27,875 |

Other current liabilities consisted of the following as of June 30, 2017 and December 31, 2016 (in thousands):

| | <u>June 30, 2017</u> | <u>December 31, 2016</u> |
|--|----------------------|--------------------------|
| Current portion of deferred purchase price | \$ 4,000 | \$ 3,948 |
| Other | 980 | 843 |
| Total | \$ 4,980 | \$ 4,791 |

Note G - Fair Value Measurements

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

The fair values of our contingent purchase price considerations, \$6.5 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.

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

| <u>Description</u> | <u>June 30, 2017</u> | <u>Quoted Prices in Active Markets for Identical Assets (Level 1)</u> | <u>Significant Other Observable Inputs (Level 2)</u> | <u>Significant Unobservable Inputs (Level 3)</u> |
|--|------------------------------|---|--|--|
| Assets: | | | | |
| Cash equivalents | \$ 19,954 | \$ 19,954 | \$ — | \$ — |
| Short-term investments | 14,936 | 14,936 | — | — |
| Total | <u>\$ 34,890</u> | <u>\$ 34,890</u> | <u>\$ —</u> | <u>\$ —</u> |
| Liabilities: | | | | |
| Contingent purchase price considerations | \$ 6,500 | \$ — | \$ — | \$ 6,500 |
| Total | <u>\$ 6,500</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 6,500</u> |
| | | | | |
| <u>Description</u> | <u>December 31, 2016</u> | <u>Quoted Prices in Active Markets for Identical Assets (Level 1)</u> | <u>Significant Other Observable Inputs (Level 2)</u> | <u>Significant Unobservable Inputs (Level 3)</u> |
| Assets: | | | | |
| Cash equivalents | \$ 9,990 | \$ 9,990 | \$ — | \$ — |
| Short-term investments | 4,988 | 4,988 | — | — |
| Total | <u>\$ 14,978</u> | <u>\$ 14,978</u> | <u>\$ —</u> | <u>\$ —</u> |
| Liabilities: | | | | |
| Contingent purchase price consideration | \$ 7,561 | \$ — | \$ — | \$ 7,561 |
| Total | <u>\$ 7,561</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 7,561</u> |

The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3), as of June 30, 2017 (in thousands):

| | |
|--|-----------------|
| Balance, December 31, 2016 | \$ 7,561 |
| Change in fair value of contingent purchase price considerations during the period | (1,061) |
| Balance, June 30, 2017 | <u>\$ 6,500</u> |

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

The fair value of our outstanding debt balance at June 30, 2017 and December 31, 2016 was \$136.5 million and \$129.2 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 both June 30, 2017 and December 31, 2016 was \$114.1 million.

Note H - Collaboration Agreement

On February 14, 2017, we amended our License, Development and Commercialization Agreement, dated January 9, 2015, with Incyte Corporation (“Incyte”) by entering into a First Amendment to License, Development and Commercialization Agreement (the “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 the two undisclosed targets were removed from the collaboration, with one reverting to Incyte and one to us. 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. We are now eligible to receive up to an additional \$510.0 million in future potential development, regulatory and commercial milestones across all programs in the collaboration. The Company recognized the \$20.0 million received as revenue during the six months ended June 30, 2017.

On February 14, 2017, we also entered into a Stock Purchase Agreement (the “Stock Purchase Agreement”) with Incyte, pursuant to which Incyte purchased 10 million shares of our common stock (the “Shares”) at a purchase price of \$6.00 per share. Immediately following the transaction, Incyte owned approximately 18.1% of our outstanding shares. Under the Stock Purchase Agreement, Incyte agreed not to dispose of any of the Shares for a period of 12 months and to vote the Shares in accordance with the recommendations of the Agenus board of directors in connection with certain equity incentive plan or compensation matters for a period of 18 months, and we agreed to certain registration rights with respect to the Shares. Under the Amendment, the parties also revised the existing standstill provision to permit Incyte’s acquisition of the Shares, but Incyte is precluded from acquiring any additional shares of our voting stock until December 31, 2019.

Note I - 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 six months ended June 30, 2017 is presented below:

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value |
|---|------------|--|---|---------------------------------|
| Outstanding at December 31, 2016 | 11,693,400 | \$ 4.52 | | |
| Granted | 4,020,507 | 3.78 | | |
| Exercised | (45,950) | 3.14 | | |
| Forfeited | (249,163) | 5.02 | | |
| Expired | (131,013) | 6.67 | | |
| Outstanding at June 30, 2017 | 15,287,781 | \$ 4.30 | 7.66 | \$ 3,318,756 |
| Vested or expected to vest at June 30, 2017 | 15,285,056 | \$ 4.30 | 7.66 | \$ 3,318,756 |
| Exercisable at June 30, 2017 | 7,798,961 | \$ 4.48 | 6.26 | \$ 2,628,920 |

The weighted average grant-date fair values of stock options granted during the six months ended June 30, 2017 and 2016 were \$1.94 and \$1.83, respectively.

As of June 30, 2017, \$12.8 million of total unrecognized compensation cost related to stock options granted to employees and directors is expected to be recognized over a weighted average period of 2.6 years.

As of June 30, 2017, 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 \$1.7 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 nonvested stock. The fair value of nonvested stock is calculated based on the closing sale price of our common stock on the date of issuance.

A summary of nonvested stock activity for the six months ended June 30, 2017 is presented below:

| | Nonvested Shares | Weighted Average Grant Date Fair Value |
|----------------------------------|---------------------|---|
| Outstanding at December 31, 2016 | 1,942,476 | \$ 6.45 |
| Granted | 700,050 | 1.80 |
| Vested | (580,427) | 7.75 |
| Forfeited | (39,775) | 8.78 |
| Outstanding at June 30, 2017 | <u>2,022,324</u> | <u>\$ 4.42</u> |

As of June 30, 2017, there was approximately \$7.8 million of unrecognized share-based compensation expense related to these nonvested shares awarded to employees which pertained primarily to performance based awards for which, if all milestones are achieved, will be recognized over a 1.3 year period. The total intrinsic value of shares vested during the six months ended June 30, 2017, was \$2.0 million.

During the six months ended June 30, 2017, 56,627 shares were issued under the 2009 Employee Stock Purchase Plan, 580,427 shares were issued as a result of the vesting of nonvested stock and 45,950 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 six months ended June 30, 2017 and 2016, was as follows (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--|--------------------------------|-----------------|---------------------------|-----------------|
| | 2017 | 2016 | 2017 | 2016 |
| Research and development | \$ 1,272 | \$ 581 | \$ 2,399 | \$ 2,872 |
| General and administrative | 1,480 | 974 | 2,730 | 3,446 |
| Total share-based compensation expense | <u>\$ 2,752</u> | <u>\$ 1,555</u> | <u>\$ 5,129</u> | <u>\$ 6,318</u> |

Note J - Benefit Plans

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

For the three and six months ended June 30, 2017, we contributed approximately \$41,000 and \$83,000, respectively, and for the three and six months ended June 30, 2016 we contributed approximately \$39,000 and \$78,000, respectively to our international multiple employer benefit plan. For the remainder of the year ending December 31, 2017, we expect to contribute approximately \$74,000 to our international multiple employer benefit plan.

Note K - Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers, ("ASU 2014-09"). ASU 2014-09 amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. This new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. In March 2016, the FASB issued an amendment to the standard, ASU 2016-8,

Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net) (“ASU 2016-08”), which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued an additional amendment to the standard, ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing (“ASU 2016-10”), which clarifies the guidance on identifying performance obligations and the implementation guidance on licensing. In August 2015, the FASB issued ASU No. 2015-14, which defers the effective date by one year to December 15, 2017 for annual reporting periods beginning after that date, including interim periods within those periods. The FASB also approved permitting early adoption of the standard, but not before the original effective date of December 15, 2016. ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2017. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. The Company has not yet determined which method will be used. We are currently evaluating the potential impact that ASU 2014-09 may have on our financial position and results of operations. To date, the Company’s sources of collaboration and other revenue have primarily been collaboration agreements. The most significant differences between Topic 606 and previous guidance for license and collaboration revenue are: (i) allocating consideration to performance obligations; and (ii) estimating and determining the timing of recognition of variable consideration received from licensees, including up-front license payments, contingent milestones and royalties. Revenues from contingent milestone payments may be recognized earlier under Topic 606 than under Topic 605, based on an assessment of the probability of a significant reversal of such milestone revenue at each reporting date. This assessment may result in recognizing milestone revenue before the milestone event has been achieved. Under previous guidance, milestone revenue was typically recognized when the milestone event was achieved.

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. Footnote 15 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, 2016, we expect to recognize assets and liabilities of approximately \$13.8 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 March 2016, the FASB issued ASU 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, (“ASU 2016-09”). ASU 2016-09 provides for the simplification of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 applies to all entities and is effective for the annual effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. We adopted ASU 2016-09 on January 1, 2017, and recorded a cumulative adjustment of \$1.2 million in retained earnings to reflect the retrospective change in awards expected to vest.

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. ASU 2017-01 is effective for the Company in the first quarter of 2018, with early adoption permitted, and prospective application required. We will apply the provisions of ASU 2017-01 to any relevant transactions no later than the first quarter of 2018 and may consider earlier adoption for relevant transactions which occur in 2017.

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, 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 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. The adoption of ASU 2017-09, which

will become effective for annual periods beginning after December 15, 2017 and for interim periods within those annual periods, is not expected to have any impact on our financial statement presentation or disclosures.

No other new accounting pronouncement issued or effective during the six months ended June 30, 2017 had or is expected to have a material impact on our consolidated financial statements or disclosures.

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

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

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Overview

We are a clinical-stage immuno-oncology (“I-O”) company focused on the discovery and development of therapies that engage the body’s immune system to fight cancer. Our approach to cancer immunotherapy involves a diverse portfolio consisting of antibody-based therapeutics, adjuvants and cancer vaccine platforms. We, in collaboration with our partners, are developing a number of immuno-modulatory antibodies against important nodes of immune regulation. These include antibodies targeting CTLA-4, GITR, OX40, and PD-1 that are in clinical development. Our discovery pipeline includes a number of proprietary checkpoint modulating (“CPM”) antibodies against innovative targets such as TIGIT and 4-1BB (also known as CD137). We believe that tailored combination therapies are essential to combat some of the most resistant cancers. Accordingly, our immune education strategy focuses on pursuing antibodies as well as vaccine candidates in conjunction with adjuvants.

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 produce quality human antibodies;
- our antibody candidate programs, including our CPM programs;
- our vaccine programs, including Prophage™, AutoSynVax™ and PhosPhoSynVax™ ; and
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon® adjuvant, or QS-21 Stimulon.

We also have our own good manufacturing practices manufacturing facility with the capacity to support early phase clinical 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. We are currently collaborating with companies such as Incyte Corporation (“Incyte”), Merck Sharpe & Dohme and Recepta Biopharma SA (“Recepta”). Through these alliances, as well as our own internal programs, we currently have more than 10 antibody programs, including our anti-CTLA-4 (partnered with Recepta for certain South America territories) and anti-GITR and anti-OX40 (both partnered with Incyte) antibody programs that each commenced clinical trials during 2016, and our anti-PD-1 antibody that in April 2017 entered the clinic. 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. We are now eligible to receive royalties on global net sales

at a flat 15% rate for each of these programs. There are now no more profit-share programs under the collaboration, and we are eligible to receive up to a total of \$510.0 million in future potential development, regulatory and commercial milestones across all programs in the collaboration. Pursuant to the amended agreement, we received accelerated milestone payments of \$20.0 million from Incyte related to the clinical development of an anti-GITR agonist and an anti-OX40 agonist. Concurrent with the execution of the amendment, we and Incyte also entered into a separate 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.

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 will evaluate the effect of our autologous vaccine candidate, Prophage, in combination with pembrolizumab (Keytruda®, Merck & Co., Inc. (“Merck”)) in patients with ndGBM. Under this collaboration, we are supplying Prophage, Merck is providing pembrolizumab and the NCI and Brain Tumor Trials Collaborative (“BTTC”) member sites are recruiting patients and conducting the trial. We also initiated our first clinical trial for our synthetic vaccine candidate, AutoSynVax (“ASV”) earlier this year.

Our QS-21 Stimulon adjuvant is partnered with GlaxoSmithKline (“GSK”) and is a key component in multiple GSK vaccine programs that target prophylactic or therapeutic impact in a variety of infectious diseases and cancer. These programs are in various stages, with the most advanced being GSK’s shingles and malaria programs, which GSK first announced positive Phase 3 results for in December 2014 and October 2013, respectively. In 2015, we monetized a portion of the future royalties we are contractually entitled to receive from GSK from sales of its shingles and malaria vaccines through a Note Purchase Agreement (“NPA”) and received net proceeds of approximately \$78.2 million. In 2016, GSK filed for approval of its shingles vaccine candidate in the United States, European Union and Canada, and in 2017 it filed for approval in Japan. Assuming regulatory approval, the first products containing QS-21 Stimulon are anticipated to be launched by GSK in 2018. 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.

Historical Results of Operations

Three months ended June 30, 2017 compared to the three months ended June 30, 2016

Revenue: We recognized revenue of approximately \$4.2 million and \$6.6 million during the three months ended June 30, 2017 and 2016, respectively. Revenues primarily included fees earned under our license agreements, including \$3.2 million and \$3.4 million for the three months ended June 30, 2017 and 2016, respectively, related to the reimbursement of development costs under our License, Development and Commercialization Agreement, dated January 9, 2015, with Incyte. During the three months ended June 30, 2017 and 2016, we recorded revenue of 840,000 and \$1.1 million, respectively, from the amortization of deferred revenue.

Research and development: Research and development expenses include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, costs of consultants, and administrative costs. Research and development expense increased 15% to \$25.8 million for the three months ended June 30, 2017 from \$22.4 million for the three months ended June 30, 2016. Increased expenses in 2017 include a \$2.7 million increase in third-party services and other expenses related primarily to the advancement of our CPM programs.

General and administrative: General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 14% to \$8.1 million for the three months ended June 30, 2017 from \$7.1 million for the three months June 30, 2016. Increased general and administrative expenses in 2017 primarily relate to increased payroll and share-based compensation expense due primarily to increased headcount period over period.

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 result 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: Non-operating expense includes our foreign currency translation adjustment and other income or expense. Non-operating income increased for the three months ended June 30, 2017 compared to the three months ended June 30, 2016 due to an increase in our foreign currency gain.

Interest expense, net: Interest expense, net increased to approximately \$4.5 million for the three months ended June 30, 2017 from \$4.2 million for the three months ended June 30, 2016 due to the compounding of interest on our debt under our Note Purchase Agreement.

Six months ended June 30, 2017 compared to the six months ended June 30, 2106

Revenue: We recognized revenue of approximately \$31.2 million and \$12.6 million during the six months ended June 30, 2017 and 2016, respectively. Revenues in 2017 and 2016 primarily included fees earned under our license agreements, including \$20.0 million for the six months ended June 30, 2017 related to the acceleration of milestone payments, and \$9.5 million and \$7.5 million for the six months ended June 30, 2017 and 2016, respectively, related to the reimbursement of development costs under our Collaboration Agreement with Incyte, which have increased due to the stage of programs under the collaboration. During the six months ended June 30, 2017 and 2016, we recorded revenue of \$1.5 million and \$2.7 million, respectively, from the amortization of deferred revenue.

