

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2019

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

Securities registered or to be registered pursuant to Section 12(b) of the Act.

| Title of each class | Trading symbol(s) | Name of each exchange on which registered |
|--------------------------------|-------------------|---|
| Common stock, par value \$0.01 | AGEN | The Nasdaq Capital Market |

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

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

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

| | | | |
|-------------------------|--------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/> | Accelerated filer | <input checked="" type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> | Smaller reporting company | <input checked="" 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 November 1, 2019: 137,361,477 shares

Agenus Inc.
Nine Months Ended September 30, 2019
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Item 1. *Financial Statements*

AGENUS INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share amounts)

| | September 30, 2019 (unaudited) | December 31, 2018 |
|--|-----------------------------------|-------------------|
| ASSETS | | |
| Cash and cash equivalents | \$ 93,274 | \$ 53,054 |
| Inventories | 55 | 55 |
| Accounts receivable | 2,328 | 938 |
| Prepaid expenses | 10,441 | 19,265 |
| Other current assets | 1,088 | 1,496 |
| Total current assets | 107,186 | 74,808 |
| Property, plant and equipment, net of accumulated amortization and depreciation of \$41,566 and \$38,068 at September 30, 2019 and December 31, 2018, respectively | 25,029 | 25,116 |
| Operating lease right-of-use assets | 7,684 | — |
| Goodwill | 22,757 | 22,925 |
| Acquired intangible assets, net of accumulated amortization of \$8,878 and \$7,472 at September 30, 2019 and December 31, 2018, respectively | 10,853 | 12,338 |
| Other long-term assets | 1,298 | 1,214 |
| Total assets | <u>\$ 174,807</u> | <u>\$ 136,401</u> |
| LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT | | |
| Current portion, long-term debt | \$ 13,847 | \$ 146 |
| Current portion, liability related to sale of future royalties and milestones | 38,125 | 27,443 |
| Current portion, deferred revenue | 34,230 | 1,814 |
| Current portion, operating lease liabilities | 1,311 | — |
| Accounts payable | 16,424 | 13,624 |
| Accrued liabilities | 28,744 | 24,551 |
| Other current liabilities | 267 | 484 |
| Total current liabilities | 132,948 | 68,062 |
| Long-term debt, net of current portion | — | 13,212 |
| Liability related to sale of future royalties and milestones, net of current portion | 171,973 | 182,817 |
| Deferred revenue, net of current portion | 31,290 | 1,165 |
| Operating lease liabilities, net of current portion | 8,245 | — |
| Contingent purchase price considerations | 4,218 | 3,038 |
| Other long-term liabilities | 4,088 | 2,773 |
| Commitments and contingencies | | |
| CONVERTIBLE PREFERRED STOCK | | |
| Preferred stock, par value \$0.01 per share; 5,000,000 shares authorized: | | |
| Series C-1 convertible preferred stock; 12,459 shares and 18,459 shares designated, issued, and outstanding at September 30, 2019 and December 31, 2018, respectively | 26,917 | 39,879 |
| STOCKHOLDERS' DEFICIT | | |
| Series A-1 convertible preferred stock; 31,620 shares designated, issued, and outstanding at September 30, 2019 and December 31, 2018; liquidation value of \$32,988 at September 30, 2019 | 0 | 0 |

| | | |
|--|-------------------|-------------------|
| Common stock, par value \$0.01 per share; 400,000,000 and 240,000,000 shares authorized at September 30, 2019 and December 31, 2018, respectively; 137,357,407 and 119,996,331 shares issued at September 30, 2019 and December 31, 2018, respectively | 1,374 | 1,200 |
| Additional paid-in capital | 1,055,159 | 1,005,183 |
| Accumulated other comprehensive loss | (1,282) | (1,539) |
| Accumulated deficit | (1,254,938) | (1,177,311) |
| Total stockholders' deficit attributable to Agenus Inc. | (199,687) | (172,467) |
| Non-controlling interest | (5,185) | (2,078) |
| Total stockholders' deficit | (204,872) | (174,545) |
| Total liabilities, convertible preferred stock and stockholders' deficit | <u>\$ 174,807</u> | <u>\$ 136,401</u> |

See accompanying notes to unaudited condensed consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(Amounts in thousands, except per share amounts)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|--------------------|---------------------------------|---------------------|
| | 2019 | 2018 | 2019 | 2018 |
| Revenue: | | | | |
| Research and development | \$ 5,751 | \$ 6,276 | \$ 81,022 | \$ 18,385 |
| Other revenue | 1,985 | — | 4,453 | — |
| Non-cash royalty revenue related to the sale of future royalties | 12,204 | 6,526 | 30,073 | 11,948 |
| Total revenues | 19,940 | 12,802 | 115,548 | 30,333 |
| Operating expenses: | | | | |
| Research and development | (46,132) | (29,854) | (131,506) | (88,569) |
| General and administrative | (11,512) | (9,203) | (33,723) | (27,616) |
| Contingent purchase price consideration fair value adjustment | 1,781 | 180 | (1,180) | 1,456 |
| Operating loss | (35,923) | (26,075) | (50,861) | (84,396) |
| Other expense: | | | | |
| Loss on early extinguishment of debt | — | — | — | (10,767) |
| Non-operating (expense) income | 304 | (117) | (250) | (1,490) |
| Interest expense, net | (10,658) | (7,538) | (29,598) | (16,543) |
| Net loss | (46,277) | (33,730) | (80,709) | (113,196) |
| Dividends on Series A-1 convertible preferred stock | (52) | (52) | (156) | (155) |
| Less: net loss attributable to non-controlling interest | (803) | (605) | (3,107) | (1,258) |
| Net loss attributable to Agenus Inc. common stockholders | \$ (45,526) | \$ (33,177) | \$ (77,758) | \$ (112,093) |
| Per common share data: | | | | |
| Basic and diluted net loss attributable to Agenus Inc. common stockholders | \$ (0.33) | \$ (0.29) | \$ (0.58) | \$ (1.04) |
| Weighted average number of Agenus Inc. common shares outstanding: | | | | |
| Basic and diluted | 137,619 | 114,977 | 134,014 | 107,601 |
| Other comprehensive loss: | | | | |
| Foreign currency translation (loss) gain | \$ (204) | \$ (38) | \$ 257 | \$ 553 |
| Other comprehensive (loss) income | (204) | (38) | 257 | 553 |
| Comprehensive loss | \$ (45,730) | \$ (33,215) | \$ (77,501) | \$ (111,540) |

See accompanying notes to unaudited condensed consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Unaudited)
(Amounts in thousands)

| | Series C-1 Convertible Preferred Stock | | Series A-1 Convertible Preferred Stock | | Common Stock | | | Accumulated Other Comprehensive Income (Loss) | Non- controlling Interest | Accumulated Deficit | Total |
|--|--|-----------|--|--------------|------------------------|--------------|----------------------------------|--|---------------------------------|------------------------|--------------|
| | Number of Shares | Amount | Number of Shares | Par Value | Number of Shares | Par Value | Additional Paid-In Capital | | | | |
| Balance at December 31, 2018 | 18 | \$ 39,879 | 32 | \$ 0 | 119,996 | \$ 1,200 | \$ 1,005,183 | \$ (1,539) | \$ (2,078) | \$ (1,177,311) | \$ (174,545) |
| Net income (loss) | — | — | — | — | — | — | — | — | (1,071) | 18,506 | 17,435 |
| Other comprehensive loss | — | — | — | — | — | — | — | (682) | — | — | (682) |
| Adoption of ASC 842 | — | — | — | — | — | — | — | — | — | (25) | (25) |
| Share-based compensation | — | — | — | — | — | — | 1,843 | — | — | — | 1,843 |
| Shares sold under stock purchase agreement | — | — | — | — | 11,111 | 111 | 29,889 | — | — | — | 30,000 |
| Conversion of Series C-1 convertible preferred stock | (3) | (6,481) | — | — | 3,000 | 30 | 6,451 | — | — | — | 6,481 |
| Payment of consultant in shares | — | — | — | — | 14 | 0 | 37 | — | — | — | 37 |
| Exercise of stock options and employee share purchases | — | — | — | — | 85 | 1 | 172 | — | — | — | 173 |
| Balance at March 31, 2019 | 15 | \$ 33,398 | 32 | \$ 0 | 134,206 | \$ 1,342 | \$ 1,043,575 | \$ (2,221) | \$ (3,149) | \$ (1,158,830) | \$ (119,283) |
| Net loss | — | \$ — | — | \$ — | — | \$ — | \$ — | \$ — | \$ (1,233) | \$ (50,634) | \$ (51,867) |
| Other comprehensive income | — | — | — | — | — | — | — | 1,143 | — | — | 1,143 |
| Share-based compensation | — | — | — | — | — | — | 1,917 | — | — | — | 1,917 |
| Conversion of Series C-1 convertible preferred stock | (3) | (6,481) | — | — | 3,000 | 30 | 6,451 | — | — | — | 6,481 |
| Vesting of nonvested shares | — | — | — | — | 53 | 1 | (1) | — | — | — | — |
| Balance at June 30, 2019 | 12 | \$ 26,917 | 32 | \$ 0 | 137,259 | \$ 1,373 | \$ 1,051,942 | \$ (1,078) | \$ (4,382) | \$ (1,209,464) | \$ (161,609) |
| Net loss | — | \$ — | — | \$ — | — | \$ — | \$ — | \$ — | \$ (803) | \$ (45,474) | \$ (46,277) |
| Other comprehensive income | — | — | — | — | — | — | — | (204) | — | — | (204) |
| Share-based compensation | — | — | — | — | — | — | 3,084 | — | — | — | 3,084 |
| Payment of consultant in shares | — | — | — | — | 7 | 0 | 19 | — | — | — | 19 |
| Exercise of stock options and employee share purchases | — | — | — | — | 44 | 0 | 115 | — | — | — | 115 |
| Vesting of nonvested shares | — | — | — | — | 48 | 1 | (1) | — | — | — | — |
| Balance at September 30, 2019 | 12 | \$ 26,917 | 32 | \$ 0 | 137,358 | \$ 1,374 | \$ 1,055,159 | \$ (1,282) | \$ (5,185) | \$ (1,254,938) | \$ (204,872) |

AGENUS INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Unaudited)
(Amounts in thousands)