Research and development: Research and development expenses include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, costs of consultants, and administrative costs. Research and development expense increased 23% to \$58.5 million for the six months ended June 30, 2017 from \$47.4 million for the six months ended June 30, 2016. Increased expenses in 2017 primarily relate to an increase in third-party services and other related expenses of \$6.3 million primarily relating to the advancement of our antibody programs, \$2.9 million increase related to milestone and license fees and \$1.8 million increase in payroll related expenses due to increases in headcount.

General and administrative: General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses decreased 3% to \$15.9 for the six months ended June 30, 2017 from \$16.3 million for the six months ended June 30, 2016. Decreased general and administrative expenses in 2017 primarily relate to a decrease in share-based compensation expense due to the recognition of a performance grant during the quarter ended June 30, 2016.

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 expense: Non-operating income increased for the six months ended June 30, 2017 compared to the six months ended June 30, 2016 due to an increase in our foreign currency gain.

Interest expense, net: Interest expense, net increased to approximately \$9.1 million for the six months ended June 30, 2017 from \$8.3 million for the six months ended June 30, 2016 due to the compounding of interest on our debt under our Note Purchase Agreement.

Research and Development Programs

For the six months ended June 30, 2017, our research and development programs consisted largely of our antibody programs as indicated in the following table (in thousands).

| Research and Development Program | Product | Six Months Ended June 30, | Year Ended December 31, | | | | Prior to 2014 | Total |
|---|-------------------|---------------------------|-------------------------|------------------|------------------|-------------------|-------------------|-------|
| | | 2017 | 2016 | 2015 | 2014 | | | |
| Heat shock proteins for cancer | Prophage Vaccines | \$ 7,822 | \$ 8,202 | \$ 5,508 | \$ 6,153 | \$ 303,528 | \$ 331,213 | |
| Antibody programs* | | 45,520 | 83,919 | 63,290 | 13,422 | — | 206,151 | |
| Heat shock proteins for infectious diseases | HerpV | 19 | 11 | 293 | 2,443 | 30,309 | 33,075 | |
| Vaccine adjuvant | QS-21 | 52 | 77 | 142 | 321 | 13,336 | 13,928 | |
| Other research and development programs | Stimulon | 5,051 | 2,761 | 1,211 | 10 | 33,556 | 42,589 | |
| Total research and development expenses | | <u>\$ 58,464</u> | <u>\$ 94,970</u> | <u>\$ 70,444</u> | <u>\$ 22,349</u> | <u>\$ 380,729</u> | <u>\$ 626,956</u> | |

* Prior to 2014, costs were incurred by Agenus Switzerland Inc. (formerly known as 4-Antibody AG), a company we acquired in February 2014.

Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions and our review of the status of each program. Our product candidates are in various stages of development and significant additional expenditures will be required if we start new clinical trials, encounter delays in our programs, apply for regulatory approvals, continue development of our technologies, expand our operations, and/or bring our product candidates to market. The total cost of any particular clinical trial is dependent on a number of factors such as trial design, length of the trial, number of clinical sites, number of patients, and trial sponsorship. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because our CPM antibody programs are 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 \$954.6 million as of June 30, 2017. 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 been successful in financing 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 June 30, 2017, we have raised aggregate net proceeds of approximately \$906.4 million through the sale of common and preferred stock, the exercise of stock options and warrants, proceeds from our Employee Stock Purchase Plan, and the issuance of convertible and other notes.

We maintain an effective registration statement (the “Shelf Registration Statement”), which originally covered the offering of up to \$150.0 million of common stock, preferred stock, warrants, debt securities and units. As of June 30, 2017, \$64.3 million remained available under the Shelf Registration Statement. The Shelf Registration Statement also includes a prospectus covering the offer, issuance and sale of up to 10 million shares of our common stock from time to time in “at the market offerings” pursuant to an At Market Sales Issuance Agreement (the “Sales Agreement”) entered into with MLV & Co. LLC (the “Sales Agent”). Pursuant to the Sales Agreement, sales will be made only upon instructions by us to the Sales Agent. As of June 30, 2017, we had 8.6 million shares available for sale under the Sales Agreement.

As of June 30, 2017, we had debt outstanding of \$114.1 million in principal, and \$27.7 million in accrued interest. 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 our wholly-owned subsidiary Antigenics LLC (“Antigenics”) entered into the NPA with certain purchasers pursuant to which Antigenics issued, and we guaranteed, limited recourse notes in the aggregate principal amount of \$100.0 million, with an option to issue an additional \$15.0 million principal amount of limited recourse notes. The limited recourse notes are due on the earlier of (i) the 10th anniversary of the first commercial sale of GSK’s shingles or malaria vaccines and (ii) September 8, 2030.

As of December 31, 2016, we along with all public companies, adopted the provisions of Accounting Standards Update 2014-15 (“ASU 2014-15”), Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern which requires management to assess the Company’s ability to continue as a going concern for twelve months after the date each periodic financial statement is issued. This disclosure is a result of and in accordance with the provisions of this standard. Our cash, cash equivalents, and short-term investments at June 30, 2017 were \$96.8 million, an increase of \$20.3 million from December 31, 2016. We believe that, based on our current plans and activities, our cash, cash equivalents, and short-term investments of \$96.8 million as of June 30, 2017 will be sufficient to satisfy our liquidity requirements through the first quarter of 2018. We continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be feasible, restrict capital expenditures and/or reduce the scale of our operations, if necessary.

Based on our current plans and activities, our cash, cash equivalents and short-term investments balance of \$96.8 million as of June 30, 2017 would only be sufficient to satisfy our liquidity requirements through the first quarter of 2018 without any additional funding before that time, which we anticipate. Regardless of this anticipated funding, in accordance with ASU 2014-15 this is deemed to be a condition which raises substantial doubt regarding our ability to continue as a going concern for at least one year from when these financial statements were issued. In order to continue as a going concern, we expect to raise additional funding from currently contemplated transactions before year end. We also continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be feasible, restrict capital expenditures and/or reduce the scale of our operations, if necessary.

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. We anticipate raising additional funding by: (1) pursuing collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities. 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. Satisfying long-term liquidity needs may require the successful commercialization and/or substantial out-licensing or partnering arrangements for our antibody discovery platforms, antibody programs, HSP-based vaccines, and vaccines containing QS-21 Stimulon under development by our licensees. Our long-term success will also depend on the successful identification, development and commercialization of other potential product candidates, each of which will require additional capital with no certainty of timing or probability of success. If we incur operating losses for longer than we expect and/or we are unable to raise additional capital, we may become insolvent and be unable to continue our operations.

Our future cash requirements include, but are not limited to, supporting clinical trial and regulatory efforts and continuing our other research and development programs. Since inception, we have entered into various agreements with contract manufacturers, institutions, and clinical research organizations (collectively “third party providers”) to perform pre-clinical activities and to conduct and monitor our clinical studies and trials. Under these agreements, subject to the enrollment of patients and performance by the applicable third party provider, we have estimated our total payments to be \$149.4 million over the term of the related activities. Through June 30, 2017, we have expensed \$109.9 million as research and development expenses and \$108.0 million has been paid under these agreements. The timing of expense recognition and future payments related to these agreements is subject to the enrollment of patients and performance by the applicable third party provider. We have also entered into sponsored research agreements related to our product candidates that required payments of \$8.6 million, of which \$7.5 million have been paid as of June 30, 2017. We plan to enter into additional agreements with third party providers as well as sponsored research agreements, and we anticipate significant additional expenditures will be required to initiate and advance our various programs.

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

Net cash used in operating activities for the six months ended June 30, 2017 and 2016 was \$42.2 million and \$40.0 million, respectively. Subject to regulatory submission and approval, the first products containing QS-21 Stimulon are anticipated to be launched in 2018. We are generally entitled to royalties on sales by GSK of vaccines using QS-21 Stimulon for at least ten years after commercial launch, with some exceptions. In September 2015, we entered into the NPA and partially monetized the potential royalties we are entitled to receive from GSK. Our future ability to generate cash from operations will depend on achieving regulatory approval and market acceptance of our product candidates, achieving benchmarks as defined in existing collaboration agreements, and our ability to enter into new collaborations. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Forward Looking Statements” in Part I, Item 2 of this Quarterly Report on Form 10-Q and the risks highlighted under Part 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 June 30, 2017.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, (“ASU 2014-09”). ASU 2014-09 amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. This new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. In March 2016, the FASB issued an amendment to the standard, ASU 2016-8, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net) (“ASU 2016-08”), which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued an additional amendment to the standard, ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing (“ASU 2016-10”), which clarifies the guidance on identifying performance obligations and the implementation guidance on licensing. In August 2015, the FASB issued ASU No. 2015-14, which defers the effective date by one year to December 15, 2017 for annual reporting periods beginning after that date, including interim periods within those periods. The FASB also approved permitting early adoption of the standard, but not before the original effective date of December 15, 2016. ASU 2014-09 is effective for interim and annual periods

beginning after December 15, 2017. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. The Company has not yet determined which method will be used. We are currently evaluating the potential impact that ASU 2014-09 may have on our financial position and results of operations. To date, the Company's sources of collaboration and other revenue have primarily been collaboration agreements. The most significant differences between Topic 606 and previous guidance for license and collaboration revenue are: (i) allocating consideration to performance obligations; and (ii) estimating and determining the timing of recognition of variable consideration received from licensees, including up-front license payments, contingent milestones and royalties. Revenues from contingent milestone payments may be recognized earlier under Topic 606 than under Topic 605, based on an assessment of the probability of a significant reversal of such milestone revenue at each reporting date. This assessment may result in recognizing milestone revenue before the milestone event has been achieved. Under previous guidance, milestone revenue was typically recognized when the milestone event was achieved.

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. Footnote 15 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, 2016, we expect to recognize assets and liabilities of approximately \$13.8 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 March 2016, the FASB issued ASU 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, ("ASU 2016-09"). ASU 2016-09 provides for the simplification of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 applies to all entities and is effective for the annual effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. We adopted ASU 2016-09 on January 1, 2017, and recorded a cumulative adjustment of \$1.2 million in retained earnings to reflect the retrospective change in awards expected to vest.

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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. ASU 2017-01 is effective for the Company in the first quarter of 2018, with early adoption permitted, and prospective application required.

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, 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 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. The adoption of ASU 2017-09, which will become effective for annual periods beginning after December 15, 2017 and for interim periods within those annual periods, is not expected to have any impact on our financial statement presentation or disclosures.

No other new accounting pronouncement issued or effective during the six months ended June 30, 2017 had or is expected to have a material impact on our consolidated financial statements or disclosures.

Item 3. *Quantitative and Qualitative Disclosures About Market Risk*

Our primary market risk exposure is foreign currency exchange rate risk. International revenues and expenses are generally transacted by our foreign subsidiaries and are denominated in local currency. Approximately 3% and 39% of our cash used in

operations for the six months ended June 30, 2017 and the year ended December 31, 2016, 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 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, 2016.

We had cash, cash equivalents and short-term investments at June 30, 2017 of \$96.8 million, which are exposed to the impact of interest rate changes, and our interest income fluctuates as interest rates change. Additionally, in the normal course of business, we are exposed to fluctuations in interest rates as we seek debt financing and invest excess cash. Due to the short-term nature of our investments in money market funds and U.S. Treasury Bills, our carrying value approximates the fair value of these investments at June 30, 2017.

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 six months ended June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 March 31, 2017.

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, 2016, 2015, and 2014, were \$127.2 million, \$87.9 million, and \$42.5 million, respectively. During the six months ended June 30, 2017, we generated a net loss of \$48.8 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 June 30, 2017, we had \$96.8 million in cash, cash equivalents, and short-term investments. We believe that, based on our current plans and activities, our working capital resources as of June 30, 2017 will be sufficient to satisfy our liquidity requirements through the first quarter of 2018. In order to alleviate the doubt regarding our ability to continue as a going concern for at least one year from when these financial statements were issued, we expect to raise additional funding from currently contemplated transactions before year end. We also continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be feasible, restrict capital expenditures and/or reduce the scale of our operations, if necessary.

To date, we have been successful in financing 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 product candidates and conducting pre-clinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our and our licensees’ product candidates;
- the cost of manufacturing;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such arrangements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property rights;

- the costs associated with any successful commercial operations; and
- the timing, receipt and amount of sales of, or royalties on, our future products and those of our partners, if any.

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

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

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

On September 8, 2018, each purchaser has the option to require Antigenics to repurchase up to 15% of the Notes issued to such purchaser on the Closing Date (the "Put Notes") at a purchase price equal to the principal amount thereof plus accrued and unpaid interest thereon (the "Put Payment"). On the earlier of (i) September 8, 2027 and (ii) the Maturity Date, Antigenics is required to pay the purchasers an amount equal to the following (the "Make-Whole Payment"): \$100.0 million (or \$115.0 million if the Additional Notes are sold) minus the aggregate amount of all payments made in respect of the Notes (regardless of whether characterized as principal or interest at the time of payment), including the original principal amount of any repaid Put Notes.

The NPA specifies a number of events of default (some of which are subject to applicable cure periods), including (i) failure to cause royalty payments to be deposited into the segregated bank account, (ii) payment defaults, (iii) breaches of representations and warranties made at the time the Notes were, or the Additional Notes are, issued, (iv) covenant defaults, (v) a final and unappealable judgment against Antigenics for the payment of money in excess of \$1.0 million, (vi) bankruptcy or insolvency defaults, (vii) the failure to maintain a first-priority perfected security interest in the collateral in favor of the collateral agent and (viii) the occurrence of a change of control of Agenesis. Upon the occurrence of an event of default, subject to cure periods in certain circumstances and some limited exceptions, the collateral agent may declare the Notes immediately due and payable, in which case Antigenics would owe a payment equal to the following (the "Accelerated Default Payment"): the outstanding principal amount of the Notes, plus all accrued and unpaid interest thereon, plus a premium payment that would yield an aggregate internal rate of return ("IRR") for the purchasers as follows: (i) an IRR of 20% if the event of default occurs within 24 months of the Closing Date, (ii) an IRR of 17.5% if the event of default occurs after 24 months but within 48 months of the Closing Date, and (iii) an IRR of 15% if the event of default occurs more than 48 months after the Closing Date. Upon the occurrence and during the continuance of any event of default, interest on the Notes also increases by 2.5% per annum.

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

In February 2015, we exchanged senior subordinated promissory notes that we issued in 2013 for new senior subordinated promissory notes in the aggregate principal amount of \$5.0 million with annual interest at 8%, and we issued an additional \$9.0 million principal amount of such notes (the "2015 Subordinated Notes"). The 2015 Subordinated Notes 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 any of the Put Payment, the Make-Whole Payment or the Accelerated Default Payment when due, or to otherwise service our 2015 Subordinated Notes, we may be required, among other things, to:

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

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

We are dependent upon our collaboration with Incyte to further develop, manufacture and commercialize antibodies against certain targets. If we or Incyte fail to perform as expected, the potential for us to generate future revenues under the collaboration 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 two undisclosed targets were removed from the collaboration, with one reverting to Incyte and one to Agenus, 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 investigational new drug application (“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 announced that we are transferring manufacturing responsibilities to Incyte for antibodies under that collaboration. Any delays or weaknesses in this transfer process or 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 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 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' Phase 1 trials produce positive results, they may not necessarily be predictive of the results of future clinical trials in humans. Many companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in pre-clinical development or Phase 1 trials, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including adverse events. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials nonetheless failed to obtain regulatory approval. If we and our partners fail to produce positive results in future clinical trials of antibodies, our business and financial prospects would 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 towards 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 4-Antibody in January 1, 2014 we have nearly tripled our headcount, in part through various acquisitions and the expansion of our research and development activities both nationally and internationally. While we have recently embarked on consolidation efforts, 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 office in 2016 and consolidated these operations in the United Kingdom and Switzerland. In March 2017, we announced a reduction in force in our Lexington, MA facility in line with our prioritization efforts, including certain members of management, and that we are closing down our office in Basel, Switzerland and will transfer our research and development assets and capabilities there to the United Kingdom. We are currently winding down our operation in Switzerland and expect to transfer all of the assets and capabilities by the end of 2017. If these transition efforts are delayed or unsuccessful, or if we identify management or operational gaps in connection with our changes, this 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.