| | Series C-1 Convertible Preferred Stock | | Series A-1 Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Other Comprehensive Income (Loss) | Non- controlling Interest | Accumulated Deficit | Total |
|--|--|--------|--|--------------|------------------------|--------------|----------------------------------|--|---------------------------------|------------------------|--------------|
| | Number of Shares | Amount | Number of Shares | Par Value | Number of Shares | Par Value | | | | | |
| Balance at December 31, 2017 | — | \$ — | 32 | \$ 0 | 101,706 | \$ 1,017 | \$ 951,812 | \$ (2,169) | \$ — | \$ (1,026,476) | \$ (75,816) |
| Net loss | — | — | — | — | — | — | — | — | (121) | (54,141) | (54,262) |
| Other comprehensive loss | — | — | — | — | — | — | — | (537) | — | — | (537) |
| Adoption of ASC 606 | — | — | — | — | — | — | — | — | — | 8,856 | 8,856 |
| AgenTus share distribution | — | — | — | — | — | — | — | — | 274 | — | 274 |
| Share-based compensation | — | — | — | — | — | — | 1,932 | — | — | — | 1,932 |
| Vesting of nonvested shares | — | — | — | — | 53 | 1 | (1) | — | — | — | — |
| Shares sold at the market | — | — | — | — | 1,202 | 12 | 5,246 | — | — | — | 5,258 |
| Exercise of stock options and employee share purchases | — | — | — | — | 320 | 3 | 1,057 | — | — | — | 1,060 |
| Balance at March 31, 2018 | — | \$ — | 32 | \$ 0 | 103,281 | \$ 1,033 | \$ 960,046 | \$ (2,706) | \$ 153 | \$ (1,071,761) | \$ (113,235) |
| Net loss | — | \$ — | — | \$ — | — | \$ — | \$ — | \$ — | (533) | (24,671) | (25,204) |
| Other comprehensive income | — | — | — | — | — | — | — | 1,129 | — | — | 1,129 |
| Share-based compensation | — | — | — | — | — | — | 1,584 | — | — | — | 1,584 |
| Shares sold at the market | — | — | — | — | 7,917 | 79 | 22,558 | — | — | — | 22,637 |
| Balance at June 30, 2018 | — | \$ — | 32 | \$ 0 | 111,198 | \$ 1,112 | \$ 984,188 | \$ (1,577) | \$ (380) | \$ (1,096,432) | \$ (113,089) |
| Net loss | — | \$ — | — | \$ — | — | — | — | — | (605) | (33,125) | (33,730) |
| Other comprehensive income | — | — | — | — | — | — | — | (38) | — | — | (38) |
| Share-based compensation | — | — | — | — | — | — | 1,905 | — | — | — | 1,905 |
| Exercise of stock options and employee share purchases | — | — | — | — | 93 | 1 | 13,314 | — | — | — | 13,315 |
| Shares sold at the market | — | — | — | — | 7,062 | 71 | 172 | — | — | — | 243 |
| Balance at September 30, 2018 | — | \$ — | 32 | \$ 0 | 118,353 | \$ 1,184 | \$ 999,579 | \$ (1,615) | \$ (985) | \$ (1,129,557) | \$ (131,394) |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Nine Months Ended September 30, | |
|--|---------------------------------|------------------|
| | 2019 | 2018 |
| Cash flows from operating activities: | | |
| Net loss | \$ (80,709) | \$ (113,196) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 5,001 | 4,745 |
| Share-based compensation | 6,844 | 5,695 |
| Non-cash royalty revenue | (30,073) | (11,948) |
| Non-cash interest expense | 30,400 | 16,063 |
| Loss on disposal of assets | — | 118 |
| Change in fair value of contingent obligations | 1,180 | (1,456) |
| Loss on extinguishment of debt | — | 10,767 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (1,390) | (4,934) |
| Inventories | — | 24 |
| Prepaid expenses | 8,780 | (3,470) |
| Accounts payable | 3,100 | 2,882 |
| Deferred revenue | 62,551 | (1,064) |
| Accrued liabilities and other current liabilities | 5,406 | 222 |
| Other operating assets and liabilities | 2,008 | 269 |
| Net cash provided by (used in) operating activities | 13,098 | (95,283) |
| Cash flows from investing activities: | | |
| Proceeds from sale of plant and equipment | — | 6 |
| Purchases of plant and equipment | (3,601) | (2,996) |
| Net cash used in investing activities | (3,601) | (2,990) |
| Cash flows from financing activities: | | |
| Net proceeds from sale of equity | 30,000 | 41,280 |
| Proceeds from employee stock purchases and option exercises | 287 | 1,234 |
| Proceeds from sale of future royalties | — | 204,878 |
| Transaction costs from sale of future royalties and milestones | — | (494) |
| Repayments of debt | — | (161,847) |
| Payment of finance lease obligation | (232) | (193) |
| Net cash provided by financing activities | 30,055 | 84,858 |
| Effect of exchange rate changes on cash | 668 | (602) |
| Net increase (decrease) in cash and cash equivalents | 40,220 | (14,017) |
| Cash and cash equivalents, beginning of period | 53,054 | 60,187 |
| Cash and cash equivalents, end of period | <u>\$ 93,274</u> | <u>\$ 46,170</u> |
| Supplemental cash flow information: | | |
| Cash paid for interest | \$ 925 | \$ 838 |
| Supplemental disclosures - non-cash activities: | | |
| Purchases of plant and equipment in accounts payable and accrued liabilities | — | 122 |
| Issuance of common stock, \$0.01 par value, in connection with payment to consultant | 56 | — |
| Lease right-of-use assets obtained in exchange for new operating lease liabilities | 3,017 | — |

See accompanying notes to unaudited condensed consolidated financial statements.

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 immunology (“I-O”) company with a pipeline of immune modulating antibodies, vaccines, adjuvants and adoptive cell therapies dedicated to becoming a leader in the discovery and development of innovative combination therapies and committed to bringing effective medicines to patients with cancer. Our business is designed to drive success in I-O through speed, innovation, and effective combination therapies. In addition to a diverse pipeline, we have assembled fully integrated capabilities including novel target discovery, antibody generation, cell line development, and good manufacturing practice (“GMP”) manufacturing. We believe that these fully integrated capabilities enable us to produce novel candidates on timelines that are shorter than the industry standard. Leveraging our science and capabilities, we have forged important partnerships to advance our innovation.

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

- our multiple antibody discovery platforms, including our proprietary display technologies, designed to drive the discovery of future CPM antibody candidates;
- our antibody candidate programs, including our CPM programs;
- our vaccine programs, including Prophage™, AutoSynVax™ and PhosPhoSynVax™;
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon™ adjuvant, or QS-21 Stimulon; and
- our cell therapy subsidiary, AgenTus Therapeutics, Inc., which is designed to drive the discovery of future adoptive cell therapy, or “living drugs” (Activated, CAR-T and TCR) programs.

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

Our cash and cash equivalents at September 30, 2019 were \$93.3 million, an increase of \$40.2 million from December 31, 2018.

We have incurred significant losses since our inception. As of September 30, 2019, we had an accumulated deficit of \$1.3 billion. We are likely to continue to incur losses until we become a commercial company generating profits. Our first commercial product launches are planned for as early as the first half of 2021.

Since our inception, we have successfully financed our operations through the sale of equity, notes, corporate partnerships, advance royalty sales and interest income. Based on our current plans we believe that our cash resources of \$93.3 million as of September 30, 2019, plus anticipated license fees and milestones, will be sufficient to satisfy our liquidity requirements into the second quarter of 2020.

Management continues to address the Company’s liquidity position. We also continue to monitor the likelihood of success of our key initiatives and can discontinue funding of such activities if they do not prove to be successful, restrict capital expenditures and/or reduce the scale of our operations if necessary. Our future liquidity needs will be determined primarily by the success of our operations with respect to the progression of our product candidates and key development and regulatory events in the future. Potential sources of additional funding include: (1) pursuing collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities.

Based on our recurring losses from operations and expectation of continuing losses, we will require additional capital to finance our operations through and beyond the second quarter of 2020. Based on current revenue trends from GlaxoSmithKline’s Shingrix vaccine and the progress trends of our clinical stage programs, we expect to receive additional milestone payments during 2020. In addition, we are currently pursuing transactions designed for significant capital infusion to satisfy our cash requirements. Until we are successful in our efforts for capital infusion through these transactions or other financing options, in accordance with accounting

guidance, we are required to disclose that a substantial doubt exists about our ability to continue as a going concern for a period of one year after the date of filing of this Quarterly Report on Form 10-Q.

The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the financial statements have been prepared on a basis that assumes we will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) for interim financial information and with the instructions to Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete annual consolidated financial statements. In the opinion of our management, the condensed consolidated financial statements include all normal and recurring adjustments considered necessary for a fair presentation of our financial position and operating results. All significant intercompany transactions and accounts have been eliminated in consolidation. Operating results for the nine months ended September 30, 2019, are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. 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, 2018 filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2019.

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

For our foreign subsidiaries, the local currency is the functional currency. Assets and liabilities of our foreign subsidiaries are translated into U.S. dollars using rates in effect at the balance sheet date while revenues and expenses are translated into U.S. dollars using average exchange rates during the period. The cumulative translation adjustment resulting from changes in exchange rates are included in the consolidated balance sheets as a component of accumulated other comprehensive loss in total stockholders’ deficit.

Note B - Summary of Significant Accounting Policies

Except as detailed below, there have been no material changes to our significant accounting policies during the nine months ended September 30, 2019, as compared to the significant accounting policies disclosed in Note 2 of the Consolidated Financial Statements in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018.

Leases

In February 2016, the Financial Accounting Standards Board (“FASB”) issued ASU 2016-02, Leases (Topic 842) (“ASC 842”) which supersedes Topic 840, Leases (“ASC 840”). We adopted ASC 842 on January 1, 2019 using the alternative transition method and recorded a cumulative effect adjustment to beginning retained earnings without restating prior periods. Accordingly, all financial information and disclosures for periods before January 1, 2019 continue to be presented under the requirements of ASC 840. We elected the package of practical expedients, which allowed us to carry forward our historical lease classification, our assessment of whether a contract is or contains a lease and our initial direct costs for any leases that existed prior to adoption of the new standard.

At the inception of an agreement, we determine whether the contract contains a lease. If a lease is identified in such arrangement, we recognize a right-of-use asset and liability on our consolidated balance sheet and determine whether the lease should be classified as a finance or operating lease. We have elected not to recognize assets or liabilities for leases with lease terms of 12 months or less.

A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset by the end of the lease term, (ii) we hold an option to purchase the leased asset that we are reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, or (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term. All other leases are recorded as operating leases.

Finance and operating lease right-of-use assets and liabilities are recognized at the lease commencement date. Lease liabilities are recognized as the present value of the lease payments over the lease term using the discount rate implicit in the lease. If the implicit rate is not readily determinable, as is the case with all our current leases, we utilize our incremental borrowing rate at the lease

commencement date. Right-of-use assets are recognized based on the amount of the lease liability, adjusted for any advance lease payments paid, initial direct costs incurred, or lease incentives received prior to commencement. Right-of-use assets are subject to evaluation for impairment or disposal on a basis consistent with other long-lived assets.

Operating lease payments are expensed using the straight-line method as an operating expense over the lease term, unless the right-of-use asset reflects impairment. We will then recognize the amortization of the right-of-use asset on a straight-line basis over the remaining lease term with rent expense still included in operating expense in our condensed consolidated statement of operations.

Finance lease assets are amortized to depreciation expense using the straight-line method over the shorter of the useful life of the related asset or the lease term, unless the lease includes a provision that either (i) results in the transfer of ownership of the underlying asset at the end of the lease term or (ii) includes a purchase option whose exercise is reasonably certain. In either of these instances, the right-of-use asset is amortized over the useful life of the underlying asset. Finance lease payments are bifurcated into (i) a portion that is recorded as imputed interest expense and (ii) a portion that reduces the finance lease liability.

We do not separate lease and non-lease components for any of our current asset classes when determining which lease payments to include in the calculation of its lease assets and liabilities. Variable lease payments are expensed in the period incurred. If a lease includes an option to extend or terminate the lease, we reflect the option in the lease term if it is reasonably certain the option will be exercised. Our right of use assets and lease liabilities generally exclude periods covered by renewal options and include periods covered by early termination options (based on our conclusion that it is not reasonably certain that we will exercise such options).

We account for the sublease of space in our main Lexington, Massachusetts facility from the perspective of a lessor. Our sublease is classified as an operating lease. We record sublease income as a reduction of operating expense.

Operating leases are recorded in “Operating lease right-of-use assets”, “Current portion, operating lease liabilities” and “Operating lease liabilities, net of current portion”, while finance leases are recorded in “Property, plant and equipment, net”, “Other current liabilities” and “Other long-term liabilities” on our condensed consolidated balance sheet.

Impact of Adopting ASC 842 on the Condensed Consolidated Financial Statements

We recorded the following adjustments to our condensed consolidated balance sheet on the date of adoption (in thousands):

| | <u>As Reported</u> <u>December 31, 2018</u> | <u>ASC 842 Adjustment</u> | <u>Adjusted January 1,</u> <u>2019</u> |
|---|--|---------------------------|---|
| Condensed Consolidated Balance Sheet Data: | | | |
| Operating lease right-of-use assets | \$ — | \$ 5,687 | \$ 5,687 |
| Current portion, operating lease liabilities | — | 1,510 | 1,510 |
| Other current liabilities | 484 | (95) | 389 |
| Operating lease liabilities, net of current portion | — | 6,216 | 6,216 |
| Other long-term liabilities | 2,773 | (1,921) | 852 |
| Accumulated deficit | \$ (1,177,311) | \$ (25) | \$ (1,177,336) |

The adoption did not have an impact on our condensed consolidated statement of operations or our condensed consolidated statement of cash flows. See Note L for additional information regarding our leases.

Note C - Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our Directors' Deferred Compensation Plan, or "DDCP"). Diluted income per common share is calculated by dividing net income attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our DDCP) plus the dilutive effect of outstanding instruments such as warrants, stock options, non-vested shares, convertible preferred stock, and convertible notes. Because we reported a net loss attributable to common stockholders for all periods presented, diluted loss per common share is the same as basic loss per common share, as the effect of utilizing the fully diluted share count would have reduced the net loss per common share. The following securities (listed on an as-if-converted-to-Common-Stock basis) have been excluded from the computation of diluted weighted average shares outstanding as of September 30, 2019 and 2018, as they would be anti-dilutive (in thousands):

| | Three and Nine Months Ended September 30, | |
|--|---|--------|
| | 2019 | 2018 |
| Warrants | 1,400 | 2,900 |
| Stock options | 24,890 | 16,918 |
| Non-vested shares | 2,117 | 2,222 |
| Series A-1 convertible preferred stock | 333 | 333 |
| Series C-1 convertible preferred stock | 12,459 | - |

Note D - Investments

Cash equivalents consisted of the following as of September 30, 2019 and December 31, 2018 (in thousands):

| | September 30, 2019 | | December 31, 2018 | |
|----------------------------------|--------------------|----------------------|-------------------|----------------------|
| | Cost | Estimated Fair Value | Cost | Estimated Fair Value |
| Institutional money market funds | \$ 87,491 | \$ 87,491 | \$ 29,948 | \$ 29,948 |

As a result of the short-term nature of our investments, there were minimal unrealized holding gains or losses for the nine months ended September 30, 2019 and 2018.