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

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

GSK manages its product development process, and we cannot predict its requirements for QS-21 Stimulon in the future or to what extent, if any, it will develop and commercialize vaccines that use QS-21 Stimulon as an adjuvant. GSK may initiate or terminate programs containing QS-21 Stimulon at any time. In addition, even if GSK successfully completes clinical trials with vaccine candidates using QS-21 Stimulon or these vaccine candidates receive positive decisions from regulatory bodies, there is no guarantee that these products will ultimately obtain regulatory approval or, if so approved, will have a successful commercial launch or generate any future milestones or royalty payments. In September 2015, we entered into the NPA and monetized a portion of the potential royalties we are entitled to receive from GSK on future sales of its shingles and malaria vaccines, if any. All of the royalties that are payable to us from GSK on sales of these products candidates, if any, will be used entirely to satisfy our obligations to the purchasers of the Notes. However, there is no guarantee that GSK's shingles and malaria vaccines will be approved in any territories for which they seek regulatory approval. Even if GSK's shingles and/or malaria vaccines are approved, there is no guarantee that GSK will have a successful commercial launch of either product or generate any revenues from sales to help satisfy our obligations under the NPA. Any inability to receive anticipated revenues, or a reduction in revenues, generated from QS-21 Stimulon could have a material adverse effect on our business, financial condition and results of operations.

Our synthetic Heat Shock Protein (“HSP”) peptide-based platform is in early stage development, and there is no guarantee that a product candidate will progress from this platform.

In June 2014, we reported positive results from a Phase 2 trial with HerpVTM, 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 April 2017; however, there is no guarantee that results of this trial or any potential future clinical trials will be positive. Furthermore, it is possible that research and discoveries by others will render any product candidate from this platform as obsolete or noncompetitive

We may not be able to advance clinical development or commercialize 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, none of our clinical trials with Prophage vaccines have resulted in a marketing approval, except in Russia where commercialization of the approved product was unsuccessful. All of our currently planned trials involving Prophage are intended to be sponsored by third parties, and there is no guarantee that they will occur at all. In addition, while we believe Prophage vaccines may provide clinical benefit to some patients as a monotherapy and in combination with other therapies, there is no guarantee that, if completed, subsequent Prophage trials would yield useful translational and/or efficacy data.

Our current clinical trial plans with Prophage vaccines entails 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 and has recently closed. In addition, our other cancer vaccine programs (ASV and PSV) are in Phase 1 and preclinical development, respectively, and there is no guarantee that they will successfully advance in and through the clinic. 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 December 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.

The long-term success of the antibody pilot plant manufacturing facility and capabilities that we acquired from XOMA will depend, in part, on our ability to realize the anticipated synergies, business opportunities and growth prospects from combining our manufacturing facilities in Lexington, MA with the antibody pilot plant manufacturing facility in Berkeley, CA. We may never realize

these anticipated synergies, business opportunities and growth prospects. Assumptions underlying estimates of expected cost savings as a result of the acquisition of the antibody pilot plant manufacturing facility may be inaccurate. If any of these factors limit our ability to successfully manufacture antibodies to support our current and future clinical trials, the expectations of future results of operations, including certain cost savings and synergies expected to result from the acquisition of XOMA's antibody pilot plant manufacturing facility, might not be met. In addition, in March 2017 announced that we are transferring manufacturing responsibilities to Incyte for antibodies under that collaboration. Any delays or weaknesses in this transfer process or the ability of Incyte to successfully manufacture could have an adverse impact on those programs.

We currently manufacture our Prophage vaccines in our Lexington, MA facility. Manufacturing of the Prophage vaccines is complex, and various factors could cause delays or an inability to supply the vaccine. Deviations in the processes controlling manufacture or deficiencies in size or quality of source material could result in production failures. Specific vulnerabilities in the process may exist in tumor types in which quality or quantity of tissue is limited. In addition, regulatory bodies may require us to make our manufacturing facility a single product facility. In such an instance, we would no longer have the ability to manufacture Prophage vaccines in addition to other product candidates in our current facility.

We have given our corporate QS-21 Stimulon licensee, GSK, manufacturing rights for QS-21 Stimulon for use in their product programs. If GSK or its third party CMO encounters problems with QS-21 Stimulon manufacturing, any of their programs containing QS-21 Stimulon could be delayed or terminated, and this could have an adverse effect on our potential license fees, milestone payments and royalties that we may otherwise receive from these programs and use to satisfy our obligations under the NPA. We have retained the right to manufacture QS-21 for ourselves and third parties, although no other such programs are anticipated to bring us substantial revenues in the near future, if ever.

Our ability to efficiently manufacture our product candidates is contingent, in part, upon our own, and our CMOs', ability to ramp up production in a timely manner without the benefit of years of experience and familiarity with the processes, which we may not be able to adequately transfer. We currently rely upon and expect to continue to rely upon third parties, potentially including our collaborators or licensees, to produce materials required to support our product candidates, pre-clinical studies, clinical trials, and any future commercial efforts. A number of factors could cause production interruptions at either our manufacturing facility or the facilities of our CMOs or suppliers, including equipment malfunctions, labor or employment retention problems, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers. Alternatively, there is the possibility we may have excess manufacturing capacity if product candidates do not progress as planned.

As mentioned above, reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured all of our product candidates ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, and the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Biopharmaceutical manufacturing is also subject to extensive government regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with current good manufacturing practices. 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 have research and development operations in Switzerland and the United Kingdom; however, in March 2017, we announced that we are closing our Switzerland office and transferring our capabilities there to the United Kingdom. We expect to pursue pathways to develop and commercialize our product candidates in both U.S. and non-U.S. jurisdictions. Various risks associated with foreign operations may impact our success. Possible risks of foreign operations include fluctuations in the value of foreign and domestic currencies requirements to comply with various jurisdictional requirements such as data privacy regulations, disruptions in the import, export, and transportation of patient tumors and our products or product candidates, the product and service needs of foreign customers, difficulties in building and managing foreign relationships, the performance of our licensees or collaborators, geopolitical instability, unexpected regulatory, economic, or political changes in foreign 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 preclinical 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 and OX40. 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) Bristol-Myers Squibb (“BMS”) markets ipilimumab, an anti-CTLA-4 antibody, and nivolumab, an anti-PD-1 antibody, and is developing agonists to GITR and OX-40, (2) Merck has an approved anti-PD-1 antibody in the United States, a anti-CTLA-4 antagonist and an anti-GITR agonist, (3) Ono Pharmaceuticals has an approved anti-PD-1 antibody in Japan, (4) AstraZeneca has an approved anti PD-L1 antibody, as well as anti-CTLA-4, PD-1, GITR and OX40 targeting antibodies in development, (5) Pfizer has an approved anti-PD-L1 (with Merck KgaA) as well as anti-PD-1, and anti-OX40 antibodies in clinical development, (6) Novartis has anti-PD-1, anti-PD-L1 and anti-GITR antibodies in clinical trials, and (7) Roche/Genentech has an approved anti-PD-L1 and an anti-OX40 antibody in clinical development. We are also aware of other competitors with PD-1/PD-L1 antibodies in clinical development, including Tesaro, Beigene, Regeneron, CureTech, Eli Lilly, Jiangsu HengRui Medicine, Shanghai Junshi and MacroGenics. We are also aware of competitors with preclinical antibodies against these targets. In addition, we are also aware of competitors with clinical stage antibodies against targets in our earlier stage programs such as TIM-3, LAG-3, 4-1BB, TIGIT and other undisclosed targets. These include, but are not limited to, BMS, Pfizer, Novartis, Merck, Roche, Tesaro and Regeneron. Additionally, we are also aware of competitors with assets against these targets that are in preclinical development. There is no guarantee that our antibody product candidates will be able to compete with our competitors’ antibody products and product candidates.

We are planning to develop our anti PD-1 antibody in second line cervical cancer. We are aware of exploratory, industry sponsored clinical trials that are underway in cervical cancer. Our competitors include, but are not restricted to, Merck (anti-PD-1), Ono Pharmaceuticals and BMS (anti-PD-1 alone or in combination with anti-CTLA-4 or anti-LAG-3), Advaxis (HPV targeting vaccine alone or in combination with AstraZeneca’s anti-PD-L1 antibody or BMS’ anti-PD-1 antibody) and Lion Biotechnologies (autologous TILs). Additionally, we are also aware of other early stage clinical trials testing alternate CPM targets in cervical cancer patients. These include, but are not restricted to, PD-L1 + IDO (Roche), VISTA (Janssen), OX40 +/- 4-1BB (Pfizer) and PD-1 + IDO (BMS).

We have autologous vaccine programs in development including our Prophage vaccine in clinical development for GBM and our neo-antigen based AutoSynVax vaccine in clinical development. We are aware of many companies pursuing personalized cancer vaccines in preclinical or clinical development, including, without limitation, the following: Neon Therapeutics, Gritstone Oncology, Advaxis, BioNTech, Moderna and Merck, Nouscom, Immatix and Green Peptides.

Several companies have products that utilize similar technologies and/or patient-specific medicine techniques that compete with our HSP based vaccines. 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, such as Green Cross Cell - formerly Innocell Corp (Immuncell-LC), ImmunoCellular Therapeutics (ICT-107), Northwest Biotherapeutics (DC-Vax),

Mimivax Inc. (SurVaxM), Annias Immunotherapeutics (CMV Vaccine) and Activartis Biotech (GBM-Vax). Other companies may begin development programs as well.

To the extent we develop our vaccines in other indications or in combination with other product candidates, such as available standard of care agents (Avastin®), or with CPMs, they could face additional competition in those indications or in those combinations. In addition, and prior to regulatory approval, if ever, our vaccines and our other product candidates may compete for access to patients with other products in clinical development, with products approved for use in the indications we are studying, or with off-label use of products in the indications we are studying. We anticipate that we will face increased competition in the future as new companies enter markets we seek to address and scientific developments surrounding immunotherapy and other traditional cancer and infectious disease 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 include, but are not limited to, (1) oligonucleotides, under development by Pfizer, Idera, Colby, and Dynavax, (2) MF59, under development by Novartis, (3) IC31, under development by Intercell (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. 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 or 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 Agenus Switzerland Inc., formerly known as 4-Antibody AG (“4-AB”), in February 2014, we have completed numerous additional strategic acquisitions and licensing transactions. The ultimate success of these strategic transactions entails numerous operational and financial risks, including:

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

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

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

As previously noted, our ability to advance our antibody programs depends in part on collaboration agreements such as our collaboration with Incyte. See “Risk Factors—Risks Related to Our Business—We are dependent upon our collaboration with Incyte to further develop, manufacture and commercialize antibodies against certain targets. 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, 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 candidates. Disagreements or the failure of either party to perform satisfactorily could have an adverse impact on these programs.

In addition, substantially all product candidates containing QS-21 Stimulon depend on the success of GSK, our licensee. Such product candidates depend on GSK successfully enrolling patients and completing clinical trials, being committed to dedicating the resources necessary to advance these product candidates, obtaining regulatory approvals, and successfully manufacturing and commercializing product candidates.

The Brain Tumor Trials Collaborative 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. In addition, substantially all product candidates containing QS-21 Stimulon depend on the success of our collaboration partner. Such product candidates depend on our collaborator successfully enrolling patients and completing clinical trials, being committed to dedicating the resources to advance these product candidates, obtaining regulatory approvals, and successfully manufacturing and commercializing product candidates.

Development activities for our collaboration programs may fail to produce marketable products due to unsuccessful results or abandonment of these programs, failure to enter into future collaborations or license agreements, or the inability to manufacture product supply requirements for our collaborators and licensees. Several of our agreements also require us to transfer important rights and regulatory compliance responsibilities to our collaborators and licensees. As a result of these collaboration agreements, we will not control the nature, timing, or cost of bringing these product candidates to market. Our collaborators and licensees could choose not to, or be unable to, devote resources to these arrangements or adhere to required timelines, or, under certain circumstances, may terminate these arrangements early. They may cease pursuing product candidates or elect to collaborate with different companies. In addition, these collaborators and licensees, outside of their arrangements with us, may develop technologies or products that are competitive with those that we are developing. From time to time, we may also become involved in disputes with our collaborators or licensees. Such disputes could result in the incurrence of significant expense, or the termination of collaborations. We may be unable to fulfill all of our obligations to our collaborators, which may result in the termination of collaborations. As a result of these factors,

our strategic collaborations may not yield revenue. Furthermore, we may not be able to enter into new collaborations on favorable terms or at all. Failure to generate significant revenue from collaborations could increase our need to fund our operations through sales of debt or equity securities and would negatively affect our business prospects.

Our internal computer systems, or those of our third-party CROs, CMOs, licensees, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption in our business and operations or could subject us to sanctions and penalties that could have a material adverse effect on our reputation or financial condition.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs, CMOs, licensees, collaborators and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, on-going or future clinical trials could result in delays in our regulatory approval efforts and significant costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture 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 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.

Both Garo H. Armen, Ph.D., the Chairman of our Board of Directors and our Chief Executive Officer who co-founded the Company in 1994, and Dr. Jean-Marie Cuillerot, our Chief Medical Officer who joined the Company in July 2016, are integral to building our company and developing our technology. If either Dr. Armen or Dr. Cuillerot is unable or unwilling to continue his relationship with Agenus, our business may be adversely impacted. We have employment agreements with both Dr. Armen and Dr. Cuillerot. They both play important roles in our day-to-day activities. We do not carry key employee insurance policies for Dr. Armen, Dr. Cuillerot 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.

We rely on a small staff of highly trained and experienced senior management and scientific, administrative and operations personnel and consultants to conduct our business in certain key areas of our organization. The competition for qualified personnel in the biotechnology field is intense, and if we are not able to continue to attract and retain qualified personnel and/or maintain positive relationships with our outside consultants, we may not be able to achieve our strategic and operational objectives. Moreover, in connection with our recently announced 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.

As previously disclosed, we intend to advance our cell therapy portfolio by spinning it out into a separate business entity that is majority owned by Agenus and funded externally. Any such spinout 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 our cell therapy portfolio. There is no guarantee that 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 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. Although we intend for our cell therapy subsidiary to ultimately have a separate management team and governance structure, that is currently not the case. According, all efforts associated with this spinout are being led by Agenus' management team and internal resources. Any delay in securing funding or partnership opportunities could cause management and Agenus resources to be distracted from Agenus' own core pipeline and programs.

The assets necessary to spinoff our cell therapy portfolio are currently owned or controlled by Agenus in the United States and Switzerland. In connection with forming a separate business entity to advance this program, these assets will be transferred to new legal entities within the United States and from Switzerland to the United Kingdom. Transferring these assets requires that taxes be paid based on the fair market value of the assets. We are currently in the process of valuing these assets and working with the relevant tax authorities to determine our total tax liabilities. 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 our cell therapy subsidiary. There is no guarantee that any such dividend will be tax-free or that it will be issued at all. 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. In December 2015, we acquired an antibody pilot plant manufacturing facility and leased additional office space in Berkeley, CA. This location is in an area of seismic activity near active earthquake faults. Any earthquake, terrorist attack, fire, power shortage or other calamity affecting our facilities or those of third parties upon whom we depend may disrupt our business and could have a material adverse effect on our business, results of operations, financial condition and prospects. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses and delays as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Risks Related to Regulation of the Biopharmaceutical Industry

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

Drug development, including non-clinical testing and clinical development, and the process of obtaining regulatory approvals for new therapeutic products, is lengthy, expensive, and uncertain. For example, as of June 30, 2017, we had spent approximately 20 years and \$627.0 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 115th 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.