Note E - Goodwill and Acquired Intangible Assets

The following table sets forth the changes in the carrying amount of goodwill for the nine months ended September 30, 2019 (in thousands):

| | |
|---|------------------|
| Balance, December 31, 2018 | \$ 22,925 |
| Foreign currency translation adjustment | (168) |
| Balance, September 30, 2019 | <u>\$ 22,757</u> |

Acquired intangible assets consisted of the following as of September 30, 2019 and December 31, 2018 (in thousands):

| | As of September 30, 2019 | | | |
|-------------------------------------|-----------------------------|-----------------------|--------------------------|---------------------|
| | Amortization period (years) | Gross carrying amount | Accumulated amortization | Net carrying amount |
| Intellectual property | 7-15 years | \$ 16,462 | \$ (7,530) | \$ 8,932 |
| Trademarks | 4.5 years | 811 | (811) | - |
| Other | 2-6 years | 567 | (537) | 30 |
| In-process research and development | Indefinite | 1,891 | — | 1,891 |
| Total | | <u>\$ 19,731</u> | <u>\$ (8,878)</u> | <u>\$ 10,853</u> |

In January 2018, we, through our wholly-owned subsidiary Antigenics, LLC (“Antigenics”), entered into a Royalty Purchase Agreement (the “HCR Royalty Purchase Agreement”) with Healthcare Royalty Partners III, L.P. and certain of its subsidiaries (collectively, “HCR”). Pursuant to the terms of the HCR Royalty Purchase Agreement, we sold to HCR 100% of Antigenics’ worldwide rights to receive royalties from GlaxoSmithKline (“GSK”) on sales of GSK’s vaccines containing our QS-21 Stimulon adjuvant. At closing, we received gross proceeds of \$190.0 million from HCR. Although we sold all of our rights to receive royalties on sales of GSK’s vaccines containing QS-21, as a result of our obligation to HCR, we are required to account for these royalties as revenue when earned, and we recorded the \$190.0 million in proceeds from this transaction as a liability on our condensed consolidated balance sheet that will be amortized using the interest method over the estimated life of the HCR Royalty Purchase Agreement. The liability is classified between the current and non-current portion of liability related to sale of future royalties and milestones in the condensed consolidated balance sheets based on the estimated recognition of the royalty payments to be received by HCR in the next 12 months from the financial statement reporting date.

During the nine months ended September 30, 2019, we recognized \$30.1 million of non-cash royalty revenue, and we recorded \$29.9 million of related non-cash interest expense related to the HCR Royalty Purchase Agreement.

As royalties are remitted to HCR from GSK, the balance of the recorded liability will be effectively repaid over the life of the HCR Royalty Purchase Agreement. To determine the amortization of the recorded liability, we are required to estimate the total amount of future royalty payments to be received by HCR. The sum of these amounts less the \$190.0 million proceeds we received will be recorded as interest expense over the life of the HCR Royalty Purchase Agreement. Periodically, we assess the estimated royalty payments to be paid to HCR from GSK, and to the extent the amount or timing of the payments is materially different from our original estimates, we will prospectively adjust the amortization of the liability. During the nine months ended September 30, 2019, our estimate of the effective annual interest rate over the life of the agreement increased to 21.1%, which results in a prospective interest rate of 19.1%.

Note H - Accrued Liabilities

Accrued liabilities consisted of the following as of September 30, 2019 and December 31, 2018 (in thousands):

| | September 30, 2019 | December 31, 2018 |
|------------------------------|--------------------|-------------------|
| Payroll | \$ 7,065 | \$ 8,770 |
| Professional fees | 4,836 | 3,528 |
| Contract manufacturing costs | 7,531 | 5,947 |
| Research services | 8,070 | 5,348 |
| Other | 1,242 | 958 |
| Total | \$ 28,744 | \$ 24,551 |

Note I - Fair Value Measurements

We measure our contingent purchase price considerations at fair value.

The fair values of our contingent purchase price considerations, \$4.2 million, are based on significant inputs not observable in the market, which require them to be reported as Level 3 liabilities within the fair value hierarchy. The valuation of these liabilities use assumptions we believe would be made by a market participant and are based on estimates from a Monte Carlo simulation of our market capitalization and share price, and other factors impacting the probability of triggering the milestone payments. Market capitalization and share price were evolved using a geometric Brownian motion, calculated daily for the life of the contingent purchase price considerations.

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

| <u>Description</u> | <u>September 30, 2019</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> |
|--|-------------------------------|---|--|--|
| Liabilities: | | | | |
| Contingent purchase price considerations | \$ 4,218 | \$ — | \$ — | \$ 4,218 |
| Total | <u>\$ 4,218</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 4,218</u> |

| <u>Description</u> | <u>December 31, 2018</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> |
|---|------------------------------|---|--|--|
| Liabilities: | | | | |
| Contingent purchase price consideration | \$ 3,038 | \$ — | \$ — | \$ 3,038 |
| Total | <u>\$ 3,038</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 3,038</u> |

The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3), as of September 30, 2019 (in thousands):

| | |
|--|-----------------|
| Balance, December 31, 2018 | \$ 3,038 |
| Change in fair value of contingent purchase price considerations during the period | 1,180 |
| Balance, September 30, 2019 | <u>\$ 4,218</u> |

The fair value of our outstanding debt balance at both September 30, 2019 and December 31, 2018 was \$14.2 million, 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 September 30, 2019 and December 31, 2018 was \$14.1 million.

Note J - Revenue from Contracts with Customers

Gilead Collaboration Agreement

On December 20, 2018, we entered into a series of agreements with Gilead Sciences, Inc. (“Gilead”) focused on the development and commercialization of up to five novel immuno-oncology therapies. Pursuant to the terms of the license agreement, the option and license agreements and the stock purchase agreement we entered into with Gilead (each defined below and, collectively, the “Gilead Collaboration Agreements”), at the closing of the transaction on January 23, 2019 (the “Effective Date”), we received an upfront cash payment from Gilead of \$120.0 million and Gilead made a \$30.0 million equity investment in Agenus. We are also eligible to receive up to \$1.7 billion in aggregate potential milestones.

License Agreement

Pursuant to the terms of a license agreement between the parties (the “License Agreement”), we granted Gilead an exclusive, worldwide license under certain of our intellectual property rights to develop, manufacture and commercialize our preclinical bispecific antibody, AGEN1423 (now GS-1423), in all fields of use. Pursuant to the License Agreement, Gilead is responsible for all of the development, manufacturing and commercialization costs for any products that Gilead may develop under the License Agreement. In addition, Gilead also received the right of first negotiation for two of our undisclosed antibody programs. The License Agreement will continue until all of Gilead’s applicable payment obligations under the License Agreement have been performed or have expired, or the agreement is earlier terminated. Under the terms of the License Agreement, each party has the right to terminate the agreement for material breach by, or insolvency of, the other party. Gilead may also terminate the License Agreement in its entirety, or on a product-by-product or country-by-country basis, for convenience upon ninety (90) days’ notice. Pursuant to the terms of the License Agreement, we are eligible to receive potential development and commercial milestones of up to \$552.5 million in the aggregate, as well as tiered royalty payments on aggregate net sales ranging from the high single digit to mid-teen percent, subject to

certain reductions under certain circumstances as described in the License Agreement. We filed an investigational new drug (“IND”) application for AGEN1423 (now GS-1423) in February 2019, and the IND was accepted by the FDA in March 2019.

Option and License Agreements

Pursuant to the terms of two separate option and license agreements between the parties (each, an “Option and License Agreement” and together, the “Option and License Agreements”), we granted Gilead exclusive options to license exclusively (“License Option”) our bispecific antibody, AGEN1223, and our monospecific antibody, AGEN2373 (together, the “Option Programs”), during the respective Option Periods (defined below). Pursuant to the terms of the Option and License Agreements, we agreed to grant Gilead an exclusive, worldwide license under our intellectual property rights to develop, manufacture and commercialize AGEN1223 or AGEN2373, as applicable, in all fields of use upon Gilead’s exercise of the applicable License Option. Gilead is entitled to exercise its License Option for either or both Option Programs at any time up until ninety (90) days following Gilead’s receipt of a data package with respect to the first complete Phase 1b clinical trial for each Option Program (the “Option Period”). During the Option Period, we are responsible for the costs and expenses related to the development of the Option Programs. After Gilead’s exercise of a License Option, if at all, Gilead would be responsible for all development, manufacturing and commercialization activities relating to the relevant Option Program at Gilead’s cost and expense.

During the Option Period, we are eligible to receive milestones of up to \$30.0 million in the aggregate. If Gilead exercises a License Option, it would be required to pay an upfront license exercise fee of \$50.0 million for each License Option that is exercised. Following any exercise of a License Option, we would be eligible to receive additional development and commercial milestones of up to \$520.0 million in the aggregate for each such Option Program, as well as tiered royalty payments on aggregate net sales. For either, but not both, of the Option Programs, we will have the right to opt-in to share Gilead’s development and commercialization costs in the United States for such Option Program in exchange for a profit (loss) share on a 50:50 basis and revised milestone payments. If we opt-in under one Option and License Agreement, our right to opt-in under the other Option and License Agreement automatically terminates.

Unless earlier terminated, each Option and License Agreement will continue until the earlier of (i) the expiration of the Option Period, without Gilead’s exercise of the License Option; and (ii) the date all of Gilead’s applicable payment obligations under the Option and License Agreement have been performed or have expired. Under the terms of each Option and License Agreement, we and Gilead each have the right to terminate the agreement for material breach by, or insolvency of, the other party. Gilead may also terminate an Option License Agreement in its entirety, or on a product-by-product or country-by-country basis for convenience upon ninety (90) days’ notice.

Stock Purchase Agreement

Pursuant to the terms of a stock purchase agreement between the parties (the “Stock Purchase Agreement”), Gilead purchased 11,111,111 shares of Agenus common stock (the “Shares”) for an aggregate purchase price of \$30.0 million, or \$2.70 per share. Gilead owned approximately 8.5% of the outstanding shares of Agenus common stock after such purchase. Under the Stock Purchase Agreement, Gilead has agreed (i) not to dispose of any of the Shares for a period of 12 months, (ii) to certain standstill provisions that generally preclude it from acquiring more than 15% of Agenus’ outstanding voting stock after taking into account the purchase of the Shares and (iii) 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 12 months. In the Stock Purchase Agreement we agreed to register the Shares for resale under the Securities Act of 1933, and in October 2019 we filed a registration statement with the SEC accordingly.

Collaboration Revenue

We identified the following performance obligations under the Gilead Collaboration Agreements: (1) the license that we granted to Gilead pursuant to the License Agreement (the “AGEN1423 License”), (2) our obligation to complete manufacturing and know-how tech transfer activities to Gilead pursuant to the License Agreement to enable Gilead or its third party contract manufacturing organization to manufacture the licensed antibody (the “AGEN1423 Technology Transfer”), (3) our obligation to advance development of AGEN1223 to the option exercise point pursuant to the AGEN1223 Option and License Agreement (such development activities, the “AGEN1223 R&D Services”), and (4) our obligation to advance development of AGEN2373 to the option exercise point pursuant to the AGEN2373 Option and License Agreement (such development activities, the “AGEN2373 R&D Services”).

We determined that the AGEN1423 License was both capable of being distinct and distinct within the context of the contract given both the advanced stage of development and that the IND was anticipated to be accepted within a short period of time after the

Effective Date. Gilead can begin deriving benefit from the license prior to the AGEN1423 Technology Transfer being completed. The technology transfer plan includes an extensive list of items to be transferred over time and is separate from the transfer of the AGEN1423 License which occurred at contract inception. As a result, we concluded that the AGEN1423 License and AGEN1423 Technology Transfer are separate performance obligations.

We considered whether the AGEN1223 R&D Services and AGEN2373 R&D Services were distinct from one another and from the performance obligations related to AGEN1423. We determined that the research and development services related to each antibody were both capable of being distinct and distinct within the context of the contract given that each program is governed by a separate option agreement with a separate development plan. The services performed to develop each program are independent of one another, and the antibodies are in different stages of development. We concluded that the AGEN1223 R&D Services and AGEN2373 R&D Services are separate performance obligations.

We determined that there were no significant financing components, noncash consideration, or amounts that may be refunded to the customer, and as such the total upfront fixed consideration of license and research and development fees totaling \$120.0 million would be included in the total transaction price. In addition to the fixed consideration, the variable consideration milestones related to IND acceptance for each of the three antibodies was also included in the transaction price. We determined that based on the likelihood of the triggering event occurring for the acceptance of each IND filing, the most likely amount for each of the three milestones was the stated value, totaling \$22.5 million. The variable consideration related to each performance obligation will be allocated entirely to that specific performance obligation. The remaining fixed consideration will be allocated using the relative standalone selling price method.