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 40 issued United States patents and approximately 125 issued foreign patents. We also own, co-own or have exclusive rights to approximately 30 pending United States patent applications and approximately 70 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 AIA introduced new procedures, including inter partes review and post grant review. These procedures may be used by competitors to challenge the scope and/or validity of our patents, including those that patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges.

Even after they have been issued, our patents and any patents which we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

The following are non-exclusive examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

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

- third parties may initiate opposition proceedings, post-grant review, inter partes review, or reexamination proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and/or licensors or licensees to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us;
- the USPTO may initiate an interference or derivation proceeding between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our collaborators and/or licensors or licensees to participate in an interference or derivation proceeding to determine the priority of invention, which could jeopardize our patent rights; or
- third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. There is a risk that a court or administrative body could decide that our patents are invalid or not infringed by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents could limit our ability to assert our patents against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. An adverse outcome may also put our pending patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administrative panel to affect the validity or enforceability of a claim, for example, if a priority claim is found to be improper. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our relevant product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

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

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable.

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

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. In particular the patent landscape around the discovery, development, manufacture and commercial use of our pre-clinical CPM antibody programs and therapeutic antibodies is crowded.

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

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

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us or our licensors or licensees, we or our licensors or licensees may be required to participate in interference, derivation or other proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is a risk that a court would decide that we or our collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our collaborators may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

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

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

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

We are currently party to various intellectual property license agreements. These license agreements impose, and we expect that future license agreements may impose, various diligence, milestone payment, royalty, insurance and other obligations on us. These licenses typically include an obligation to pay an upfront payment, yearly maintenance payments and royalties on sales. If we fail to comply with our obligations under the licenses, the licensors may have the right to terminate their respective license agreements, in

which event we might not be able to market any product that is covered by the agreements. Termination of the license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, which could adversely affect our competitive business position and harm our business.

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

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

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery.

As is common in the biopharmaceutical industry, we employ individuals who were previously or concurrently employed at research institutions and/or other biopharmaceutical, biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel or service providers to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. In addition, we are responsible for the payment of patent fees for patent rights that we have licensed from other parties.

If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights.

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

Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and

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

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

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-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 requires us to be cognizant of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

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

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

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

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

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

Risks Related to Litigation

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

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

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

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

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

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

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

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

We face an inherent risk of product liability exposure related to testing our product candidates in human clinical trials and manufacturing antibodies in our Berkeley, CA facility and may face even greater risks if we ever sell products commercially. An

individual may bring a product liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. Product liability claims may result in:

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

We manufacture the Prophage vaccines from a patient's cancer cells, and medical professionals must inject the vaccines into the same patient from which they were manufactured. A patient may sue us if a hospital, a shipping company, or we fail to receive the removed cancer tissue or deliver that patient's vaccine. We do not have any other insurance that covers loss of or damage to the Prophage vaccines or tumor material, and we do not know whether such insurance will be available to us at a reasonable price or at all. We have limited product liability coverage for use of our product candidates. Our product liability policy provides \$10.0 million aggregate coverage and \$10.0 million per occurrence coverage. This limited insurance coverage may be insufficient to fully cover us for future claims.

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

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

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

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

Risks Related to our Common Stock

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

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us without the consent of our Board of Directors. Our certificate of incorporation provides for a staggered board and removal of directors only for cause. Accordingly, stockholders may elect only a minority of our Board at any annual meeting, which may have the effect of delaying or preventing changes in management. In addition, under our certificate of incorporation, our Board of Directors may issue additional shares of preferred stock and determine the terms of those shares of stock without any further action by our stockholders. Our issuance of additional preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock and thereby effect a change in the composition of our Board of Directors. Our certificate of incorporation also provides that our stockholders may not take action by written consent. Our bylaws require advance notice of stockholder proposals and director nominations and permit only our president or a majority of the Board of Directors to call a special stockholder meeting. These

provisions may have the effect of preventing or hindering attempts by our stockholders to replace our current management. In addition, Delaware law prohibits a corporation from engaging in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our Board of Directors may use this provision to prevent changes in our management. Also, under applicable Delaware law, our Board of Directors may adopt additional anti-takeover measures in the future.

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 June 30, 2017, and the six months ended June 30, 2017, the closing price of our common stock has fluctuated between \$1.80 (or \$0.30 pre-reverse stock split) and \$315.78 (or \$52.63 pre-reverse stock split) per share and \$3.24 and \$4.54 per share, respectively. The average daily trading volume for the six months ended June 30, 2017 was approximately 1,083,948 shares, while the average daily trading volume for the year ended December 31, 2016 was approximately 1,207,067. The market may experience significant price and volume fluctuations that are often unrelated to the operating performance of individual companies. In addition to general market volatility, many factors may have a significant adverse effect on the market price of our stock, including:

- continuing operating losses, which we expect over the next several years as we continue our development activities;
- announcements of decisions made by public officials or delays in any such announcements;
- results of our pre-clinical studies and clinical trials or delays in anticipated timing;
- delays in our regulatory filings or those of our partners;
- announcements of new collaboration agreements with strategic partners or developments by our existing collaboration partners;
- announcements of acquisitions;
- announcements of technological innovations, new commercial products, failures of products, or progress toward commercialization by our competitors or peers;
- failure to realize the anticipated benefits of acquisitions;
- developments concerning proprietary rights, including patent and litigation matters;
- publicity regarding actual or potential results with respect to product candidates under development;
- quarterly fluctuations in our financial results, including our average monthly cash used in operating activities;
- variations in the level of expenses related to any of our product candidates or clinical development programs;
- additions or departures of key management or scientific personnel;
- conditions or trends in the biopharmaceutical, biotechnology and pharmaceutical industries generally;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

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

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

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

The sale by us or the resale by stockholders of a significant number of shares of our common stock could cause the market price of our common stock to decline. As of June 30, 2017, we had 99,602,582 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. 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 20,101,002 shares of common stock pursuant to various private placement agreements (including 1,400,000 shares of common stock issuable upon the exercise of certain warrants that we issued in February 2015) and to permit the sale of approximately 10,000,000 shares of our common stock pursuant to our At Market Issuance Sales Agreement. As of June 30, 2017, an aggregate of approximately 32,000,000 of these shares remained available for sale. In connection with our acquisition of 4-AB in February 2014, we are obligated to make contingent milestone payments to the former shareholders of 4-AB, payable in cash or shares of our common stock at our option, as follows (i) \$10.0 million upon our market capitalization exceeding \$750.0 million for 30 consecutive trading days prior to the earliest of (a) 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 addition, as additional consideration for assets that we purchased from Celexion, we agreed to pay to Celexion \$4.1 million in shares of our common stock in November 2017. 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. Pursuant to a technology transfer and license agreement that we entered into with Iontas Limited ("Iontas") in September 2015, we agreed to pay up to an aggregate of \$3,500,000 upon the completion of certain milestones, payable in cash or shares of our common stock at our election. In November 2016, we issued 157,513 shares of our common stock to Iontas as consideration for a \$1.0 million milestone payment, and in January 2017 we filed a registration statement to provide for the resale of these shares. In March 2017, we issued an additional 373,351 shares of our common stock to Iontas as consideration for a \$1.5 million milestone payment and amended the registration statement to incorporate these additional shares. We are also obligated to file registration statements covering any additional shares that may be issued to Celexion, XOMA, Iontas or the former shareholders of PhosImmune in the future pursuant to the terms of our agreements with Celexion, XOMA, Iontas and PhosImmune, respectively. The market price of our common stock may decrease based on the expectation of such sales. The market price of our common stock may decrease based on the expectation of such sales.

As of June 30, 2017, warrants to purchase approximately 4,351,450 shares of our common stock with a weighted average exercise price per share of \$9.01 were outstanding.

As of June 30, 2017, options to purchase 15,287,781 shares of our common stock with a weighted average exercise price per share of \$4.33 were outstanding. These options are subject to vesting that occurs over a period of up to four years following the date of grant. As of June 30, 2017, we had 7,184,446 vested options and 2,022,324 nonvested shares outstanding.

As of June 30, 2017, our outstanding shares of Series A-1 Convertible Preferred Stock were convertible into 333,333 shares of our common stock.

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

We do not intend to pay 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.

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, 2016, 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 5. *Other Information*

On April 14, 2017, we entered into a Development and Manufacturing Services Agreement ("DMSA") with the CMC ICOS Biologics, Inc. ("CMC Bio"), pursuant to which CMC Bio will perform manufacturing process development for our AGEN1884 and AGEN2034 molecules. Costs under the DMSA are expected to be approximately \$20 million per molecule for transfer and scale-up of the manufacturing process, GMP production, characterization, validation, QC and stability, through completion of three validation runs each. Total costs are expected to be paid over time through 2020. Commercial supply will be covered under separate agreement; however, we expect that the supply provided under the DMSA will be adequate for all clinical needs and provide drug substance for early commercial launch efforts. Agenus can terminate the DMSA or any particular services on 60 business days' notice, provided that cancelled manufacturing runs may be subject to cancellation fees depending on how far in advance termination notice is given. The manufacturing process may be transferred in-house to Agenus or its affiliates at any time, and to a single qualified third party manufacturer during the term (or upon termination). The foregoing description of the DMSA is a summary and is qualified in its entirety by the DMSA itself, which is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

Item 6. *Exhibits*

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

(b) Exhibits

AGENUS INC.

SIGNATURES

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

Date: August 7, 2017

AGENUS INC.

/s/ CHRISTINE M. KLASKIN

Christine M. Klaskin
VP, Finance, Principal Financial Officer, Principal
Accounting Officer

Exhibit Index

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 10.1 (1) | Development and Manufacturing Services Agreement dated April 14, 2017 by and between CMC ICOS Biologics, Inc. and Agenus Inc. Filed herewith. |
| 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 406 of the Securities Act or Rule 24b -2 of the Securities Exchange Act. |

[*****] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT

This agreement is made as of April 14, 2017 (“**Effective Date**”) between CMC ICOS BIOLOGICS, INC., a Washington corporation (“**CMC**”), and AGENUS INC., a Delaware corporation (“**Customer**”).

- CMC provides bioprocessing services to pharmaceutical and biotechnology companies;
- Customer wishes to contract with CMC for the provision of the Services pursuant to one or more Work Statements that may be entered into from time to time during the Term; and
- CMC is willing to perform the Services on the terms in this agreement and the Quality Agreement.

Therefore, the parties agree as follows:

1. DEFINITIONS. Capitalized terms used in the main body of this agreement but not otherwise defined in the main body are defined in Appendix I.

2. PERFORMANCE OF THE SERVICES

- 2.1 **Work Statements.** The Services will be described in one or more Work Statements. As of the Effective Date, the parties are entering into Work Statement No. 1 attached as Appendix III. From time to time during the Term, the parties may enter into additional Work Statements for the performance of Services. Each Work Statement will be signed by each party and will be governed by this agreement.
- 2.2 **Standards.** CMC must use commercially reasonable efforts to (a) perform the Services in accordance with the applicable Work Statement(s) and any other mutually agreed instructions and plans, in a good and professional manner, consistent with applicable industry standards and industry best practices, using persons or entities (“**Personnel**”) reasonably competent and trained to perform such Services, (b) meet the applicable Timeline and Specification and, (c) comply with all applicable laws in the jurisdictions where Services are performed by CMC and, where required by the Work Statement, comply with applicable cGMP standards. The parties will evaluate CMC’s efforts taking into account the experimental nature of the Services, and the Services being dependent on living systems.
- 2.3 **Totality of Services.** CMC will not perform any Services other than those described in the Work Statement. Due to the nature of the Services, however, changes to the Services may be necessary to achieve the Objective. If changes to the Services are necessary, the parties will promptly meet to negotiate and agree on those changes in writing. Changes to the Services may affect the Price and Timeline.
- 2.4 **Project Team**
- 2.4.1 Each party will name and notify the other party of its representatives who will form the project team and who will be responsible for planning, executing and discussing issues regarding the Services and communicating with the other party (“**Project Team**”). Each Project Team shall be represented by a primary point of

[*****] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

contact, responsible for coordinating communication within and between the Project Teams on behalf of its Party (the "**Project Leader**"). The initial CMC Project leader shall be notified to Customer promptly after the Effective Date. The initial Customer Project Leader shall be [*****]. Each party shall use its reasonable endeavours not to change its respective Project Leader, and each Party shall notify the other of any change to its Project Leader as reasonably in advance as possible.

2.4.2 The Project Team will schedule meetings at regular intervals for the purpose of communicating updates on the performance of the Services and providing an initial forum for discussing and resolving any issues encountered with the Services. These meetings will be conducted by telephone or, if necessary, by face-to-face meetings. Each party is responsible for its own costs in attending these meetings.

2.4.3 Any decision by the Project Team that amends the Services will not be binding unless it is recorded in writing and signed by authorized representatives of both parties per Section 15.4.

2.5 Regulatory Submissions. CMC may communicate with regulatory authorities without Customer input with respect to matters primarily directed to CMC's equipment and facilities, and all other regulatory written submissions by CMC primarily relating to the Product itself (rather than CMC's facilities or activities) shall be subject to mutual agreement unless a response is required from CMC pursuant to applicable laws or rules and agreement cannot (practically or otherwise) be reached. CMC shall provide Customer with a copy of any submission CMC is obliged to make to any regulatory bodies in connection with the Product manufactured pursuant to Services, or in the case of certain CMC Confidential Information, CMC shall supply such information directly to the regulatory bodies with concurrent confirmation and summary of information submitted to Customer. All submissions provided to Customer shall be deemed CMC Confidential Information, except to the extent they contain information originally supplied by or on behalf of Customer, or otherwise contain Customer Confidential Information. CMC grants Customer the right to use or refer to any and all information contained therein, including without limitation a right of reference to the Product drug master files filed by CMC, in each case solely for Customer undertaking its regulatory activities solely in connection with the Product.

2.6 Records. CMC will maintain those complete and accurate records ordinarily expected to be generated by a biologics manufacturer in performing the Services, recording its performance of Services, including without limitation those required of it pursuant to the Quality Agreement (if any). Such records shall be held for the longer of ten (10) years after expiration of the Products to which they pertain or the period of time required by applicable law. CMC shall make such of those records (in so far as they are applicable to the Product and excluding or redacted to remove CMC's Confidential Information, including without limitation its proprietary SOPs) available to Customer or its representative for inspection pursuant to obligations of confidentiality upon reasonable request. CMC shall not knowingly destroy such records without first notifying Customer and giving Customer a reasonable opportunity to take possession of such records (in so far as they are applicable

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to the Product and excluding CMC's Confidential Information, including without limitation its proprietary SOPs).

- 2.7 Debarment. CMC represents and warrants that neither CMC nor so far as it is aware any of its Personnel has been, and neither CMC nor its personnel, nor so far as it is aware, any of its subcontractors, are currently debarred, suspended, or proposed for debarment in the United States pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. §335(a), as amended, or in any other country in which Services will be performed under any similar federal or state law or regulation, or otherwise disqualified or restricted by any regulatory authority related to government contracts or healthcare programs. CMC will use commercially reasonable efforts to ensure that CMC does not use any debarred, excluded or disqualified Personnel for the performance of Services under this Agreement.
- 2.8 Steering Committee.
- 2.8.1 Promptly after the Effective Date, the Parties shall establish a joint steering committee (the "JSC"). The JSC shall be comprised of two (2) named representatives of CMC and two (2) named representatives of Customer (or such other number as the Parties may agree). A member of the Project Team may simultaneously serve as a member of the JSC. Each party may replace one or more of its representatives, in its sole discretion, effective upon sixty (60) days' written notice to the other party of such change. Either party may, from time to time, invite additional representatives or consultants to attend JSC meetings, subject to such representative's or consultant's written agreement to comply with confidentiality obligations substantially the same as those set forth in Article 9. The JSC shall meet once a calendar quarter or as needed either in person or by teleconference. Each party shall bear its own expenses related to the attendance at JSC meetings by its representatives. The JSC shall be co-chaired by a representative from each party.
- 2.8.2 The JSC's responsibilities shall include: (i) coordinating the activities of the parties under this Agreement, including facilitating communications between the parties; (ii) providing a forum for discussion; (iii) approving updates and amendments to the Work Statement, in particular those that represent a substantial increase in risk to the timely completion of a material activity under the Work Statement; (iv) reviewing the Timeline; (v) making recommendations with respect to budgets to the Work Statement or proposed costs for conducting activities under this Agreement; (vi) directing and overseeing the Project Team; (vii) attempting to resolve issues presented to it by the Project Team; and, (viii) considering and acting upon such other matters as specified in this Agreement. The JSC may

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delegate any of its responsibilities to the Project Team or require the Project Team to cede any of its responsibilities to the JSC.

2.8.3 The initial composition of the JSC shall be as follows:

CMC:

[*****]
[*****]
[*****]

Customer:

[*****]
[*****]
[*****]

2.8.4 JSC members shall communicate openly and promptly among each other with respect to all matters subject to their review, and shall use good faith efforts to resolve all disputes brought before the JSC. If a JSC dispute cannot be resolved, such dispute shall be escalated to a senior executive of each of Customer and CMC in accordance with Section 15.11.

3. CUSTOMER MATERIALS

- 3.1 Transfer and Use. Customer shall deliver and successfully transfer to the CMC Facility and CMC's personnel the Customer Materials and other information described in the Work Statement the deadline in the Work Statement. If relevant, that information will include a full description of the Process and all Customer Know-How relevant to the Cell Line, Customer Materials, Drug Substance and Process, including that set out in the Work Statement. All information must be provided in written form and in English. CMC shall not use, nor permit the use of, Customer Materials for any purpose other than the Services or for the benefit of itself or any Third Party outside of this agreement. CMC shall not, nor permit any Affiliate or Third Party to, reverse engineer, deconstruct, or determine the sequence of any Customer Materials except as reasonably required in performance of the Services or as otherwise set forth in the applicable Work Statement. The Customer Materials shall not be transferred to any Third Party (other than Testing Laboratories where those Third Parties are undertaking activities pursuant to the Services) without the express written consent of Customer.
- 3.2 Customer Assistance. Customer must promptly and, in any event, within five Business Days after the request, make available to CMC suitably qualified and skilled employees to assist in the successful transfer of the Customer Know-How, Customer Materials and Process to CMC.
- 3.3 MSDS. At least 30 Business Days before the delivery of the Customer Materials (including, where applicable, the Cell Line) Customer shall provide to CMC an accurate and complete written risk assessment (in English) for genetically modified organisms that details the hazards, storage and handling recommendations for the Customer Materials ("**Materials and Safety Data Sheet**").
- 3.4 Return of Customer Materials. Within 30 days after completion of the Services, Customer must notify CMC whether it wants CMC to return the Customer Materials to Customer or a Third Party storage facility or if it wants CMC to dispose of the Customer Materials, in each case, at Customer's expense. If Customer fails to give the notice required by this Section 3.4 within 30 days after the completion of the relevant Services, CMC may, after

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notifying Customer, dispose of them at Customer's expense, or return them to the Customer at Customer's expense, in its sole discretion and without liability to Customer, but in each case in accordance with applicable laws and any Materials and Safety Data Sheet.

4. TIMELINE CHANGES, SPECIFICATION AND CGMP CHANGES

4.1 Timeline Changes

4.1.1. The parties may revise the Timeline by mutual agreement; provided, that the revised Timeline is in writing and agreed by the Project Team.

4.1.2. In addition, CMC may revise the Timeline to the extent necessary to accommodate a Non-Fault Delay, keeping the revised Timeline as close as possible to the Timeline in effect immediately before the Non-Fault Delay. Subject to Section 2.2, CMC is not liable for any failure to meet the Timeline that is or results from a consequence of any Non-Fault Delay.

4.2 Specification and Quantities

4.2.1. CMC must use commercially reasonable efforts to manufacture Product to meet the Specification where required by the Work Statement. However, Customer acknowledges that CMC may be unable to manufacture Product to meet the Specification despite its commercially reasonable efforts if:

- (a) the Product has not been previously manufactured to that Specification by CMC at the same scale and using the same Process and Cell Line; or
- (b) the Batch is the first cGMP Batch to be manufactured to Specification or it has never been manufactured to Specification by CMC under this agreement.

Any such failure will not constitute breach of this Section 4.2.1 provided that CMC has complied with Section 2.2. Nothing in this Section 4.2.1 will relieve CMC of liability for delivering an inaccurate Certificate of Analysis.

4.2.2. The Specification may be revised by the parties if agreed by the Project Team in writing and signed by both parties. If the parties cannot agree to a revised Specification, the previous agreed on Specification applies.

4.2.3. All quantities of Product are estimates only. Save as provided below, CMC is not liable for any low or unexpected yield. Upon completion of the successful manufacture to the same consistent Specification of a statistically relevant number of Batches (at the same scale, using the same Process, Raw Materials and Cell Line), the parties will agree upon a yield expected from a Batch (to be conducted at the same scale, meeting the same Specification and using the same Process, Raw Materials and Cell Line), and thereafter Batches shall (when manufactured to

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the same scale, using the same Process, Raw Materials and Cell Line) subject to Clause 2.1, be expected to meet that yield.

4.3 Changes in cGMP. If there are any material and unforeseen changes in cGMP or manufacturing regulations issued under law that impact the Services and

4.3.1 are specific to the Product and not of general requirement for biologics contract manufacturing services of a similar nature; and

4.3.2 require capital or other investment by CMC for the performance of the Services in excess of the total Price of the Services resulting in the financial returns under this agreement being substantially affected to CMC's detriment;

then CMC must notify Customer and provide documentation reasonably substantiating the financial detriment, and the parties must in good faith discuss ways to continue the Services while overcoming the financial detriment by, for example, increasing the Price in an equitable and reasonable manner. If the parties do not reach agreement within 60 Business Days after CMC has delivered notice and substantiated the financial detriment, then CMC may terminate this agreement on an additional sixty (60) days' prior written notice to Customer.

5. MANUFACTURING CAPACITY AND CANCELLATION FEES

5.1 Reservations and Scheduling

5.1.1 As of the Effective Date, and at the execution of each Work Statement, CMC will reserve Slots in its cGMP manufacturing suite for those cGMP Batches to be manufactured under the Services according to the then-current Timeline.

5.1.2 If the Timeline is amended and that amendment affects the scheduled Slot for any Batch, CMC will update its manufacturing schedule and reserve a new Slot for each affected Batch. CMC will reserve those Slots as near in time to the existing vacated Slots as CMC's then-current schedule will permit, taking into account reserved slots under CMC's existing manufacturing schedule for its whole facility.

5.2 Cancellation of cGMP Batches

5.2.1 Customer must pay CMC the cancellation fees stated below if any cGMP Batch or other Batch scheduled for manufacture in CMC's cGMP facility (e.g., an engineering batch) is delayed, vacated or cancelled as a result of

(a) Customer terminating the Batch, Slot or this agreement except for termination of this agreement under Section 12.2 ("Termination for Default") where CMC is the "Defaulting Party;" or

(b) CMC terminating the Batch, Slot or this agreement pursuant to Section 12.2 ("Termination for Default") where Customer is the "Defaulting Party" ;

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(c) [*****]

(d) [*****]

5.2.2 Customer must pay the following amounts to CMC for each Cancelled Batch or Unfeasible Batch (“Cancellation Fees”):

| Timing of Notice of Cancellation | Cancellation Fees |
|---|-------------------|
| Notice of [*****] served on or after the scheduled Commencement Date and notice of cancellation served during a Batch. | [*****] |
| Notice of [*****] served [*****] or fewer before the scheduled Commencement Date. | [*****] |
| Notice of [*****] served more than [*****] but fewer than [*****] before the scheduled Commencement Date. | [*****] |
| (i) Cancellation or termination of any [*****] at any time fewer than [*****] before the scheduled Commencement Date; or, (ii) notice of Cancelled Batch served at least [*****] but fewer than [*****] before the scheduled Commencement Date. | [*****] |

For Section 5.2.2, the date of service of notice of a Cancelled Batch is the earlier of (a) the date notice to terminate a Batch, Slot or this agreement is given by the terminating party to the other party; (b) the date that the new Timeline has been agreed by the parties; or (c) the date CMC has given notice that the Timeline has been updated. CMC shall use its commercially reasonable efforts to secure a new project or a new Batch from any new or existing customer for the manufacturing space vacated by the Cancelled Batch. If it is able to do so, then CMC shall credit Customer with such proportion of the Cancellation Fees paid by Customer as exceed the price charged by CMC to the Third Party Batch manufactured in the manufacturing space vacated by the Cancelled Batch (less any out-of-pocket costs reasonably incurred by CMC in accomplishing such mitigation).

6. PACKAGING, DELIVERY, STORAGE, EXAMINATION, DEFECTS AND SAMPLES

6.1 Packaging. CMC will package all Cell Lines, Product and perishable Deliverables to be Delivered per CMC’s applicable packaging SOPs and Regulatory Obligations.

6.2 Delivery.

6.2.1 CMC will provide Customer with advance notice of the anticipated date of Delivery of Product. Notice will be provided at least five Business Days before CMC is to Deliver that Product.

6.2.2 Except as stated in Section 6.2.4 or in the Specifications, all Product that CMC manufactures under this agreement will be released to Customer Ex Works

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(Incoterms 2012) at CMC's Facilities at 9:00 am local time on the date specified in CMC's notice to Customer, provided that CMC will properly pack and mark Product in accordance with CMC's standard operating procedures and reasonable Customer instructions. Product will be considered "delivered" on the date Product is so released and the corresponding Release Documentation delivered ("**Delivery**" or "**Delivered**"). Customer may arrange collection at any time during normal business hours on Business Days or other times as may be agreed by the parties.

- 6.2.3 CMC has no obligation to clear for export or import any Deliverables nor is CMC obligated to obtain, or assist Customer in obtaining, export or import licenses, consents or permissions.
- 6.2.4 Data, results, Batch records and Drug History Records will be delivered by mail, electronic mail, or where available other secure electronic portal.
- 6.2.5 CMC will deliver to Customer a Certificate of Analysis, Certificate of Compliance (if separate from the Certificate of Analysis), and the consolidated Batch processing and packaging records (excluding CMC's proprietary SOPs) applicable to that Batch of Product (including closed out deviations, QC analytical data and test results and TSE/BSE certifications for raw materials used) (the "**Release Documentation**") on or before the date of Delivery of such Product, unless Product is made available first for Release for Further Processing.

6.3 Release For Further Processing. Subject to, and if permitted by, Regulatory Obligations, Customer may request that CMC Deliver Product to Customer before CMC issues a Certificate of Analysis ("**Release For Further Processing**"). Any Product that is the subject of Release For Further Processing must, until the applicable Certificate of Analysis is issued by CMC

- 6.3.1 not be administered to any multi-cellular living organism;
- 6.3.2 be handled by Customer with the utmost care as if it were an unknown substance; and
- 6.3.3 be held and tested (without prejudice to Section 6.3.1) by Customer at Customer's sole risk and liability.

CMC is not liable for any loss or damage caused by Product that is the subject of Release For Further Processing unless and until the applicable Certificate of Analysis is issued by

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CMC and where the Product does not at the date of Delivery under the Release For Further Processing conform with that Certificate of Analysis.

6.4 Title and Risk. Title and risk of loss in the Deliverables transfers to Customer on Delivery.

6.5 Storage and Transport. If Customer elects to have a shipping company or other agent (“**Shipping Company**”) collect and transport the Product on Delivery, Customer must

6.5.1 inform CMC of Customer’s designated Shipping Company before the collection of the Product;

6.5.2 coordinate with the Shipping Company for the shipment of the Product; and

6.5.3 ensure that the Product is stored and transported in accordance with the Shipping Guidelines.

CMC is not responsible for any shipping costs of the Shipping Company.

6.6 Storage. If Customer or Customer’s Shipping Company is unable to collect the Product at the time of Delivery, CMC will store the Product for a period of 20 Business Days after Delivery, at Customer’s request. Storage of the Product at CMC’s premises after Delivery is at Customer’s sole risk and liability provided that CMC takes commercially reasonable efforts consistent with industry standards to (a) comply with the storage specifications set forth in the applicable Work Statement and (b) keep the Product within a reasonably secure environment with reasonably sufficient safeguards to prevent tampering, diversion or loss of the Product. If the Product has not been collected by Customer or Customer’s Shipping Company within 20 Business Days after Delivery, CMC will notify Customer. If Customer or Customer’s Shipping Company fails to collect the Product within 10 Business Days after the date of that notice, CMC may, without notifying Customer and without any liability to Customer, either, in its sole discretion, destroy the Product or continue to store the Product at a cost to Customer in the amount stated in Appendix II. If CMC elects to continue to store the Product, then CMC may subsequently destroy the Product if Customer or Customer’s Shipping Company fails to collect the Product within five Business Days after notice given in accordance with Section 15.9.

6.7 Samples. Unless Customer elects to store reserve samples elsewhere, CMC will store regulatory reserve samples (e.g., GMP retention samples) of all cGMP Product released by CMC’s quality department with a Certificate of Analysis for the period required by applicable Regulatory Obligations, which in the absence of a definitive time period is 15 years from the date of release or Delivery of the applicable Product. CMC is solely responsible for the maintenance and disposal of these regulatory reserve samples. After the expiration of the relevant time period, CMC may, without notifying Customer, destroy the samples unless Customer contacts CMC in writing pursuant to Section 15.9 before the expiration date, and CMC and Customer then agree to an alternate plan in a written agreement signed by both parties before the expiration of that period.

6.8 Shipping Guidelines. If Customer intends to test the Product and wants to reserve its right to make a claim against CMC under Section 6.9 for defective Product, Customer must ensure that the Product since collection from CMC’s Facility is always stored and

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transported in accordance with the Shipping Guidelines. Failure to comply with the Shipping Guidelines before or after serving a Defect Notice (as defined below) will invalidate Customer's right to make any claim under this agreement for defects in those Products.