We determined the estimated standalone selling price of the AGEN1423 License by applying a risk adjusted, net present value, estimate of future cash flow approach. We determined the estimated standalone selling price of the AGEN1423 Technology Transfer, and AGEN1223 R&D Services and AGEN2373 R&D Services by using the estimated costs of satisfying these performance obligations, plus an appropriate margin for such services.

Revenue attributable to the AGEN1423 License was recognized at a point-in-time, upon delivery of the license to Gilead at the Effective Date. The AGEN1423 Technology Transfer, AGEN1223 R&D Services and AGEN2373 R&D Services are satisfied over time and revenue attributable to these performance obligations will be recognized as the related services are being performed using the input of costs incurred over total costs expected to be incurred. We believe this is the best measure of progress because other measures do not reflect how we transfer our performance obligations to Gilead. A cost-based input method of revenue recognition requires management to make estimates of costs to complete our performance obligations. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete our performance obligations will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

For the three months ended September 30, 2019, we recognized \$3.6 million of license and collaboration revenue related to the Gilead Collaboration Agreement. This amount included \$3.6 million of the transaction price recognized based on the partial satisfaction of the over time performance obligations as of quarter end.

For the nine months ended September 30, 2019, we recognized \$77.7 million of license and collaboration revenue related to the Gilead Collaboration Agreement. This amount included \$12.2 million of the transaction price recognized based on the partial satisfaction of the over time performance obligations as of period end.

We expect to recognize deferred research and development revenue of \$6.9 million, \$37.2 million, and \$20.8 million for the remainder of 2019, 2020, and 2021, respectively, related to performance obligations that are unsatisfied or partially unsatisfied as of September 30, 2019.

Incyte Collaboration Agreement

For the three months ended September 30, 2019, we recognized approximately \$2.1 million of research and development revenue. This amount included \$1.7 million of the transaction price for the collaboration agreement (“Incyte Collaboration Agreement”) we entered into with Incyte Corporation (“Incyte”) recognized based on the partial satisfaction of the over time performance obligations as of quarter end and \$0.4 million for research and development services. For the three months ended September 30, 2018, we recognized approximately \$6.3 million of research and development revenue. This amount included \$0.3 million of the transaction price for the Incyte Collaboration Agreement recognized based on the partial satisfaction of the over time

performance obligations as of quarter end, \$5.0 million for the achievement of a milestone and \$1.0 million for research and development services.

For the nine months ended September 30, 2019, we recognized approximately \$3.3 million of research and development revenue. This amount included \$2.0 million of the transaction price for the Incyte Collaboration Agreement recognized based on the partial satisfaction of the over time performance obligations as of period end and \$1.3 million for research and development services. For the nine months ended September 30, 2018, we recognized approximately \$14.4 million of research and development revenue. This amount included \$1.1 million of the transaction price for the Incyte Collaboration Agreement recognized based on proportional performance, \$10.0 million for the achievement of a milestone and \$3.3 million for research and development services.

We expect to recognize deferred research and development revenue of \$0.1 million for the remainder of 2019 related to performance obligations that are unsatisfied or partially unsatisfied as of September 30, 2019. These amounts exclude amounts (milestones, research and development services and royalties) where we have a right to invoice the customer in the amount that corresponds directly with the value of the performance completed to date.

Disaggregation of Revenue

The following tables present revenue (in thousands) for the three and nine months ended September 30, 2019 and September 30, 2018, disaggregated by geographic region and revenue type. Revenue by geographic region is allocated based on the domicile of our respective business operations.

| Revenue Type | Three months ended September 30, 2019 | | |
|---------------------------------------|---------------------------------------|--------|-----------|
| | United States | Europe | Total |
| Research and development services | \$ 441 | \$ — | \$ 441 |
| Recognition of deferred revenue | 5,310 | — | 5,310 |
| Recognition of deferred grant revenue | 6 | 445 | 451 |
| Manufacturing services | 1,534 | — | 1,534 |
| Non-cash royalty revenue | 12,204 | — | 12,204 |
| | \$ 19,495 | \$ 445 | \$ 19,940 |

| Revenue Type | Three months ended September 30, 2018 | | |
|--------------------------------------|---------------------------------------|--------|-----------|
| | United States | Europe | Total |
| Research and development services | \$ 1,014 | \$ — | \$ 1,014 |
| License and collaboration milestones | 5,000 | — | 5,000 |
| Recognition of deferred revenue | 262 | — | 262 |
| Non-cash royalty revenue | 6,526 | — | 6,526 |
| | \$ 12,802 | \$ — | \$ 12,802 |

| Revenue Type | Nine months ended September 30, 2019 | | |
|---------------------------------------|--------------------------------------|--------|------------|
| | United States | Europe | Total |
| Research and development services | \$ 1,341 | \$ — | \$ 1,341 |
| License fee revenue | 65,500 | — | 65,500 |
| Recognition of deferred revenue | 14,181 | — | 14,181 |
| Recognition of deferred grant revenue | 651 | 501 | 1,152 |
| Manufacturing services | 3,301 | — | 3,301 |
| Non-cash royalty revenue | 30,073 | — | 30,073 |
| | \$ 115,047 | \$ 501 | \$ 115,548 |

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

Contract Balances

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

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

| Nine months ended September 30, 2019 | Balance at beginning of period | Additions | Deductions | Balance at end of period |
|--|--------------------------------|-----------|-------------|--------------------------|
| Contract assets: | | | | |
| Unbilled receivables from collaboration partners | \$ - | \$ - | \$ - | \$ - |
| Contract liabilities: | | | | |
| Deferred revenue | \$ 2,052 | \$ 77,000 | \$ (14,181) | \$ 64,871 |

The change in contract liabilities is primarily related to the addition of \$77.0 million of deferred revenue from the Gilead Collaboration Agreement, offset by the recognition of \$12.2 million of revenue related to this same agreement and \$2.0 million of revenue related to the Incyte Collaboration Agreement during the nine months ended September 30, 2019. Deferred revenue related to the Gilead Collaboration Agreement of \$64.8 million as of September 30, 2019, which was comprised of the \$142.5 million initial transaction price, less \$77.7 million of license and collaboration revenue recognized from the effective date of the contract, will be recognized as the combined performance obligation is satisfied. Deferred revenue related to our Incyte Collaboration Agreement of \$0.1 million as of September 30, 2019, which was comprised of the \$25.0 million upfront payment, less \$24.9 million of license and collaboration revenue recognized from the effective date of the contract, will be recognized as the performance obligation is satisfied.

We also recorded a \$2.3 million receivable as of September 30, 2019 for research and development and manufacturing services provided.

During the nine months ended September 30, 2019, we did not recognize any revenue from amounts included in the contract asset or the contract liability balances from performance obligations satisfied in previous periods. None of the costs to obtain or fulfill a contract were capitalized.

Note K - Share-based Compensation Plans

We primarily use the Black-Scholes option pricing model to value stock options granted to employees and non-employees, including stock options granted to members of our Board of Directors. However, the fair value of stock option market-based awards is calculated based on a Monte Carlo simulation as of the date of issuance. All stock options have 10-year terms and generally vest ratably over a 3 or 4-year period.

A summary of option activity for the nine months ended September 30, 2019 is presented below:

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value |
|--|-------------------|--|---|---------------------------------|
| Outstanding at December 31, 2018 | 18,613,822 | \$ 4.15 | | |
| Granted | 7,442,970 | 2.42 | | |
| Exercised | (44,228) | 2.62 | | |
| Forfeited | (819,928) | 3.49 | | |
| Expired | (302,499) | 7.15 | | |
| Outstanding at September 30, 2019 | <u>24,890,137</u> | 3.62 | 7.47 | \$ 2,908,321 |
| Vested or expected to vest at September 30, 2019 | <u>24,890,137</u> | 3.62 | 7.47 | \$ 2,908,321 |
| Exercisable at September 30, 2019 | <u>12,710,229</u> | \$ 4.32 | 5.89 | \$ 62,562 |

The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2019 and 2018 were \$1.61 and \$1.28, respectively.

As of September 30, 2019, there was approximately \$14.9 million of total unrecognized share-based compensation expense related to these stock options which, if all milestones are achieved, will be recognized over a weighted average period of 2.2 years.

Certain employees and consultants have been granted non-vested stock. The fair value of non-vested market-based awards is calculated based on a Monte Carlo simulation as of the date of issuance. The fair value of other non-vested stock is calculated based on the closing sale price of our common stock on the date of issuance.

A summary of non-vested stock activity for the nine months ended September 30, 2019 is presented below:

| | Non-vested Shares | Weighted Average Grant Date Fair Value |
|-----------------------------------|----------------------|---|
| Outstanding at December 31, 2018 | 2,213,967 | \$ 3.20 |
| Granted | 647,682 | 2.95 |
| Vested | (100,690) | 2.96 |
| Forfeited | (643,674) | 4.15 |
| Outstanding at September 30, 2019 | <u>2,117,285</u> | \$ 2.85 |

As of September 30, 2019, there was approximately \$4.2 million of unrecognized share-based compensation expense related to these non-vested shares for which, if all milestones are achieved, will be recognized over a period of 1.9 years.

During the nine months ended September 30, 2019, 84,703 shares were issued under the 2009 Employee Stock Purchase Plan, 100,690 shares were issued as a result of the vesting of non-vested stock and 44,228 shares were issued as a result of stock option exercises.

The impact on our results of operations from share-based compensation for the three and nine months ended September 30, 2019 and 2018, was as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-----------------|------------------------------------|-----------------|
| | 2019 | 2018 | 2019 | 2018 |
| Research and development | \$ 1,239 | \$ 895 | \$ 2,735 | \$ 2,535 |
| General and administrative | 1,845 | 1,010 | 4,109 | 3,160 |
| Total share-based compensation expense | <u>\$ 3,084</u> | <u>\$ 1,905</u> | <u>\$ 6,844</u> | <u>\$ 5,695</u> |

Note L – Leases

The majority of our operating lease agreements are for the office, research and development and manufacturing space we use to conduct our operations.

We lease space in Lexington, Massachusetts for our manufacturing, research and development, and corporate offices, office space in New York, New York for use as corporate offices, a facility in Berkeley, California, for manufacturing and corporate offices and facilities in Charlottesville, Virginia and Cambridge, United Kingdom for research and development and corporate offices. We have subleased a small portion of the space in our main Lexington facility for part of the associated head lease. These agreements expire at various times between 2020 and 2030.

We also have finance lease agreements for equipment used in our research and development and manufacturing activities which expire in 2020.

Lease information related to the adoption of ASC 842

The components of lease cost recorded in our condensed consolidated statement of operations were as follows (in thousands):

| | Three months ended September 30, 2019 | Nine months ended September 30, 2019 |
|----------------------|--|---|
| Operating lease cost | \$ 686 | \$ 1,841 |
| Finance lease cost | 52 | 175 |
| Variable lease cost | 411 | 1,066 |
| Sublease income | (140) | (421) |
| Net lease cost | <u>\$ 1,009</u> | <u>\$ 2,661</u> |

Variable lease cost for the three and nine months ended September 30, 2019 primarily related to common area maintenance, taxes, utilities and insurance associated with our operating leases. Short-term lease cost for the three and nine months ended September 30, 2019 was immaterial.

Cash paid for amounts included in the measurement of operating lease liabilities for the nine months ended September 30, 2019 was approximately \$1.1 million. Cash paid for amounts included in the measurement of finance lease liabilities for the nine months ended September 30, 2019 was immaterial.

The following table presents supplemental balance sheet information related to our leases as of September 30, 2019 (in thousands):

| | <u>As of September 30, 2019</u> | |
|---|---------------------------------|-------|
| Operating Leases | | |
| Operating lease right-of-use assets | \$ | 7,684 |
| Total operating lease right-of-use assets | | 7,684 |
| | | |
| Current portion, operating lease liabilities | | 1,311 |
| Operating lease liabilities, net of current portion | | 8,245 |
| Total operating lease liabilities | | 9,556 |
| | | |
| Finance Leases | | |
| Property, plant and equipment, net | | 826 |
| Total finance lease right-of-use assets | | 826 |
| | | |
| Other current liabilities | | 235 |
| Total finance lease liabilities | \$ | 235 |

Maturities of our operating lease liabilities in accordance with ASC 842 as of September 30, 2019 were as follows (in thousands):

| Year | Operating Leases | Finance leases | Expected sublease receipts | Net future lease commitments |
|------------------------------------|------------------|----------------|----------------------------|------------------------------|
| Remainder of 2019 | \$ 714 | \$ 104 | \$ (140) | \$ 678 |
| 2020 | 2,753 | 159 | (578) | 2,334 |
| 2021 | 2,531 | | | 2,531 |
| 2022 | 2,579 | | | 2,579 |
| 2023 | 2,127 | | | 2,127 |
| Thereafter | 5,523 | | | 5,523 |
| Total | \$ 16,227 | \$ 263 | \$ (718) | \$ 15,772 |
| Less imputed interest | (6,671) | (28) | | |
| Present value of lease liabilities | \$ 9,556 | \$ 235 | | |

Total future minimum lease payments of approximately \$12.5 million for an operating lease that has not yet commenced as of September 30, 2019, as we do not yet control the underlying asset, are not included in the condensed consolidated financial statements. This lease is expected to commence in the first quarter of 2020 with a term of 10 years.