6.9 Examination of Products for Defects

- 6.9.1 CMC shall notify Customer promptly if it subsequently after Delivery determines that it has Delivered a Defective Product. Customer will promptly examine the Products for (a) contamination and any other defect and non-conformity with any applicable cGMP standards that the Products are required to meet under this agreement, and (b) in the case of Product manufactured to Specification for which a Certificate of Analysis has been issued, the failure of the Product to meet Specification (a "**Defect**"). Product that is not specified in the Work Statement to meet cGMP or Specification cannot be considered Defective Product.
- 6.9.2 Where any alleged Defect is identified, Customer must notify CMC in writing ("**Defect Notice**") within 30 Business Days after Delivery of the Product. To be effective, a Defect Notice must identify
- (a) the Product;
 - (b) the date of Delivery and collection;
 - (c) reasonable detail of the Defect, including test results;
 - (d) where applicable full disclosure of the methodology of all analytical tests performed on the Product and the results of those tests;
 - (e) confirmation that the Products have been stored and transported in accordance with the applicable Shipping Guidelines; and
 - (f) where the Customer asserts that the Defect is due to CMC, the reasons for that assertion.
- 6.9.3 In consultation with CMC, Customer must return samples of the Products that are subject to the Defect Notice in accordance with the Shipping Guidelines to CMC within 15 Business Days after the date of the Defect Notice.
- 6.9.4 Following receipt of the Defect Notice, CMC must promptly investigate whether the Defect is due to CMC's negligence or failure to comply with its obligations under this agreement and must report to Customer within 20 Business Days after receipt of the samples whether CMC accepts responsibility for the Defect.
- 6.9.5 If a Defect in any Product is not notified to CMC in accordance with the provisions and time limits stipulated in this Section 6.9, the Product will be considered accepted and free of Defects, and Customer will have no further remedy against CMC for that Batch of Product, without prejudice to Section 14.3.

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6.10 Consequences of Defective Product

6.10.1 If Customer demonstrates that the Defect is due to CMC's fault and not as a result of any Third Party or Customer action or inaction and CMC accepts that finding, then CMC will use commercially reasonable efforts to correct the root cause of the nonconformance and to promptly replace or rework the Defective Product (the appropriate decision being made after consultation with Customer) and at no additional charge to Customer. CMC will undertake those efforts as soon as reasonably practicable taking into account CMC's other contractual obligations to Third Parties.

6.10.2 If there is a dispute regarding a Defect ("**Disputed Product**"), then (a) analysts from both parties must directly communicate to determine that the parties' respective methods of analysis are the same and are being executed in the same manner and to attempt to determine whether any non-compliance may have been caused during the shipment of the sample from CMC's Facility, and (b) carefully controlled and split samples as agreed must be sent from one site to the other for testing. This process may involve Customer sending a representative and a sample of the Disputed Product to CMC, and the parties conducting jointly agreed on tests on the samples. The parties must use good faith efforts for a period of 30 days after completing those tests to resolve whether the Disputed Product is Defective due to CMC's failure to manufacture in accordance with this agreement, including the applicable Work Statement and Quality Agreement (if any).

6.10.3 If the parties cannot resolve their dispute in the manner described above as to whether a Disputed Product meets the Specification, the parties must require an independent agreed-on laboratory to test the Disputed Product (the scope of such tests to be agreed between the Parties). The costs of the independent laboratory will be shared by the parties equally. The decision of the independent laboratory must be in writing. The decision will be binding on the parties as to whether the Disputed Product meets the Specification unless there has been a manifest error, in which case, the parties will revert to the dispute resolution procedure in Section 15.

6.11 Rejected Product. Customer must segregate and must not use any Product for any human clinical testing or trials or any other purpose (other than compliance testing pursuant to this Section 6) after it becomes aware of a basis for rejection or a Defect Notice. On a final determination that any Product is Defective, Customer must either (a) return all remaining Product to CMC, or (b) destroy all remaining Product, in either case the appropriate decision being made after consultation with CMC, and as soon as practicable after request by CMC.

6.12 Examination and Correction of Non-Manufacturing Deliverables. Customer must promptly examine and test the Deliverables (other than Products) for any non-conformity with any applicable standards that those Deliverables are required to meet under this agreement, the applicable Work Statement and Quality Agreement (if any). Where any alleged non-conformity is identified, Customer must notify CMC in writing within 30 Business Days after delivery of the Deliverable. To be effective, that notice must identify the Deliverable and provide reasonable detail of the non-conformity. From receipt of the notice, CMC must

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promptly investigate whether the non-conformity is due to CMC's negligence or failure to comply with its obligations under this agreement and must report to Customer within 20 Business Days after receipt of the notice whether it accepts responsibility for the non-conformity. If Customer demonstrates that the non-conformity is due to CMC's fault and not as a result of any Third Party or Customer action or inaction and CMC accepts that finding, then CMC will use commercially reasonable efforts to correct the root cause of the nonconformance and promptly replace or correct the Deliverable at no additional cost to Customer; provided, that Customer has timely and properly notified CMC of the non-conformity per this Section 6.12.

- 6.13 Exclusive Remedies. Customer may delay final payment of any invoice received under Section 7.2.2(d) for Defective Products or other defective or non-conforming Deliverables if such defect or non-conformity is identified within 30 days after receipt of such invoice, provided such payment is made promptly upon cure of such defect or non-conformity. Except as set forth in this Section 6.13 or in Section 14.3, the remedies and obligations under Sections 6.9 and 6.10 are Customer's sole remedy for Defective Products and the remedies and obligations under Sections 6.12 are Customer's sole remedy for defective or non-conforming Deliverables that are not Products.

7. PRICE AND PAYMENT TERMS

- 7.1 Amounts. All amounts stated in this agreement are denominated, and must be paid, in U.S. Dollars. The Price stated in the Work Statement is exclusive of (a) taxes, duties and other fees imposed by any government authority (other than taxes on CMC's income or CMC's internal transactions); (b) external analysis costs; (c) raw materials and (d) shipping and handling. Customer must pay these amounts in addition to the Price, provided that (in the case of (b) to (d)) Customer has agreed to the applicable expense or where informed by prior written notice, Customer has not objected within 15 days of notification. Customer must also reimburse CMC for all travel costs requested by or required by Customer.

- 7.2 Payment Schedule. Unless a different payment schedule is provided in the Work Statement, CMC will issue invoices for the Price of Stages as follows:

7.2.1 For all Stages other than those described in Section 7.2.2:

- (a) [*****]% of the Price of each Stage on commencement of the Stage; and
- (b) [*****]% of the Price of the Stage on completion by CMC.

7.2.2 For all Stages where the Stage relates to the manufacture of cGMP Product or where the performance of the Stage takes place in CMC's GMP facility:

- (a) [*****]% of the Price of the Stage as a non-refundable fee on the date of this agreement;
- (b) [*****]% of the Price of the Stage 30 days before the Commencement Date of that Stage;

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- (c) [*****]% of the Price of the Stage once the Drug Substance has been purified and put into containers; and
- (d) [*****]% of the Price of the Stage on Delivery.

For clarity, external analysis costs, raw materials and shipping and handling for Stages will be invoiced separately.

7.3 Incidental Costs

- 7.3.1 Raw Materials. The costs for raw materials and handling are described in the Work Statement.
- 7.3.2 External Analysis. The costs and handling for external analysis are described in the Work Statement.
- 7.3.3 Handling Fees. Customer must pay CMC a handling and processing fee for shipments as described in Appendix II, which covers packaging and other costs for preparing Deliverables for shipment.
- 7.3.4 Other Fees. Customer must pay CMC the other fees as described in Appendix II if relevant.

7.4 Payments. Unless otherwise directed by CMC in an applicable Work Statement, all invoices must be paid by wire transfer of immediately available funds to the following account:

Silicon Valley Bank
3003 Tasman Drive
Santa Clara, CA 95054
Routing & Transit #: [*****]
Account #: [*****]

Bank accounts details:

USD

Registration number: [*****]
Account number: [*****]
IBAN: [*****]

Unless otherwise stated on an invoice, Customer must pay all properly due invoices in full without any deductions within 30 days after delivery by CMC.

7.5 Late Payments. If any amount properly due hereunder is not paid in full within 45 days after receipt of invoice under this agreement, CMC may

- 7.5.1 charge Customer interest at a rate of [*****]% per month on the overdue amount on a compounded basis until payment is received, and

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7.5.2 following written notice to Customer, suspend the performance of the Services. Where performance is suspended, CMC will have no liability to Customer for the suspension or delay in the Timeline.

7.6 Acceptance of Invoices. All invoices will be considered accepted by Customer unless Customer notifies CMC to the contrary within 20 days after delivery of the applicable invoice.

8. INTELLECTUAL PROPERTY

8.1 Pre-Existing Intellectual Property. Each party retains sole ownership of any Intellectual Property owned or controlled by that party as of the Effective Date or before the commencement of the Services (“**Pre-Existing IPR**”). Nothing in this agreement assigns or transfers ownership of Pre-Existing IPR.

8.2 CHEF1 Technology. Notwithstanding anything to the contrary in this agreement, CMC retains sole ownership of all right, title and interest in (a) the CHEF1 Technology; (b) those portions of any polynucleotides or vectors and of any host cells transfected with those polynucleotides or vectors constituting any CHEF1 Technology; (c) all Intellectual Property rights in any of (a) or (b); and (d) all improvements or modifications to any of (a), (b) or (c) (collectively, “**CHEF1 Property**”). For avoidance of doubt, the inclusion of CHEF1 Property in a composition such as a polynucleotide or vector, or a host cell transfected with such polynucleotides or vectors, does not render the whole of that polynucleotide or vector or host cell as CHEF1 Property. Nothing in this agreement grants or obligates CMC to grant any rights in the CHEF1 Property to Customer or any Third Party. CMC shall not use any CHEF1 Property in performance of the Services under this Agreement or otherwise incorporate any CHEF1 Technology into any Products or Deliverables without the parties first executing a separate CHEF1 license agreement.

8.3 Customer’s Grant of License for the Services. Customer hereby grants to CMC and its Affiliates performing Services for the Term a non-exclusive, royalty-free, sublicensable (to any Testing Laboratory or otherwise in accordance with Section 15.6), non-transferable license under the Customer Intellectual Property Rights and Customer Project IPR solely to the extent required for the proper performance of the Services. This license terminates automatically on the termination of this agreement.

8.4 Intellectual Property Created in the Course of the Services. Without affecting Section 8.2, all data, information and Intellectual Property first developed, conceived or invented, or first reduced to practice by or on behalf of CMC in its performance of the Services and that is (i) primarily of application to the Product itself or improvements or modifications to the Product itself, or (ii) primarily an improvement or modification to the Product itself comprising an improvement of Customer’s Pre-Existing IPR or Confidential Information; will be owned by Customer (each of (i) and (ii) “**Customer Project IPR**”). CMC hereby assigns and agrees to assign to Customer all right, title and interest of CMC in any Customer Project IPR.

8.5 CMC Project IPR. All Intellectual Property that (i) primarily constitutes an improvement to CMC’s Pre-Existing IPR, or (ii) is created by or on behalf of CMC in performance of the Services other than Customer Project IPR, will be owned by CMC (“**CMC Project IPR**”).

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Customer hereby assigns to CMC all right, title and interest of Customer in any CMC Project IPR.

- 8.6 License to CMC Project IPR. CMC hereby grants to Customer a non-exclusive, royalty free, sublicensable, worldwide license to use CMC Intellectual Property Rights and CMC Project IPR (excluding any CHEF1 Property) owned or controlled by CMC to the extent necessary to make, use, sell, offer to sell and import the Product and use the Cell Line or Process to manufacture Product. However, except in performance of Article 13, this license does not include the right to disclose any Confidential Information of CMC or CMC Know-How to a Third Party without the express prior written consent of CMC. This license automatically terminates if CMC terminates the agreement pursuant to Section 12.2, but otherwise survives the Term indefinitely.
- 8.7 Right to File for Protection. Each party may file, prosecute and maintain patent applications and patents on any Intellectual Property it owns in accordance with Section 8.1, 8.2, 8.4 or 8.5, and the other party will promptly on request cooperate, at the requesting party's reasonable expense, with any requests to assist or enable the party's protection including signing and delivering documents and other information necessary for the valid filing, prosecution and maintenance of any patent application or patent. Notwithstanding the foregoing, neither party may use Confidential Information of the other party in the course of filing, prosecuting or maintaining such patent applications or patents without such other party's prior written consent.
- 8.8 Party's Name. Except as otherwise provided in this agreement or required by any applicable law, regulation or order of an administrative agency or court of competent jurisdiction, neither party shall use the name of the other party or of the other party's Affiliates, directors, officers or employees in any advertising, news release or other publication without such other party's prior written consent in each case.
- 8.9 No Implied Licenses. Except for the licenses expressly granted in this agreement, no rights or licenses are granted by implication, estoppel or otherwise.

9. CONFIDENTIAL INFORMATION

- 9.1 The Recipient Party must
- 9.1.1 use the Confidential Information of the Disclosing Party only during the Term as reasonably necessary to carry out this agreement and for no other purpose;
- 9.1.2 protect the Confidential Information of the Disclosing Party against unauthorized use or disclosure applying standards of care reasonably expected and no less stringent than the standards applied to protection of Recipient Party's own confidential information of a similar nature; and
- 9.1.3 not disclose any Confidential Information of the Disclosing Party to any person or entity except to its Permitted Recipients but then only on a need-to-know basis to those Permitted Recipients who are bound by confidentiality restrictions as restrictive as this Section 9. The Recipient Party will be responsible for any unauthorized use or disclosure of Confidential Information by its Permitted

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Recipients.

- 9.2 The obligations in Section 9.1 do not apply to information that:
- 9.2.1. at the time of its disclosure by the Disclosing Party, was available to the public and could be obtained without reference to the Confidential Information by any person in the Disclosing Party's industry or otherwise with no more than reasonable diligence;
 - 9.2.2 becomes generally available within the Disclosing Party's industry or to the public other than by reason of a breach of this agreement or any breaches of confidence by the Recipient Party or its Permitted Recipients;
 - 9.2.3 at the time of disclosure and as evidenced by the Recipient Party's written records, was lawfully already within its possession; or
 - 9.2.4 is independently developed by the Recipient Party without reference to the Confidential Information of the Disclosing Party.
- 9.3 The Recipient Party may disclose certain Confidential Information of the Disclosing Party, without violating the obligations of this agreement, solely to the extent that disclosure is required by and in compliance with a valid order of a court or other governmental body having jurisdiction or advisable by outside counsel for compliance with applicable securities rules, regulations or guidance to be disclosed to a securities commission or exchange, provided that the Recipient Party provides the Disclosing Party with reasonable prior written notice of the disclosure and makes a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order preventing or limiting the disclosure.
- 9.4 If the Recipient Party or any of its Permitted Recipients becomes aware of any actual or potential unauthorized use or disclosure of the Confidential Information of the Disclosing Party, the Recipient Party must inform the Disclosing Party as soon as reasonably possible after it becomes aware of that actual or potential unauthorized use or disclosure. The Recipient Party must use commercially reasonable efforts to cooperate in any reasonable remedial action that the Disclosing Party may decide to take.
- 9.5 Except as otherwise provided in this agreement or otherwise required by law, neither Customer nor CMC will disclose any terms of this agreement to any Third Party without the prior written consent of the other party except to its Permitted Recipients but then only on a need-to-know basis to those Permitted Recipients who are bound by confidentiality restrictions as restrictive as this Section 9. Each party may disclose the other party's Confidential Information and the terms of this Agreement to the extent such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, or other financial partner (or in the case of Customer, a strategic partner) for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; provided that in connection with such disclosure, such party inform each disclosee of the confidential nature of such Confidential Information and require the disclosees to be bound by written or fiduciary obligations of confidentiality and non-use consistent with those contained in this Agreement and further provided that such party shall be liable to the other party for any breach by the Third party of any such obligations.

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- 9.6 On the termination of this agreement or at the request of the Disclosing Party, the Recipient Party must promptly return to the Disclosing Party any Confidential Information of the Disclosing Party then in its possession or control except where that Confidential Information is covered under surviving license rights between the parties. However, each party may retain in its legal files a single copy of any document that contains the Disclosing Party's Confidential Information solely for the purpose of determining the scope of the obligations under this agreement. Neither party is obligated to destroy electronic files securely archived in accordance with its customary data retention policies.
- 9.7 Restrictions on Material Non-Public Information. Each Party acknowledges that it is aware that the United States securities laws prohibit any Person who has received material, non-public information with respect to a public company from purchasing or selling securities of that public company and from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell such securities. Each Party acknowledges that it is familiar with the United States Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (collectively, the "1934 Act"); and agrees that it will neither use, nor cause or permit any person to use, any Confidential Information in contravention of the 1934 Act, including, without limitation, Rule 10b-5 and Rule 14e-3 thereunder, or other applicable securities laws.

10. LIMITED WARRANTIES

- 10.1 Customer Warranties. Customer warrants and represents to CMC that:
- 10.1.1 to its knowledge, Customer has all necessary rights to supply to CMC the Customer Materials (including the Cell Line if provided by Customer) and the Customer Intellectual Property Rights, and CMC has and will have the right to use those items for the performance of the Services and manufacture of the Product in accordance with Section 8.3 and the applicable Work Statements and Quality Agreements (if any);
- 10.1.2 the Materials and Safety Data Sheet (if any) is accurate and complete and the Customer Materials (including the Cell Line if provided by Customer) are free from all contaminants, including virus, bacteria (other than the Cell Line itself) and other vectors, and if handled and used in accordance with the Materials and Safety Data Sheet and other written instructions supplied by Customer will not cause a health hazard or biohazard;
- 10.1.3 to its knowledge, the use of the Cell Line and Process, the Customer Materials, the practice of the Customer Intellectual Property Rights and the manufacture of the Product in accordance with the applicable Work Statements and Quality Agreements (if any) does not and will not infringe any Intellectual Property rights of any Third Parties, nor constitute misappropriation of a Third Party's trade secrets; and
- 10.1.4 (a) to its knowledge, the Cell Line and Process if provided by Customer and Customer Materials are viable, adequate and suitable for the effective performance of the Services and manufacture of the Product according to the Specification and

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(b) to its knowledge, the information supplied to CMC regarding the Cell Line provided by Customer and Process is accurate and complete, and (c) to its knowledge the Product has been successfully manufactured to Specification at a different scale and using the process to be transferred to CMC.

10.2. CMC Warranties. CMC warrants and represents to Customer that:

- 10.2.1 it has the necessary permits, facilities, Third Party contractors and skilled personnel that may be reasonably anticipated to be necessary of a biologics contract manufacturer for the regular provision of manufacturing and development services of biologic material;
- 10.2.2 all Deliverables will be Delivered free of financial encumbrances or liens created by CMC but no warranty is given in this Section 10.2.4 as to (a) non-infringement of Third Party Intellectual Property rights, or (b) freedom to use Products or Deliverables;
- 10.2.3 to its knowledge, use of the CHEF1 Property and practice of the CMC Intellectual Property Rights used in the Services in accordance with the applicable Work Statements and Quality Agreements do not and will not infringe Third Party Intellectual Property rights nor misappropriate a Third Party's trade secrets except that no warranty is given to the extent that infringement or misappropriation arises from the combination of CMC Intellectual Property Rights with the Cell Line, Process, Customer Materials or Customer Intellectual Property Rights;
- 10.2.4 where Stages are to be performed according to cGMP, CMC will apply the appropriate cGMP standards to the performance of those Stages; and
- 10.2.5 where Product is released with a Certificate of Analysis by CMC (including when the Certificate of Analysis is issued subsequent to release), the Product at the time of release will comply with the criteria specified in that Certificate of Analysis including (where applicable) the Specifications.

10.3 Disclaimer of All Other Warranties. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EXCEPT FOR THOSE EXPRESS WARRANTIES IN THIS AGREEMENT, NEITHER PARTY MAKES OR GIVES ANY OTHER WARRANTIES, EXPRESS OR IMPLIED (WHETHER BY STATUTE, CUSTOM, COURSE OF DEALING OR OTHERWISE) AND EACH PARTY HEREBY DISCLAIMS ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT AND TITLE.

11. INDEMNIFICATION

11.1 CMC's Indemnity. Customer must indemnify and defend CMC and its Affiliates and each of their respective directors and officers and Testing Laboratories ("**CMC Parties**") against any and all losses, demands, claims, liabilities, damages, costs and expenses (including court costs and reasonable attorneys' fees and expenses) ("**Claims**") that the CMC Parties incur as a result of any Claims:

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- 11.1.1 brought by Third Parties resulting from alleged or actual infringement or misappropriation of any Intellectual Property rights of any Third Party arising from CMC's use of the Cell Line, Process, Customer Intellectual Property Rights or Customer Materials in the performance of the Services or manufacture of the Product in accordance with the applicable Work Statement and Quality Agreement (if any);
- 11.1.2 brought by Third Parties resulting from the administration, use, handling, storage or other disposition of the Product or Drug Substance in any form;
- 11.1.3 resulting from contamination or damage to CMC's operations or any facility caused by the Cell Line or Customer Materials except to the extent the Cell Line and Customer Materials were not handled in accordance with the Materials and Safety Data Sheet, applicable SOPs and any written instructions of Customer that were provided in advance of or contemporaneously with delivery of the Cell Line or Customer Materials, as applicable;
- 11.1.4 brought by Third Parties resulting from use of any Product that was the subject of a Release for Further Processing in accordance with Section 6.3; and
- 11.1.5 resulting from any unlawful or negligent acts or omissions of any Third Party auditor of Customer;

in each case, except to the extent such Claims arise from CMC's material breach of its obligations under this Agreement or from CMC's gross negligence or willful misconduct.

11.2 Customer's Indemnity. CMC must indemnify and defend Customer and its Affiliates and each of their respective directors and officers ("**Customer Parties**") against any and all Claims that the Customer Parties incur as a result of any Claims:

- 11.2.1 resulting from material inaccuracy in a Certificate of Analysis such that the certified Product at the time of Delivery does not meet a Specification when certified by CMC to meet it;
- 11.2.2 resulting from failure of CMC to manufacture the Product according to the cGMP in effect when the Product is released by CMC as a cGMP Product; and
- 11.2.3 brought by Third Parties resulting from actual or alleged infringement or misappropriation of any Intellectual Property rights of any Third Party solely to the extent that infringement or misappropriation is due to the practice of CMC Intellectual Property Rights in the performance of the Services, and not the manufacture or handling of Product or Customer Materials or other activities for which Customer is obliged to indemnify CMC in Section 11.1.1;

in each case, except to the extent such Claims arise from Customer's material breach of its obligations under this Agreement or from Customer's gross negligence or willful misconduct.

11.3 Indemnification Procedure. The party ("**Indemnitee**") that claims indemnification under

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this Section 11 must:

- 11.3.1 promptly, and in any event within 15 Business Days of it receiving notice of the Claim, notify the other party (“**Indemnitor**”) in writing of the Claim; provided, that failure to give that notice will not relieve the Indemnitor of its indemnification and defense obligations except to the extent the failure materially prejudices the ability of the Indemnitor to defend against the Claim;
- 11.3.2 permit the Indemnitor to control the defense of the Claim; and
- 11.3.3 have the right (at the Indemnitee’s expense) to participate in the defense of the Claim.
- 11.4 Settlement. The Indemnitor must not settle or consent to an adverse judgment in any Claim indemnified by the Indemnitor that imposes obligations or restrictions on the Indemnitee, without the prior written consent of the Indemnitee.
- 11.5 IP Claims. Each party must promptly (and within five Business Days if permissible under applicable law or stock exchange rules) notify the other party of any Third Party allegation of infringement or misappropriation of any Third Party Intellectual Property rights of which it becomes aware in connection with the handling, storage or use of the Cell Line, Customer Materials, Products, Deliverables, Customer Intellectual Property Rights, Customer Project IPR, CMC Intellectual Property Rights, CMC Project IPR or the manufacture of the Product.

12. TERM AND TERMINATION

- 12.1 Term. The term of this agreement commences on the Effective Date and terminates on the later of (a) the date that all Stages under all Work Statements have been completed and (b) ten years from the Effective Date, unless sooner terminated in accordance with Section 4.3, 12.2, 12.3, 12.4, 12.5 or 15.1 or extended by mutual written agreement of the parties (“**Term**”).
- 12.2 Termination for Default. Either party (“**Non-Defaulting Party**”) may terminate this agreement on notice to the other party (“**Defaulting Party**”) if
 - 12.2.1 the Defaulting Party fails to pay any amount payable under this agreement within 20 Business Days after the due date;
 - 12.2.2 the Defaulting Party commits a material breach of its obligations under this agreement and fails to remedy it during a period of 20 Business Days starting on the date of receipt of notice from the Non-Defaulting Party identifying the breach and requiring it to be remedied;
 - 12.2.3 a petition is filed against the Defaulting Party for an involuntary proceeding under any applicable bankruptcy or other similar law and that petition has not been dismissed within 60 days after filing or a court having jurisdiction has appointed a receiver, liquidator, trustee or similar official of the Defaulting Party for any substantial portion of its property, or ordered the winding up or liquidation of its affairs; or

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12.2.4 the Defaulting Party commences a voluntary proceeding under applicable bankruptcy or other similar law, has made any general assignment for the benefit of creditors, or has failed generally to pay its debts as they become due.

12.3 Termination for Convenience

12.3.1 Customer may terminate this agreement or any Stage of the Services at any time before completion of the Services or Stage by giving no less than 60 Business Days' notice in writing to CMC detailing the Stages of the Services that are to be terminated.

12.3.1 CMC or Customer may terminate this agreement at any time after the completion of all Stages under all Work Statements by giving 30 days' written notice to Customer.

12.4 Termination for Scientific or Technical Difficulties. CMC may terminate this agreement or any Stage on written notice if (a) CMC reasonably concludes that it cannot technically or scientifically deliver the Services contemplated by this agreement or any Stage despite applying its commercially reasonable efforts and (b) CMC has brought the matter before the JSC and the JSC concurs with CMC's conclusion. Where CMC has become aware that a technical or scientific problem has or may arise, CMC will notify Customer of such problem in writing and the parties must in good faith discuss the difficulties and scientific and technical hurdles in an attempt to resolve those problems and refer the matter to the JSC for determination. If the parties agree during those discussions that the Services can be delivered, then the notice to terminate will expire and this agreement (or the Stage as the case may be) will continue in effect. If the JSC does not concur with CMC's conclusion within 60 days of CMC's notice to Customer of the problem, then CMC shall be entitled to appoint a third party expert reasonably acceptable to Customer to determine if its conclusion is reasonable, sound and in good faith. If the JSC or the third party expert agrees with CMC's conclusion, then this agreement or Stage, at CMC's election, will terminate on the further written notice by CMC to Customer.

12.5 Termination for Certain Unresolved Indemnity Claims. If a Claim for indemnification is made under Section 11.1.1, 11.1.3 or 11.2.3 and the parties do not reach an agreement to settle or overcome the Claim within 40 Business Days after notification under Section 11.3.1, the party to whom the indemnity Claim has been made, may, on 20 Business Days' notice in writing terminate this agreement.

12.6 Effect of Termination

12.6.1 Upon termination of this agreement for any reason, Customer shall pay to CMC:

- (a) payments due by Customer to CMC pursuant to Section 7 and any applicable Work Statement for Services performed up to and including the day of termination for all completed Stages and for partially completed Stages an amount calculated on a pro-rata basis taking into account the Price for the cancelled Stages (fairly determined by the Project Team taking into account FTE hours, materials and irreversible commitments incurred by CMC);

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- (b) payments due pursuant to Section 5.2 (if any); and
- (c) any other payments due at the time of termination pursuant to Section 7 and also in accordance with the payment terms in the Work Statement.

12.6.2 Upon termination of this agreement for any reason, provided that Customer has paid all amounts outstanding, CMC will promptly, and in any event within 30 Business Days of (a) those payments having been made or (b) the date of termination of this agreement, (whichever is the later) provide the Customer with all Deliverables then manufactured or generated and all transferable work in progress and all Product then manufactured and released, subject to Regulatory Obligations at Customer's sole risk. This section relates to pre-released Deliverables and work in progress only.

12.6.3 Upon termination of this agreement for any reason other than Customer's material breach of this agreement, CMC will provide Technology Transfer assistance in accordance with Section 13.1.

12.7 Survival. Termination or expiry will not affect the accrued rights of CMC or Customer arising under this agreement before the effective date of termination or expiry, and Sections 2.6, 3.4, 5.2, 6.6, 6.9, 6.10, 6.13, 7.5, 9, 11, 12.6, 12.7, 13, 14, 15.2, 15.9, 15.10, 15.11 of the Agreement will survive any such termination or expiry in accordance with their terms.

13. TECHNOLOGY TRANSFER

13.1 Transfer In-House. Customer will have the right to transfer the Process to itself or its Affiliates at any time, during or after the Term, and CMC will provide the Technology Transfer assistance described in this Section 13, provided that Customer is then current in all of its payment obligations.

13.2 Third Party Transfer. At any time during the Term, or upon termination or during the notice period for termination of this agreement (other than where Customer is the "Defaulting Party"), Customer may seek assistance from CMC for the transfer to a single skilled and qualified manufacturer of the then-current Process solely for the purpose of manufacturing Product for Customer ("**Technology Transfer**"); provided, that CMC is not obligated to transfer any CHEF1 Property. Following CMC's receipt of that request, the parties will establish a schedule and plan for effecting the transfer and CMC will cooperate with Customer in implementing that plan. As part of the Technology Transfer CMC will make available for collection, subject to any Regulatory Obligations and rights of third parties and Section 12.6.2, (i) all Customer Materials, Cell Line and one copy of all documentation (to the extent not previously delivered to Customer) generated pursuant to the Services (exclusive of CMC's SOPs) up to the date of termination, (ii) technical assistance reasonably necessary to complete such Technology Transfer to allow the transferee to replicate the Process.

13.3 Limits. The obligations of CMC under Section 13.2 will only be exercisable by Customer within a period of 180 days after the date of termination and CMC is not obliged to commit any human resources greater than 30 FTE days in connection with Technology Transfer. Customer must pay CMC's costs of cooperating with and providing the Technology

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Transfer at an hourly FTE rate set out in the Work Statement executed for the Technology Transfer (which shall be consistent with industry norms) and all other costs will be charged at cost plus [*****]%. Customer will not, and CMC will not be obliged to, transfer any CMC Intellectual Property Rights or CMC Project IPR pursuant to this Technology Transfer until the contract manufacturer to whom the Process is transferred enters into a limited royalty-free license and confidentiality agreement reasonably acceptable to and with CMC in order to protect CMC's Confidential Information, CMC Intellectual Property Rights and CMC Project IPR.