The weighted-average remaining lease terms and discount rates related to our operating leases were as follows:

| | <u>September 30, 2019</u> |
|--|---------------------------|
| Weighted average remaining lease term (in years) | 6.4 |
| Weighted average discount rate | 16.6% |

Additional lease information related to the application of ASC 840

The following information is disclosed in accordance with ASC 840, which was applicable until December 31, 2018. As of December 31, 2018, future minimum commitments under our facility leases were as follows (in thousands):

| Year ending December 31, | |
|--------------------------|------------------|
| 2019 | \$ 2,499 |
| 2020 | 2,279 |
| 2021 | 1,874 |
| 2022 | 1,915 |
| 2023 | 1,457 |
| Thereafter | 928 |
| Total | <u>\$ 10,952</u> |

Note M - Recent Accounting Pronouncements

Recently Issued and Adopted

In February 2016, the FASB issued ASC 842 which supersedes ASC 840, Leases. ASC 842 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. We adopted the new standard on January 1, 2019 and have used the effective date as our date of initial application. See Note B and Note L.

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting (“ASU 2018-07”). The amendments in ASU 2018-07 simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. We adopted the new standard on January 1, 2019. The adoption did not have a material impact on our consolidated financial statements.

Recently Issued, Not Yet Adopted

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

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

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

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606, Revenue from Contracts with Customers, (“ASC 606”) (“ASU 2018-18”). ASU 2018-18 (1) clarifies that certain transactions between collaborative arrangement participants should be accounted for under ASC 606, when the collaborative arrangement participant is a customer in the context of a unit of account, (2) adds unit-of-account guidance in ASC 808 to align with ASC 606 when an entity is assessing whether the collaborative arrangement, or a part of the arrangement, is within the scope of ASC 606, (3) precludes presenting transactions together with revenue when those transactions involve collaborative arrangement participants that are not directly related to third parties and are not customers. The standard will be effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of adoption of ASU 2018-18 on our consolidated financial statements.

No other new accounting pronouncement issued or effective during the nine months ended September 30, 2019 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 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 with a pipeline of immune modulating antibodies, vaccines, adjuvants and adoptive cell therapies dedicated to becoming a leader in the discovery and development of innovative combination therapies and committed to bringing effective medicines to patients with cancer. Our business is designed to drive success in I-O through speed, innovation and effective combination therapies. We believe that combination therapies and a deep understanding of each patient’s cancer will drive substantial expansion of the patient population benefiting from current I-O therapies. In addition to a diverse pipeline, we have assembled fully integrated end-to-end capabilities including novel target discovery, antibody generation, cell line development and good manufacturing practice (“GMP”) manufacturing. We believe that these fully integrated capabilities enable us to produce novel candidates on timelines that are shorter than the industry standard. Leveraging our science and capabilities, we have forged important partnerships to advance our innovation.

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

- our multiple antibody discovery platforms, including our proprietary display technologies, designed to drive the discovery of future CPM antibody candidates;
- our antibody candidate programs, including our CPM programs;
- our vaccine programs, including Prophage™, AutoSynVax™ and PhosPhoSynVax™;
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon™ adjuvant, or QS-21 Stimulon; and
- our cell therapy subsidiary, AgenTus Therapeutics, Inc. (“AgenTus Therapeutics”), which is designed to drive the discovery of future adoptive cell therapy, or “living drugs” (Activated, CAR-T and TCR) programs.

We assess development, commercialization and partnering strategies for each of our product candidates periodically based on several factors, including pre-clinical and clinical trial results, competitive positioning and funding requirements and resources. We are currently advancing our own combination of CTLA-4 and PD-1 antibodies in second line cervical cancer and are on track to file our first BLA in 2020.

We have formed collaborations with companies such as Gilead Sciences, Inc. (“Gilead”), Incyte Corporation (“Incyte”), Merck Sharpe & Dohme (“Merck”) and Recepta Biopharma SA (“Recepta”). Through these alliances, as well as our own internal programs, we currently have more than a dozen antibody programs in pre-clinical or clinical development, including our anti-CTLA-4 and anti-PD-1 antibody programs (both partnered with Recepta for certain South America territories) and anti-GITR and anti-OX40 antibody programs (both partnered with Incyte).

In February 2017, we amended our Incyte Collaboration Agreement to, among other things, convert the GITR and OX40 programs from profit-share to royalty-bearing programs, and there are no longer any profit-share programs remaining under the collaboration. Pursuant to the amended agreement, we received accelerated milestone payments of \$20.0 million from Incyte related to the clinical development of INCAGN1876 (anti-GITR agonist) and INCAGN1949 (anti-OX40 agonist). Concurrent with the execution of the amendment, we and Incyte also entered into the Stock Purchase Agreement whereby Incyte purchased an additional 10 million shares of our common stock at \$6.00 per share, resulting in additional proceeds of \$60.0 million to us. On September 20, 2018, we, through our wholly-owned subsidiary, Agenus Royalty Fund, LLC, entered into a Royalty Purchase Agreement (the “XOMA Royalty Purchase Agreement”) with XOMA (US) LLC (“XOMA”). Pursuant to the terms of the XOMA Royalty Purchase Agreement, XOMA paid us \$15.0 million at closing in exchange for the right to receive 33% of the future royalties and 10% of the future milestones that we are entitled to receive from Incyte and Merck, net of certain of our obligations to a third party. After taking into account our obligations under the XOMA Royalty Purchase Agreement, as of September 30, 2019, we remain eligible to receive up to \$450.0 million and \$85.5 million in potential development, regulatory and commercial milestones from Incyte and Merck, respectively.

In December 2018, we entered into a series of agreements with Gilead to collaborate on the development and commercialization of up to five novel I-O therapies. Pursuant to the collaboration agreements, we received an upfront cash payment from Gilead of \$120.0 million following the closing in January 2019, a milestone payment of \$7.5 million in March 2019 and \$15.0 million in milestone payments in the quarter ended September 30, 2019. We are eligible to receive up to an additional \$1.7 billion in aggregate potential fees and milestones. At closing, Gilead received worldwide exclusive rights to our bispecific antibody, AGEN1423 (now GS-1423). Gilead also received the exclusive option to license exclusively AGEN1223, a bispecific antibody, and AGEN2373, a monospecific antibody. We filed INDs for each of AGEN1423 (now GS-1423), AGEN1223 and AGEN2373 earlier this year, and all three assets are now in clinical development. We are responsible for developing the option programs up to the option decision points, at which time Gilead may acquire exclusive rights to the programs on option exercise. For either, but not both, of the option programs, we have the right to opt-in to share Gilead’s development and commercialization costs in the United States in exchange for a profit (loss) share on a 50:50 basis and revised milestone payments. Gilead also received the right of first negotiation for two additional, undisclosed programs. At the closing, Gilead also purchased 11,111,111 shares of Agenus common stock for \$30.0 million pursuant to a stock purchase agreement.

Our QS-21 Stimulon adjuvant is partnered with GlaxoSmithKline (“GSK”) and is a key component in multiple GSK vaccine programs. These programs are in various stages, with the most advanced being GSK’s shingles vaccine, Shingrix. In October 2017, GSK’s shingles vaccine was approved in the United States by the FDA. In January 2018, we entered into a Royalty Purchase Agreement with Healthcare Royalty Partners III, L.P. and certain of its affiliates (together, “HCR”), pursuant to which HCR purchased 100% of our worldwide rights to receive royalties from GSK on GSK’s sales of vaccines containing our QS-21 Stimulon adjuvant. We do not incur clinical development costs for products partnered with GSK. Pursuant to our agreement with HCR, we are entitled to receive up to \$40.35 million in milestone payments based on GSK’s sales of Shingrix as follows: (i) \$15.1 million upon reaching \$2.0 billion last-twelve-months net sales any time prior to 2024 and (ii) \$25.25 million upon reaching \$2.75 billion last-twelve-months net sales any time prior to 2026. We were obligated to pay HCR approximately \$25.9 million in 2021 if neither of the following Shingrix sales milestones were achieved: (i) 2019 sales exceed \$1.0 billion or (ii) 2020 sales exceed \$1.75 billion; however, this milestone was recently achieved when GSK announced that Shingrix sales for the first nine months of 2019 reached 1.28 billion pounds (or approximately \$1.6 billion).

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

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

Historical Results of Operations

Three months ended September 30, 2019 compared to the three months ended September 30, 2018

Research and development revenue

We recognized research and development revenue of approximately \$5.8 million and \$6.3 million during the three months ended September 30, 2019 and 2018, respectively. Research and development revenues in the third quarter of 2019 primarily consisted of \$3.6 million related to the recognition of deferred revenue earned under our Gilead Collaboration Agreement and \$1.7 million related to the recognition of deferred revenue earned under our Incyte Collaboration Agreement. Research and development revenues in the third quarter of 2018 primarily consisted of fees earned under our Incyte Collaboration Agreement, including \$5.0 million related to the recognition of a milestone and \$1.0 million related to the reimbursement of development costs. During the three months ended September 30, 2019 and 2018, we recorded revenue of \$5.3 million and \$0.3 million, respectively, from the amortization of deferred revenue.

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

In January 2018, we sold 100% of our worldwide rights to receive royalties from GSK on sales of GSK's vaccines containing our QS-21 Stimulon adjuvant to HCR. As described in Note G to our Condensed Consolidated Financial Statements, this transaction has been recorded as a liability that amortizes over the estimated life of our Royalty Purchase Agreement with HCR. As a result of this liability accounting, even though the royalties are remitted directly to HCR, we record these royalties from GSK as revenue. During the three months ended September 30, 2019 and 2018, we recognized approximately \$12.2 million and \$6.5 million, respectively, in non-cash royalty revenue related to our agreement with GSK.

Research and development expense

Research and development expense includes the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, manufacturing costs, costs of consultants, and administrative costs. Research and development expense increased 55% to \$46.1 million for the three months ended September 30, 2019 from \$29.9 million for the three months ended September 30, 2018. Increased expenses in the three months ended September 30, 2019 primarily relate to a \$10.9 million increase in third-party services and other related expenses largely relating to the advancement of our antibody programs, a \$3.9 million increase in expenses attributable to the activities of our subsidiary, AgenTus Therapeutics and a \$2.3 million increase in personnel related expenses, primarily due to increased headcount. These increases were partially offset by a \$0.5 million decrease in other research and development expenses and a \$0.4 million decrease in expenses of our foreign subsidiaries, Agenus UK Limited and Agenus Switzerland.

General and administrative expense

General and administrative expense consists primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 25% to \$11.5 million for the three months ended September 30, 2019 from \$9.2 million for the three months ended September 30, 2018. Increased expenses in the three months ended September 30, 2019 primarily relate to a \$1.5 million increase in personnel related expenses, primarily due to increased headcount, a \$0.4 million increase in other general and administrative expenses and a \$0.3 million increase in expenses attributable to the activities of our subsidiaries, AgenTus Therapeutics and Agenus UK Limited.

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) income

Non-operating (expense) income includes our foreign currency translation adjustment and other income or expense. Non-operating income increased \$0.4 million for the three months ended September 30, 2019, from expense of \$0.1 million for the three months ended September 30, 2018 to income of \$0.3 million for the three months ended September 30, 2019, primarily due to foreign currency exchange gains in the third quarter of 2019 compared to losses in the third quarter of 2018.

Interest expense, net

Interest expense, net increased to approximately \$10.7 million for the three months ended September 30, 2019 from \$7.5 million for the three months ended September 30, 2018, due to increased non-cash interest recorded in connection with our Royalty Purchase Agreement with HCR.

Nine months ended September 30, 2019 compared to the nine months ended September 30, 2018

Research and development revenue

We recognized research and development revenue of approximately \$81.0 million and \$18.4 million during the nine months ended September 30, 2019 and 2018, respectively. Research and development revenues in the first nine months of 2019 primarily consisted of amounts earned under our Gilead Collaboration Agreement, including \$65.5 million related to the recognition of an upfront license fee and \$12.2 million related to the recognition of deferred revenue earned and amounts earned under our Incyte Collaboration Agreement, including \$1.3 million related to the reimbursement of development costs. Research and development revenues in the first nine months of 2018 primarily consisted of \$4.0 million related to the recognition of a milestone under our license agreement with Merck and fees earned under our Incyte Collaboration Agreement, including \$10.0 million related to the recognition of milestones and \$3.3 million related to the reimbursement of development costs. During the nine months ended September 30, 2019 and 2018, we recorded revenue of \$14.2 million and \$1.1 million, respectively, from the amortization of deferred revenue.

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

In January 2018, we sold 100% of our worldwide rights to receive royalties from GSK on sales of GSK's vaccines containing our QS-21 Stimulon adjuvant to HCR. As described in Note G to our Condensed Consolidated Financial Statements, this transaction has been recorded as a liability that amortizes over the estimated life of our Royalty Purchase Agreement with HCR. As a result of this liability accounting, even though the royalties are remitted directly to HCR, we will record these royalties from GSK as revenue. During the nine months ended September 30, 2019 and 2018, we recognized approximately \$30.1 million and \$11.9 million, respectively, in non-cash royalty revenue related to our agreement with GSK.

Research and development expense

Research and development expense includes the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, manufacturing costs, costs of consultants, and administrative costs. Research and development expense increased 48% to \$131.5 million for the nine months ended September 30, 2019 from \$88.6 million for the nine months ended September 30, 2018. Increased expenses in the nine months ended September 30, 2019 primarily relate to a \$30.0 million increase in third-party services and other related expenses largely relating to the advancement of our antibody programs, a \$10.9 million increase in expenses attributable to the activities of our subsidiary, AgenTus Therapeutics and a \$4.6 million increase in personnel related expenses, primarily due to increased headcount. These increases were partially offset by a \$0.7 million decrease in other research and development expenses and a \$1.9 million decrease in expenses of our foreign subsidiaries, Agenus UK Limited and Agenus Switzerland.

General and administrative expense

General and administrative expense consists primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 22% to \$33.7 million for the nine months ended September 30, 2019 from \$27.6 million for the nine months ended September 30, 2018. Increased expenses in the nine months ended September 30, 2019 primarily relate to a \$3.4 million increase in personnel related expenses, primarily due to increased headcount, a \$0.4 million increase in professional fees, a \$1.2 million increase in other general and administrative expenses and a \$1.1 million increase in expenses attributable to the activities of our subsidiaries, Agenus UK Limited and AgenTus Therapeutics.

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) income

Non-operating expense includes our foreign currency translation adjustment and other income or expense. Non-operating expense decreased \$1.2 million for the nine months ended September 30, 2019, from \$1.5 million for the nine months ended September 30, 2018 to \$0.3 million for the nine months ended September 30, 2019, primarily due to our decreased foreign currency exchange losses in the first nine months of 2019 compared to the first nine months of 2018.

Interest expense, net:

Interest expense, net increased to approximately \$29.6 million for the nine months ended September 30, 2019 from \$16.5 million for the nine months ended September 30, 2018, due to increased non-cash interest recorded in connection with our Royalty Purchase Agreement with HCR.

Research and Development Programs

For the nine months ended September 30, 2019, our research and development programs consisted largely of our antibody programs as indicated in the following table (in thousands).

| Research and Development Program | Product | Nine Months Ended September 30, | Year Ended December 31, | | | | Prior to 2016 | Total |
|---|------------------|---------------------------------|-------------------------|-------------------|------------------|-------------------|-------------------|-------|
| | | 2019 | 2018 | 2017 | 2016 | | | |
| Antibody programs* | Various | \$ 99,420 | \$ 97,011 | \$ 95,656 | \$ 83,920 | \$ 76,712 | \$ 452,719 | |
| Heat shock proteins for cancer | Prophage and ASV | 10,306 | 13,235 | 12,499 | 8,202 | 315,189 | 359,431 | |
| Vaccine adjuvant | QS-21 | | | | | | | |
| | Stimulon | 753 | 211 | 222 | 77 | 13,799 | 15,062 | |
| Other research and development programs | | 21,027 | 14,143 | 7,748 | 2,772 | 67,822 | 113,512 | |
| Total research and development expenses | | <u>\$ 131,506</u> | <u>\$ 124,600</u> | <u>\$ 116,125</u> | <u>\$ 94,971</u> | <u>\$ 473,522</u> | <u>\$ 940,724</u> | |

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

Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions and our review of the status of each program. Our product candidates are in various stages of development and significant additional expenditures will be required if we start new clinical trials, encounter delays in our programs, apply for regulatory approvals, continue development of our technologies, expand our operations, and/or bring our product candidates to market. The total cost of any particular clinical trial is dependent on a number of factors such as trial design, length of the trial, number of clinical sites, number of patients, and trial sponsorship. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because our CPM antibody programs are early stage, and because further development of HSP-based vaccines is dependent on clinical trial results, among other factors, we are unable to reliably estimate the cost of completing our research and development programs or the timing for bringing such programs to various markets or substantial partnering or out-licensing arrangements, and, therefore, when, if ever, material cash inflows are likely to commence. Active programs involving QS-21 Stimulon depend on our licensee successfully completing clinical trials, successfully manufacturing QS-21 Stimulon to meet demand, obtaining regulatory approvals and successfully commercializing product candidates containing QS-21 Stimulon.

Liquidity and Capital Resources

We have incurred annual operating losses since inception, and we had an accumulated deficit of \$1.3 billion as of September 30, 2019. 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. We are likely to continue to incur losses until we become a commercial company generating profits. Our first commercial product launches are planned for as early as the first half of 2021. To date, we have financed our operations primarily through the sale of equity, notes, corporate partnerships, advance royalty sales and interest income. From our inception through September 30, 2019, we have raised aggregate net proceeds of approximately \$1.2 billion through the sale of common and preferred stock, the exercise of stock options and warrants, proceeds from our Employee Stock Purchase Plan, royalty monetization transactions, and the issuance of convertible and other notes.

We maintain an effective registration statement (the "Registration Statement"), covering the offering of up to \$250 million of common stock, preferred stock, warrants, debt securities and units. The Registration Statement includes prospectuses covering the offer, issuance and sale of up to 50 million shares of our common stock from time to time in "at-the-market offerings" pursuant to an At Market Issuance Sales Agreement (the "Sales Agreement") with B. Riley FBR, Inc. as our sales agent. As of September 30, 2019, approximately 34.1 million shares remain available for sale under the Sales Agreement.

As of September 30, 2019, we had debt outstanding of \$14.1 million in principal. In February 2015, we issued subordinated notes in the aggregate principal amount of \$14.0 million with annual interest at 8% (the "2015 Subordinated Notes"). The 2015 Subordinated Notes are due in February 2020.

Our cash, cash equivalents, and short-term investments at September 30, 2019 were \$93.3 million, an increase of \$40.2 million from December 31, 2018. Based on our current plans, we believe that our cash resources of \$93.3 million as of September 30, 2019, plus anticipated license fees and milestones, will be sufficient to satisfy our liquidity requirements into the second quarter of 2020. We continue to address our liquidity position. We also continue to monitor the likelihood of success of our key initiatives and can discontinue funding of such activities if they do not prove to be successful, restrict capital expenditures and/or reduce the scale of our operations if necessary.

Based on our recurring losses from operations and expectation of continuing losses, we will require additional capital to finance our operations through and beyond the second quarter of 2020. Based on current revenue trends from GSK's Shingrix vaccine and the progress trends of our clinical stage programs, we expect to receive additional milestone payments during 2020. In addition, we are currently pursuing transactions designed for significant capital infusion to satisfy our cash requirements. Until we are successful in our efforts for capital infusion through these transactions or other financing options, in accordance with accounting guidance, we are required to disclose that a substantial doubt exists about our ability to continue as a going concern for a period of one year after the date of filing of this Quarterly Report on Form 10-Q.

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

Our future cash requirements include, but are not limited to, supporting clinical trial and regulatory efforts and continuing our other research and development programs. Since inception, we have entered into various agreements with contract manufacturers, institutions, and clinical research organizations (collectively "third party providers") to perform pre-clinical activities and to conduct and monitor our clinical studies and trials. Under these agreements, subject to the enrollment of patients and performance by the applicable third-party provider, we have estimated our total payments to be \$313.1 million over the term of the related activities. Through September 30, 2019, we have expensed \$234.6 million as research and development expenses and \$221.3 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 \$10.0 million, of which \$8.9 million have been paid as of September 30, 2019. We plan to enter into additional agreements with third party providers as well as sponsored research agreements, and we anticipate significant additional expenditures will be required to initiate and advance our various programs.

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

Net cash provided by (used in) operating activities for the nine months ended September 30, 2019 and 2018 was \$13.1 million and (\$95.3) million, respectively. Our future ability to generate cash from operations will depend on achieving regulatory approval and market acceptance of our product candidates, achieving benchmarks as defined in existing collaboration agreements, and our ability to enter into new collaborations. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Forward Looking Statements" in Part I, Item 2, and the risks highlighted under Part II, Item 1A. "Risk Factors", of this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of September 30, 2019.

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 4% and 1% of our cash used in operations for the nine months ended September 30, 2019 and the year ended December 31, 2018, 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 Euro, Swiss Franc and British Pound, in large part due to our subsidiaries, AgenTus Therapeutics SA, with operations in Belgium, Agenus Switzerland a company formally with operations in Switzerland, and Agenus UK Limited, with operations in England. There has been no material change to our interest rate exposure and our approach toward interest rate and foreign currency exchange rate exposures, as described in our Annual Report on Form 10-K for the year ended December 31, 2018.

We had cash and cash equivalents at September 30, 2019 of \$93.3 million, which are exposed to the impact of interest rate changes, and our interest income fluctuates as interest rates change. Additionally, in the normal course of business, we are exposed to fluctuations in interest rates as we seek debt financing and invest excess cash. Due to the short-term nature of our investments in money market funds, our carrying value approximates the fair value of these investments at September 30, 2019.

We invest our cash and cash equivalents in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs, and maximize yields. We review our investment policy annually and amend it as deemed necessary. Currently, the investment policy prohibits investing in any structured investment vehicles and asset-backed commercial paper. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer, or type of investment. We do not invest in derivative financial instruments. Accordingly, we do not believe that there is currently any material market risk exposure with respect to derivatives or other financial instruments that would require disclosure under this item.

Item 4. Controls and Procedures***Evaluation of Disclosure Controls and Procedures***

Under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Exchange Act. Based on this evaluation, our Principal Executive Officer and our Principal Financial Officer concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective and were designed to ensure that information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our Principal Executive Officer and Principal Financial Officer have each concluded that our disclosure controls and procedures as of the end of the period covered by this report are effective at a level that provides such reasonable assurances.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended September 30, 2019 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 June 30, 2019 filed with the SEC on August 9, 2019.

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, 2018, 2017, and 2016, were \$162.0 million, \$120.7 million, and \$127.0 million, respectively. During the nine months ended September 30, 2019, we generated a net loss of \$80.7 million. We expect to incur additional losses over the next several years as we continue to research and develop our technologies and pursue partnering opportunities, regulatory strategies, commercialization, and related activities. Furthermore, our ability to generate cash from operations is dependent on the success of our licensees and collaboration partners, as well as the likelihood and timing of new strategic licensing and partnering relationships and/or successful development and commercialization of product candidates, including through our antibody programs and platforms, our vaccine programs, and our saponin-based vaccine adjuvants.

On September 30, 2019, we had \$93.3 million in cash and cash equivalents. We believe that, based on our current plans and activities, our working capital resources at September 30, 2019, plus anticipated license fees and milestones, will be sufficient to satisfy our liquidity requirements into the second quarter of 2020. We also continue to monitor the likelihood of success of our key initiatives and can discontinue funding of such activities if they do not prove to be successful, restrict capital expenditures and/or reduce the scale of our operations if necessary.

To date, we have financed our operations primarily through the sale of equity, assets, notes, corporate partnerships and interest income. 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. We have in the past offered Biotech Electronic Security Tokens, but we are not currently offering such tokens at this time and have not issued any to date.

There are a number of factors that will influence our future capital requirements, including, without limitation, the following:

- the number and characteristics of the product candidates we and our partners pursue;
- our and our partners’ ability to successfully develop, manufacture, and commercialize product candidates;
- the scope, progress, results and costs of researching and developing our future product candidates and conducting pre-clinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our and our licensees’ product candidates;
- the cost of manufacturing;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such arrangements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property rights;
- the costs associated with any successful commercial operations; and

the timing, receipt and amount of sales of, or royalties on, our future products and those of our partners, if any.