14. LIMITATIONS OF LIABILITY

- 14.1 Limitation of Liability. Except as provided in Section 14.3, CMC's aggregate liability to Customer for any loss or damage suffered by Customer as a result of breach of this agreement or any other liability (including negligence or misrepresentation) under this agreement or in connection with the Services is limited, in the aggregate, to the lesser of [*****].
- 14.2 Disclaimer of Certain Damages. EXCEPT AS PROVIDED IN SECTION 14.3, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, PUNITIVE, CONSEQUENTIAL (INCLUDING LOST PROFITS) OR SPECIAL DAMAGES ARISING OUT OF ITS BREACH OF THIS AGREEMENT OR ANY OTHER LIABILITY (INCLUDING NEGLIGENCE, MISREPRESENTATION OR CLAIMS UNDER THE INDEMNITIES) ARISING IN CONNECTION WITH THIS AGREEMENT, EVEN IF THOSE DAMAGES WERE FORESEEABLE AND WHETHER THOSE DAMAGES ARISE IN TORT, IN CONTRACT OR OTHERWISE.
- 14.3 Exclusions. The limitations in Sections 14.1 and 14.2 do not apply to (a) claims arising from either party's gross negligence or willful misconduct; (b) liability for any fraud or fraudulent misrepresentation; (c) amounts owing by a party under Section 7; or (d) claims indemnified by Customer under Sections [*****].

15. MISCELLANEOUS

- 15.1 Excused Performance. Neither party will be liable to the other party nor be considered to have breached this agreement for failure or delay in performing to the extent, and for so long as, the failure or delay is caused by or results from causes beyond the reasonable control of such party ("**Force Majeure**"). The party seeking relief under this Section 15.1 must notify the other party of any Force Majeure event that prevents the first party from performing its obligations hereunder. If a Force Majeure event continues for more than [*****] days after such notice, and is adversely affecting the performance of this agreement, each party will have the right terminate this agreement on 30 days' notice.
- 15.2 Insurance. During the Term, CMC must maintain a comprehensive general liability insurance against claims for bodily injury or property damage arising from CMC's activities in performing the Services, with insurance companies and in amounts as CMC customarily maintains for similar activities. Customer must during the Term and for the longer of (a) 5 years after the termination of this agreement and (b) 5 years after the last use of the Product maintain comprehensive general liability insurance and product liability insurance (including clinical trials coverage) covering all liability and claims arising or that may arise

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from the use, supply, licensing or distribution of the Product with insurance companies and in amounts as customarily maintained.

15.3 Omitted.

15.4 Amendment. Other than as provided for elsewhere in this agreement, any amendment of this agreement (or any document entered into pursuant to this agreement) will be valid only if it is in writing and signed by each party.

15.5 Assignment. CMC may not assign this agreement or any rights or obligations under this agreement without Customer's prior written consent (not to be unreasonably withheld) except as set forth in Section 15.6 or to its Affiliate. Except as provided in this Section 15.5, Customer may not without the prior written consent of CMC (that consent not to be unreasonably withheld) assign this agreement or any rights under this agreement. Any purported assignment in breach of this Section 15.5 is void and confers no rights on the purported assignee. Customer may on giving written notice to CMC to assign its rights under this agreement to an Affiliate of Customer provided that Customer must procure that the assignee must assign those rights to another Affiliate on ceasing to be an Affiliate of Customer. A change of control of Customer through a consolidation, sale of all or substantially all of the assets to which this agreement relates, stock acquisition or merger where Customer is the surviving entity shall not be deemed an assignment for which consent of CMC is required; provided, that Customer notifies CMC of that acquisition or merger within five Business Days after the earlier of the public announcement or closing of that transaction. No assignment will relieve Customer of any of its obligations under this agreement.

15.6 Subcontracting. CMC may subcontract to (a) its Affiliates, any of the Services provided that the Affiliate may not further subcontract those Services; (b) Testing Laboratories, only those parts of the Services identified in the Work Statement; and (c) any other Third Party, any of the Services with the prior written consent of Customer (that consent not to be unreasonably withheld, delayed or conditioned). CMC will remain responsible for the activities of its subcontractors except to the extent that Customer requires CMC to use a subcontractor that Customer selects over CMC's objection.

15.7 Waiver. In no event will any delay, failure or omission (in whole or in part) in enforcing, exercising or pursuing any right, power, privilege, claim or remedy conferred by or arising under this agreement or by law, be deemed to be or construed as a waiver of that or any other right, power, privilege, claim or remedy in respect of the circumstances in question, or operate so as to bar the enforcement of that, or any other right, power, privilege, claim or remedy, in any other instance at any time or times subsequently.

15.8 Severability. If any provision of this agreement is found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, that invalidity or unenforceability will not affect the other provisions of this agreement which shall remain in full force and effect. The parties must, in the circumstances referred to in this Section 15.8, attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision that achieves to the greatest extent possible the same effect as would have been achieved by the invalid or unenforceable provision.

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- 15.9 Notices. Any notice or other communication given under this agreement (including under Section 3.4 or 6.6) must be in writing and in English and signed (manually or electronically) by or on behalf of the party giving it and must be given by hand, via email, or by delivering it or sending it by prepaid post or overnight delivery service, to the address and for the attention of the relevant party set out in this Section 15.9 (or as otherwise notified by that party under this Section 15.9). Any notice will be deemed to have been received:
- 15.9.1 if hand delivered or sent by prepaid overnight delivery service, at the time of delivery;
 - 15.9.2 if sent by certified mail, return receipt requested, two Business Days from the date of posting; or
 - 15.9.3 if sent electronically, upon confirmation of delivery.

The addresses of the parties for the purposes of this Section 15.9 are:

CMC ICOS Biologics, Inc.
22021 20th Ave. S.E.
Bothell, Washington U.S.A. 98021
For the attend of: Legal Department

Agenus West, LLC
793 Heinz Avenue
Berkeley, California 94710
Attention: Al Dadson

With a copy to:

Agenus Inc.
3 Forbes Road
Lexington, Massachusetts 02421
Attn: LEGAL DEPARTMENT

Neither party has any obligation to notify any person or entity other than as provided in Section 15.9.

- 15.10 Applicable Law. This agreement will be interpreted and governed, and all rights and obligations of the parties determined, in accordance with the laws of the state of New York (regardless of choice of law provisions to the contrary). The parties waive application of the provisions of the 1980 U.N. Convention on Contracts for the International Sale of Goods, as amended.
- 15.11 Dispute Resolution. Before resorting to litigation, unless emergency relief is required by either party when either party will be free to resort to litigation, the parties must use their reasonable efforts to negotiate in good faith and settle amicably any dispute that may arise out of or relate to this agreement (or its construction, validity or termination) (a "**Dispute**"). If a Dispute cannot be settled through negotiations by appropriate representatives of each of the parties, either party may give to the other a notice in writing (a "**Dispute Notice**").

[*****] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

Within seven days of the Dispute Notice being given the parties must each refer the Dispute to their respective Chief Executive Officers who shall meet in order to attempt to resolve the dispute. If within 30 days of the Dispute Notice (a) the Dispute is not settled by agreement in writing between the parties or (b) the parties have failed to discuss the Dispute or use good faith negotiations, the Dispute may be submitted to and finally be settled by the state or federal courts located in the state of New York.

- 15.12 Relationship of the Parties. Nothing in this agreement operates to create a partnership or joint venture between the parties or authorizes either party to act as agent for the other. Neither party has authority to act in the name of or otherwise to bind the other in any way.
- 15.13 Entire Agreement. This agreement, and the documents referred to in it, constitutes the entire agreement and understanding of the parties and supersedes any previous agreement between the parties relating to the subject matter of this agreement. If any term of this agreement conflicts with any term of the Quality Agreement, the conflicting term of this agreement will prevail. This Agreement is written in English, and the English version of this Agreement will control.
- 15.14 Counterparts. This agreement may be executed in any number of counterparts.



[*****] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

THIS DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT has been executed by the parties on the date first written above.

CMC ICOS Biologics, Inc.)
)
Signature: /s/ Gustavo Mahler)
)
Print Name: Gustavo Mahler)
)
Position : CEO & President)
)

CUSTOMER)
)
Signature: /s/ Alex Duncan)
)
Name : Alex Duncan)
)
Position : CTO)
)

Definitions

"Affiliate" means, with respect to any entity, any other entity that directly or indirectly controls, is controlled by or is under common control with that entity. For this definition, "control" means that more than 50% of the controlled entity's shares or ownership interests representing the right to make decisions for that entity are owned or controlled, directly or indirectly, by the controlling entity.

"Batch" means one fermentation run using the Cell Line at a specified fermenter scale and those purification, analytical and further processing steps applicable to the Drug Substance harvested from that run as described in the Work Statement.

"Business Day" means any day that is not a Saturday, Sunday or U.S. public holiday.

"Cell Line" means the cell line described in the Work Statement provided by Customer or to be developed by CMC using Customer Materials as part of the Services, any derivative of such cell line provided or developed, any modified strains of that cell line constructed in accordance with the Services and any progeny or clone of those cell lines.

"Certificate of Analysis" means CMC's standard form certificate of analysis appropriate for the Services requested confirming that Product to which the certificate relates meets the Specification and any other criteria identified on the certificate.

"cGMP" means Current Good Manufacturing Practices as promulgated under each of the following as in effect on the Effective Date and as amended or revised after the Effective Date: (a) the U.S. Food, Drug & Cosmetics Act (21 U.S.C. § 301 *et seq.*) and related U.S. regulations, including 21 Code of Federal Regulations (Chapters 210 and 211) and other FDA regulations, policies, or guidelines in effect at a particular time for the manufacture, testing and quality control of investigational drugs; and (b) the ICH guide Q7a "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients" as applied to investigational drugs (Section 19).

"cGMP Batch" means a Batch that is stipulated in the Work Statement to be manufactured according to cGMP.

"cGMP Product" means Product manufactured under a cGMP Batch.

"CHEF1® Technology" means the [*****].

"CMC Facility" means CMC's then current facility at Bothell, Washington or any of CMC's or its Affiliates' facilities in Berkeley, California, Copenhagen, Denmark or as specified in writing in a Work Statement.

"CMC Intellectual Property Rights" means Intellectual Property rights and CMC Know-How (excluding CHEF1 Technology) owned by CMC and used in the Services.

"CMC Know-How" means all information, techniques and technical information (i) known to CMC other than as a result of disclosure to CMC by Customer, or (ii) conceived, developed or reduced to practice by CMC in performance of the Services (excluding the CHEF1 Technology or improvements thereto or the Customer Project IPR), in each case that are not of general knowledge to the public or the industry.

"Commencement Date" means, with respect to a cGMP Batch, the date on which an ampoule of cells is thawed for the fermentation or cell culture for manufacture of Drug Substance.

"Confidential Information" means information of a confidential nature and in any form (oral, written or otherwise) the use of which is governed according to the provisions of Section 9.

“Customer Intellectual Property Rights” means Intellectual Property rights and Customer Know-How owned by Customer or licensed to Customer by a Third Party (and which Customer is able to license to CMC, as determined by Customer) covering any aspect of the Services or materials, techniques or processes used in the Services.

“Customer Know-How” means all information, techniques and technical information in connection with the Cell Line, Customer Materials or Process which is known to Customer other than by disclosure from CMC, and which is not of general knowledge to the public or the industry.

“Customer Materials” means the Cell Line, vectors, plasmids and all other materials supplied by Customer, its Affiliate or agent to CMC or made available to CMC by Customer including, without limitation, those described in the Work Statement.

“Deliverables” means the data, results and materials generated from the performance of the Services including Drug History Record and Product.

“Drug History Record” means all lot disposition documentation relevant to a cGMP Batch to be provided to Customer with the Product from that cGMP Batch as described in the Work Statement, including a Certificate of Analysis.

“Drug Substance” means the biological or chemical entities described or classified in the Work Statement expressed by the Cell Line and harvested in bulk from a fermentation run pursuant to the applicable Process.

“Intellectual Property” means all intellectual property rights, including patents, supplementary protection certificates, utility models, trademarks, database rights, rights in designs, copyrights (whether or not any of these are registered or capable of being registered) and including all applications and the right to apply for registered protection of the foregoing and all inventions, trade secrets, know-how, techniques and confidential information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world, in each case for their full term and together with any renewals or extensions.

“Non-Fault Delay” means a delay in the Services caused by or contributed to by (a) the acts or omissions of Customer or its representatives, including errors or defects in the Customer Materials; (b) the experimental nature of the Services or the Services being dependent on living systems; or (c) additions or changes to the Services required by the Customer; or (d) a Force Majeure event, but in each case, to the extent such delays are beyond CMC’s reasonable control and to the extent not also contributed to by the acts or omission of CMC or its representatives.

“Objective” means the desired outcome of the Services as described in the Work Statement.

“Permitted Recipients” means the directors, officers, employees, Testing Laboratories or professional advisers who are required, on a need-to-know basis, in the course of their duties to receive and consider the Confidential Information for the purpose of enabling the relevant party to perform its obligations under this agreement; provided, that those persons are under obligations of confidence no less onerous than those set out in Section 9 imposed on the Recipient Party.

“Price” means the price for the Services (or any part or Stage of the Services as context requires) as defined in the Work Statement and itemized on a Stage by Stage basis.

“Process” means the method for manufacture, harvesting and purification of the Product.

“Product” means the Drug Substance derived from a Batch.

“Quality Agreement” means the agreement between the parties defining the quality responsibilities, including cGMP standards, regarding the performance of the Services.

“Regulatory Obligations” means those mandatory regulatory requirements applicable in Europe and the U.S. to the manufacture of cGMP Product for human use.

“Services” means any or all parts of the development and manufacturing services to be conducted by or on behalf of CMC as fully described in the relevant Work Statement.

“Shipping Guidelines” means the storage and transport guidelines for the Product that are determined by mutual written agreement of the parties.

“Slot” means, with respect to CMC’s cGMP manufacturing suite, the period of time the suite is reserved in preparation for and the performance of a Batch.

“Specification” means the specification of the Product either as defined in the Work Statement or as otherwise agreed between the parties or modified in accordance with Section 4.2.2.

“Stage” means a particular activity or series of conjoined activities that constitute a main step in the Services and that is more specifically identified in the Work Statement by the breakdown of the Services into numbered stages.

“Standard Operating Procedures” or **“SOPs”** means the standard operating procedures of CMC in place from time to time that define CMC’s methods of performing activities applicable to the Services.

“Testing Laboratories” means any Third Party instructed by CMC in accordance with this agreement and the applicable Work Statement to carry out tests on the Cell Line, Customer Materials, Drug Substance or Product pursuant to the performance of the Services.

“Third Party” means a person or entity other than CMC, Customer, or their respective Affiliates, or any employee, agent or representative of the foregoing.

“Timeline” means the estimated timeline for the performance of the Services as set out in the Work Statement.

“Work Statement” means the work statement attached as Appendix III and any other work statements that may be agreed on by the parties during the Term, as may be revised by the written agreement of the parties from time to time. To be valid, a Work Statement must be signed by both parties.

Certification Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended

I, Garo H. Armen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Agenus Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles;
 - c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent function):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: August 7, 2017

/s/ GARO H. ARMEN, PH.D.

Garo H. Armen, Ph.D.

Chief Executive Officer and Principal Executive Officer

Certification Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended

I, Christine M. Klaskin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Agenus Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles;
 - c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent function):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: August 7, 2017

/s/ CHRISTINE M. KLASKIN

Christine M. Klaskin

VP, Finance and Principal Financial Officer

Certification
Pursuant to 18 U.S.C. Section 1350,
As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report on Form 10-Q of Agenus Inc. (the "Company") for the quarterly period ended June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned to his/her knowledge hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (i) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (ii) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ GARO H. ARMEN, PH.D.

Garo H. Armen, Ph.d.

Chief Executive Officer and Principal Executive Officer

/s/ CHRISTINE M. KLASKIN

Christine M. Klaskin

VP, Finance and Principal Financial Officer

Date: August 7, 2017

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished to the Securities and Exchange Commission as an exhibit to the Report and should not be considered filed as part of the Report.