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

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

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 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 the principal and interest payments when due on the 2015 Subordinated Notes. In addition, any such financing, refinancing, or sale of assets might not be available on favorable terms, if at all.

Our AGEN2034 and AGEN1884 antibody programs are in potential registrational studies, but there is no guarantee that we will be successful in advancing these through clinical development on our desired timeline, if at all, or that we will be able to commercialize them successfully.

Our anti-PD-1 and anti-CTLA-4 programs (AGEN2034 and AGEN1884, respectively) are in clinical trials that included a Phase 1 dose escalation with expansion cohorts in multiple solid tumors. These molecules are now in expansion trials with both anti-PD-1 monotherapy and anti-PD-1 and anti-CTLA-4 combination trials for patients with second-line cervical cancer that are designed to support one or more Biologic License Application (“BLA”) filings as early as 2020 under the FDA’s accelerated approval pathway. If approved, we intend to commercialize these assets during the first half of 2021. These timelines are aggressive and subject to various factors outside of our control, including patient accrual rates for our clinical trials and regulatory review and approval. If our trials are unable to accrue patients at the rate we expect, we are unlikely to hit our anticipated timelines and our business and financial prospects could be materially adversely affected. In addition, in order to file a BLA and seek accelerated approval, we must also launch a confirmatory trial and have it be substantially underway at that time. We have not yet initiated a confirmatory trial. There is no guarantee that we will be able to file a BLA in 2020, if at all.

We have previously presented early data on these programs at major oncology conferences that demonstrated a clinical benefit (i.e., complete response, partial response or disease stabilization) in more than 60% of patients treated with AGEN1884 and AGEN2034. Even though we have observed positive results to date, they may not necessarily be predictive of the final results of the trials or future clinical trials or otherwise be sufficient to support an accelerated approval. Many companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results, and we cannot be certain that we will not face similar setbacks.

Even if AGEN2034 and/or AGEN1884 are approved, there is no guarantee that we will be able to successfully commercialize

them or penetrate any commercial markets. We are initially targeting second line cervical cancer, which is a small subset of the overall market. Further, for products approved under the FDA's accelerated approval pathway, post-commercialization confirmatory trials are required to meet certain endpoints. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed and/or initiated prior to approval. Moreover, the FDA may withdraw approval of any product candidate or indication approved under the accelerated approval pathway if, for example (i) the trial or trials required to verify the predicted clinical benefit of the product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug, (ii) other evidence demonstrates that the product candidate is not shown to be safe or effective under the conditions of use, (iii) we fail to conduct any required post-approval trial of the product candidate with due diligence, or (iv) we disseminate false or misleading promotional materials relating to the product candidate.

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

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

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

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

Since our acquisition of Agenus Switzerland Inc., formerly known as 4-Antibody AG ("4-AB"), we have more than tripled our headcount, in part through various acquisitions and the expansion of our research and development activities both nationally and internationally. While we have restructured our organization over the past few years, we expect to continue increasing our headcount in certain core areas as we continue to build our development, manufacturing and commercialization capabilities and integrate our acquired technology platforms. To manage these organizational changes, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit, train and retain qualified personnel. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our timelines may be delayed, our ability to generate revenue could be reduced, and we may not be able to implement our business strategy.

As part of our efforts to optimize efficiency across our organization, we closed our Jena, Germany office in 2016 and consolidated these operations in the United Kingdom and Switzerland. In 2017, we completed a reduction in force in our Lexington, MA facility, which included certain members of our management, in line with our prioritization efforts, and we closed our office in Basel, Switzerland and transferred our research and development assets and capabilities there to the United Kingdom. If these transition efforts prove to be unsuccessful, or if we identify management or operational gaps in connection with our changes, it could cause delays in discovery timelines and increased costs for certain of our internal and partnered programs, which also could have an adverse effect on our business, financial condition and results of operations. We are still in the process of liquidating 4-AB and transferring intellectual property rights from Switzerland to the United States or elsewhere. There could be adverse tax consequences resulting from this migration of intellectual property rights, which could have an adverse effect on our business and 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. The Phase 2 trial met its formal endpoints, but subjects were not followed long enough to determine whether the magnitude of the effect on viral load would be sufficient to significantly reduce the incidence, severity, or duration of herpetic lesions or reduce the risk of viral transmission. Although we have not advanced this program into a Phase 3 trial, we initiated our ASV synthetic cancer vaccine program based on our prior findings with this platform. We initiated our first clinical trial for our first AutoSynVax product candidate in 2017 and reported safety and immunogenicity of the vaccine at CIMT2018. Although we are planning to initiate a combination trial with ASV and one or more of our antibodies, the timeline is uncertain and there is no guarantee that we will be able to do so at all. Furthermore, it is possible that research and discoveries by others will render any product candidate from this platform as obsolete or noncompetitive.

We may not be able to advance clinical development or commercialize our cancer vaccine candidates or realize any benefits from these programs.

The probability of future clinical development efforts leading to marketing approval and commercialization of Prophage vaccines is highly uncertain. Prophage vaccines have been in clinical development for over 16 years, including multiple Phase 1 and 2 trials in eight different tumor types as well as randomized Phase 3 trials in metastatic melanoma and adjuvant renal cell carcinoma. To date, the only marketing approval for Prophage is in Russia where commercialization of the approved product was unsuccessful. All of our currently planned trials involving Prophage are intended to be sponsored by third parties, and there is no guarantee that they will occur at all.

Our current clinical trial plans with Prophage vaccines entail one government sponsored IND in which we provide support and product supply. For third-party sponsored trials, we lack the ability to control trial design, timelines, tumor tissue procurement and data availability. For example, in January 2017, we announced a clinical trial collaboration with the NCI, whereby the NCI is conducting a double-blind, randomized controlled Phase 2 trial to evaluate the effect of Prophage vaccine in conjunction with Merck’s pembrolizumab on the overall survival rate of patients with newly diagnosed glioblastoma (“ndGBM”). In addition, the Phase 2 trial of Prophage vaccine in combination with bevacizumab in patients with surgically resectable recurrent glioma that was being conducted under the sponsorship of the Alliance for Clinical Trials in Oncology, a cooperative group of the NCI, has been closed. Our other cancer vaccine programs (ASV and PSV) are in Phase 1 and pre-clinical development, respectively, and there is no guarantee that they will successfully advance in and through the clinic. ASV also utilizes QS-21 Stimulon, and any inability or delay in securing adequate supplies of the adjuvant could have an adverse impact on the program or otherwise delay timelines. Current and future studies may eventually be terminated due to, among other things, slow enrollment, lack of probability that they will yield useful translational and/or efficacy data, lengthy timelines, or the unlikelihood that results will support timely or successful regulatory filings.

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

Our antibody programs will require substantial manufacturing development and investment to progress. We are currently progressing a portfolio of antibody programs that are at different stages of development. If these efforts are delayed or do not produce the desired outcomes, this will cause delays in development timelines and increased costs, which may cause us to limit the size and scope of our efforts and studies. In 2015, we secured our own antibody manufacturing capabilities with the purchase of a manufacturing pilot plant from XOMA Corporation, and we expect this facility to supply us with antibody drug substance requirements through clinical proof-of-concept studies. We will also need to develop or secure later phase and/or commercial manufacturing capabilities for larger, registrational studies or any commercial supply requirements. For the programs for which we will produce our own drug substance, we will continue to rely on third parties for fill-finish services and other parts of the manufacturing process. These services include the storage and maintenance of our drug substance during all stages of the manufacturing process. While we maintain insurance to cover certain potential losses, there is no guarantee that our insurance coverage will be adequate. Furthermore, we currently rely on contract manufacturing organizations (“CMOs”) and contract research organizations (“CROs”) to support some of our existing antibody programs. Our dependence on external CMOs for the manufacture of certain antibodies results in intrinsic risks to our performance, timelines, and costs of our accelerated development plans, and which could divert resources away from our antibody programs and/or lead to delays in the development of our product candidates. In the event that our antibody programs require progressively larger production capabilities, our options for qualified CMOs may become more limited.

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

We have given our corporate QS-21 Stimulon licensee, GSK, manufacturing rights for QS-21 Stimulon for use in their product programs. We have retained the right to manufacture QS-21 for ourselves and third parties, although no other such programs are anticipated to bring us substantial revenues in the near future, if ever. Although we have the right to secure certain quantities of QS-21 from GSK and we have some internal supply in-house, we currently do not have an alternative long-term supply partner for this adjuvant. In January 2019, we announced that the Bill & Melinda Gates Foundation awarded us a grant to develop an alternative, plant cell culture-based manufacturing process with the goal of ensuring the continuous future supply of QS-21 Stimulon adjuvant. There is no guarantee that we will be successful in these development efforts.

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

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

Biopharmaceutical manufacturing is also subject to extensive government regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with current good manufacturing practices. These regulations govern manufacturing processes and procedures (including record-keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of a product candidate. In addition, facilities are subject to on-going inspections and routine audits, and minor changes in manufacturing processes may require additional regulatory approvals and audits, either of which could cause us to incur significant additional costs, set-backs or delays and eventual loss of revenue.

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

We currently have research and development operations in the United Kingdom, and we expect to pursue pathways to develop and commercialize our product candidates in both U.S. and ex-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 planned or actual 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. Our development plans are spread out across various indications and lines of therapy, either alone or in combination with other assets. Our competitors range from small cap to large cap companies, with assets in pre-clinical or clinical stages of development. Therefore, the landscape is dynamic and constantly evolving. We and our partners have CPM antibody programs, currently in clinical stage development targeting various pathways including PD-1, CTLA-4, GITR, OX40, TIM-3, LAG-3 and CD137. We are aware of many companies that have antibody-based products on the market or in clinical development that are directed to the same biological targets as these programs, including, without limitation, the following: (1) BMS markets ipilimumab, an anti-CTLA-4 antibody, and nivolumab, an anti-PD-1 antibody, and is developing additional antagonists to LAG-3 and TIM-3. BMS also has next generation anti-CTLA-4 antibodies in the clinic, which may be competitive to our next generation anti-CTLA-4 program, (2) Merck has an approved anti-PD-1 antibody, as well as anti-CTLA-4 and LAG-3 antagonists recruiting in clinical trials, (3) Regeneron has an approved anti-PD-1 antibody as well as antibodies targeting CTLA-4 and LAG-3 in clinical development, (4) AstraZeneca has an approved anti PD-L1 antibody, as well as an anti-CTLA-4 targeting antibody in the clinic, (5) Pfizer has an approved anti-PD-L1 (with Merck KgaA) as well as anti-PD-1, and anti-OX40 and anti-CD137 antibodies in clinical development, and (6) Roche/Genentech has an approved anti-PD-L1 antibody. Besides these PD-1 and PD-L1 antibodies that were approved in the U.S., we are also aware of competitors with approved PD-1 agents in ex-U.S. geographies such as China. These include Innovent Biologics, Shanghai Junshi Biosciences and Shanghai HengRui Pharmaceuticals. We are also aware of other competitors with PD-1/PD-L1 agents in clinical development, including but not limited to AbbVie, Arcus Biosciences, Boehringer Ingelheim, GSK, Beigene, MacroGenics/Incyte, CytomX, Novartis, Symphogen, Jounce Therapeutics, Gilead Sciences, Janssen, Apollomics/Genor Biopharma, Fortress Biotech, CStone Pharmaceuticals, Suzhou Alphamab, Mabspace Biosciences, Akeso Biopharma, Sichuan Kelun Pharmaceutical, CSPC ZhongQi Pharmaceutical Technology, Yuhan Corp, Lee's Pharmaceuticals and Sinocelltech. We are also aware of competitors with pre-clinical antibodies against PD-1 or PD-L1. In addition, we are aware of competitors with clinical stage antibodies against CTLA-4, GITR, OX40, LAG-3, TIM-3 and CD137 as well as our earlier stage programs such as TIGIT. As outlined above, some of these include, but are not limited to, BMS, Pfizer, Roche, Novartis, Merck, GSK, Regeneron, CStone Therapeutics, Eli Lilly, Innovent Biologics, Boehringer Ingelheim, Arcus Biosciences, Potenza, GlaxoSmithKline, AbbVie, Leap Therapeutics, Mereo Biopharma, OncoMed, Symphogen, Alligator Biosciences and Compass Therapeutics. Additionally, we are aware of competitors developing preclinical assets against these targets, including next generation agents. We are also aware of competitors with clinical or preclinical stage bispecifics targeting PD-1, CTLA-4, GITR, OX40, TIM-3, LAG-3 and CD137. There is no guarantee that our antibody product candidates will be able to successfully compete with our competitors' antibody products and product candidates.

We are conducting both monotherapy and combination trials in second line cervical cancer. We are aware that Merck's PD-1 antagonist, Keytruda, has been approved in advanced cervical cancer. We are also aware of industry sponsored clinical trials, including exploratory studies, that are underway in this setting. Clinical stage competitors include, but are not limited to, Regeneron (anti-PD-1), Ono Pharmaceuticals and BMS (anti-PD-1 alone or in combination with CTLA-4), Seattle Genetics and Genmab (antibody drug conjugate targeting Tissue Factor), Iovance Biotherapeutics (autologous TILs), Genor Biopharma and Lee Pharmaceuticals.

We have autologous vaccine programs in development including our Prophage vaccine in clinical development for GBM. We are aware of other therapeutic options in GBM that could compete with our vaccine, including but not limited to the following: Merck markets temozolomide for treatment of patients with ndGBM and refractory astrocytoma. Other companies are developing vaccines for the treatment of patients with ndGBM, including, but not limited to, Northwest Biotherapeutics (DC-Vax), Mimivax Inc.

(SurVaxM) and Annias Immunotherapeutics (CMV Vaccine). Other companies may begin development programs as well. We are advancing our neoantigen vaccine, AutoSynVax, in solid tumors. There are companies advancing individualized or synthetic vaccine technologies and/or patient-specific medicine techniques that compete with our HSP based vaccines including, but not limited to: Neon Therapeutics, Gritstone Oncology, BioNTech, Moderna/Merck, Genocea Biosciences, ISA Pharmaceuticals, Nouscom, EpiVax Inc., and Vaccibody.

In addition, and prior to regulatory approval, if ever, our vaccines and our other product candidates may compete for access to patients with other products in clinical development, with products approved for use in the indications we are studying, or with off-label use of products in the indications we are studying. We anticipate that we will face increased competition in the future as new companies enter markets we seek to address and scientific developments surrounding immunotherapy and other traditional cancer therapies continue to accelerate.

We are aware of compounds that claim to be comparable to QS-21 Stimulon that are being used in clinical trials. Several other vaccine adjuvants are in development or in use and could compete with QS-21 Stimulon for inclusion in vaccines. These adjuvants may include but are not limited to: (1) oligonucleotides, under development by Pfizer, Idera, and Dynavax, (2) MF59, under development by Novartis, (3) IC31, under development by Intercell (now part of Valneva), and (4) MPL, under development by GSK. In the past, we have provided QS-21 Stimulon to other entities under materials transfer arrangements. In at least one instance, it is possible that this material was used without our permission to develop synthetic formulations and/or derivatives of QS-21. In addition, companies such as Adjuvance Technologies, Inc., CSL Limited, and Novavax, Inc., as well as academic institutions and manufacturers of saponin extracts, are developing saponin adjuvants, including derivatives and synthetic formulations. These sources may be competitive to our ability to execute future partnering and licensing arrangements involving QS-21 Stimulon. The existence of products developed by these and other competitors, or other products of which we are not aware, or which other companies may develop in the future, may adversely affect the marketability of products developed or sold using QS-21 Stimulon.

We are also aware of a third party that manufactures pre-clinical material purporting to be comparable to QS-21 Stimulon. The claims being made by this third party may create marketplace confusion and have an adverse effect on the goodwill generated by us and our partners with respect to QS-21 Stimulon. We are also aware of at least two additional manufacturers of QS-21. Any diminution of this goodwill may have an adverse effect on our ability to commercialize future products, if any, incorporating this technology, either alone or with a third party.

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

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

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

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

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

As previously noted, our ability to advance our antibody programs depends in part on collaboration agreements such as our collaborations with Gilead and Incyte. In addition, from time to time we engage in efforts to enter into licensing, distribution and/or collaboration agreements with one or more pharmaceutical or biotechnology companies to assist us with development and/or commercialization of our other product candidates. If we are successful in entering into such agreements, we may not be able to negotiate agreements with economic terms similar to those negotiated by other companies. We may not, for example, obtain significant upfront payments, substantial royalty rates or milestones. If we fail to enter into any such agreements in a timely manner or at all, our efforts to develop and/or commercialize our product candidates may be undermined. In addition, if we do not raise funds through any such agreements, we will need to rely on other financing mechanisms, such as sales of debt or equity securities, to fund our operations. Such financing mechanisms, if available, may not be sufficient or timely enough to advance our programs forward in a meaningful way in the short-term.

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

Part of our strategy is to develop and commercialize many of our product candidates by continuing or entering into arrangements with academic, government, or corporate collaborators and licensees. Our success depends on our ability to negotiate such agreements on favorable terms and on the success of the other parties in performing research, pre-clinical and clinical testing, completing regulatory applications, and commercializing product candidates. Our research, development, and commercialization efforts with respect to antibody candidates from our technology platforms are, in part, contingent upon the participation of institutional and corporate collaborators. For example, in February 2015, we began a broad collaboration with Incyte to pursue the discovery and development of antibodies, and in December 2018 we entered into a partnership with Gilead relating to five of our antibody programs. Furthermore, we have a collaboration arrangement with Recepta for CTLA-4 and PD-1, giving Recepta rights to certain South American countries and requiring us to agree upon development plans for these product candidates. Disagreements or the failure of either party to perform satisfactorily could have an adverse impact on these programs.

The Brain Tumor Trials Collaborative, through the NCI, is sponsoring a Phase 2 clinical trial of our Prophage vaccine candidate in combination with Merck's pembrolizumab in patients with glioma. When our licensees or third-party collaborators sponsor clinical trials using our product candidates, we cannot control the timing of enrollment, data readout, or quality of such trials or related activities.

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

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

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs, CMOs, licensees, collaborators and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Potential vulnerabilities can also be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks

of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, on-going or future clinical trials could result in delays in our regulatory approval efforts and significant costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture certain of our drug candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development and commercialization of our product candidates could be delayed. We do not maintain cyber liability insurance, and would therefore have no coverage for any losses resulting from any data security incident.

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

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

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 Jennifer Buell, Ph.D., our Chief Operating Officer, are integral to building our company and developing our technology. If either Dr. Armen or Dr. Buell is unable or unwilling to continue his or her relationship with Agenus, our business may be adversely impacted. We have employment agreements with Dr. Armen and Dr. Buell. They both play an important role in our day-to-day activities, and we do not carry key employee insurance policies for Dr. Armen, Dr. Buell 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 intend to advance our cell therapy business through our subsidiary, AgenTus Therapeutics, eventually with separate funding. Moving intellectual property assets into AgenTus Therapeutics in foreign jurisdictions could have adverse tax consequences, and there is no guarantee that we will be able to attract external funding. Moreover, even if the business is funded, there is no guarantee that it will be successful.

We are currently in the process of pursuing external funding and partnership opportunities to advance AgenTus Therapeutics, but Agenus is currently funding such operations. There is no guarantee that external funding will be available. If funding is available, there is no guarantee that it will be on attractive or acceptable terms, or that it will be adequate to advance the business to an inflection point for additional funding, including any potential initial public offering. Similarly, there is no guarantee that partnership opportunities will be available on attractive terms, if at all. If external funding is not available, we may be forced to either retire these programs or continue to use internal resources to advance them. In addition, our cell therapy assets are pre-clinical. Even if adequate

funding and partnership opportunities are available, there is no guarantee that we or AgenTus Therapeutics will be successful in advancing one or more product candidates into and through clinical development. In addition, most of the efforts being made on behalf of AgenTus Therapeutics are being led by a separate AgenTus chief executive officer, utilizing several members of Agenus' management team and Agenus' internal G&A resources. The current structure could distract management and divert Agenus resources from Agenus' own core pipeline and programs.

The cell therapy assets necessary to enable AgenTus Therapeutics are currently owned or controlled by Agenus in the United States and Switzerland. In connection with capitalizing AgenTus Therapeutics, these assets will be transferred or licensed to new legal entities within the United States and Europe and potentially others. Transferring these assets or licensing them on an exclusive basis would require that taxes be paid based on the fair market value of the assets. We may not have adequate net operating losses to offset any tax liabilities in the relevant jurisdictions. Moreover, we have previously disclosed our interest in potentially issuing a tax-free dividend to Agenus' stockholders in the form of stock of AgenTus Therapeutics. There is no guarantee that any such dividend will be tax-free or that it will be issued at all, or the timing thereof. If we issue a dividend in the form of stock, there could be adverse tax consequences for certain of our stockholders.

Natural or man-made calamities could disrupt our business and materially adversely affect our operations.

Our operations, and those of our CROs, CMOs, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could prevent us from using all or a significant portion of our facilities, and, 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. 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. We rely in part on third-party manufacturers to produce and process some of our product candidates. Our ability to obtain some of our clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

We own an antibody pilot plant manufacturing facility and lease additional office space in Berkeley, CA. This location is in an area of seismic activity near active earthquake faults and active wildfire activity. In October 2019, Pacific Gas and Electric Company ("PG&E"), the utility supplier for our Berkeley, CA facility provided notice to all residents and businesses in Alameda County (where Berkeley, CA is located) that it would shut off power to the county for a multiday period due to the risk of wildfires. The emergency backup generators located at our Berkeley, CA facility are not able to power the entire facility and only have enough fuel capacity to provide emergency power for a few hours. We have plans in place to maintain the fuel supply of our generators in the event of an extended power interruption, but there is no guarantee that such plans will be adequate to maintain emergency power at our Berkeley, CA facility. In addition, many of our employees reside in Alameda County and may be unable to leave home for the duration of any power shut off. While PG&E did not shut off power to our facility in October 2019, PG&E may do so in the future on short notice.

We are dependent upon our collaboration with Gilead to further develop and commercialize certain of our antibody programs. If we or Gilead 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 December 2018, we entered into a series of agreements with Gilead to collaborate on the development and commercialization of up to five novel I-O therapies. Pursuant to the collaboration agreements, Gilead received (i) worldwide exclusive rights to AGEN1423 (now GS-1423), a bispecific antibody, (ii) the exclusive option to license exclusively AGEN1223, a bispecific antibody, and AGEN2373, a monospecific antibody, and (iii) the right of first negotiation for two additional, undisclosed programs. Gilead has the exclusive right to develop and commercialize GS-1423, and we are eligible to receive potential development and commercial milestones of up to \$552.5 million in the aggregate, as well as tiered royalty payments on aggregate net sales ranging from the high single digit to mid-teen percent, subject to certain reductions under certain circumstances. Accordingly, the timely and successful completion by Gilead of clinical development and commercialization activities will significantly affect the timing and amount of any milestones or royalties we may receive for this program. Gilead's activities will be influenced by, among other things, the efforts and allocation of resources by Gilead, which we cannot control. With respect to the option programs, we are responsible for developing each program up to the option decision point, at which time Gilead may acquire exclusive rights to each program on option exercise. During the option period, we are eligible to receive milestones of up to \$30.0 million in the aggregate. If Gilead exercises an option, it would be required to pay an upfront license exercise fee of \$50.0 million for each option that is exercised. Following any option exercise, we would be eligible to receive additional development and commercial milestones of up to \$520.0 million in the aggregate.

for each such option program, as well as tiered royalty payments on aggregate net sales ranging from the high single digit to mid-teen percent, subject to certain reductions under certain circumstances. For either, but not both, of the option programs, we will have the right to opt-in to share Gilead's development and commercialization costs in the United State for such option program in exchange for a profit (loss) share on a 50:50 basis and revised milestone payments. There is no guarantee that we will receive any fees, milestones or royalties from Gilead. Similarly, there is no guarantee that we will be able to successfully advance the option programs to the option decision point, and, even if we do, there is no guarantee that Gilead will exercise its option for either program. If Gilead does not exercise its option for either of the option programs, there is no guarantee that we will be able to advance any such program ourselves or with another partner. If we wanted to partner either of the programs that are subject to a right of first negotiation with a third party other than Gilead, such discussions could be delayed and ultimately terminated as a result of Gilead's right of first negotiation. Accordingly, we may not be able to partner either of these programs with a third party other than Gilead on attractive terms, if at all.

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

- Gilead may terminate any of the agreements for convenience upon 90 days' notice;
- Gilead has control over the development of GS-1423, and it will have control over the option programs if and when it exercises its options;
- Gilead 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 GS-1423 or the option programs (if exercised); and
- Gilead may choose not to develop and commercialize GS-1423 or the option programs (if exercised) in all relevant markets or for one or more indications, if at all.

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

In February 2017, we amended the terms of our collaboration agreement with Incyte to, among other things, convert the GTR and OX40 programs from profit-share programs, where we and Incyte shared all costs and profits on a 50:50 basis, to royalty-bearing programs, where Incyte funds 100% of the costs and we are eligible for potential milestones and royalties. In addition, the profit-share programs relating to TIGIT and one undisclosed target were removed from the collaboration, with TIGIT reverting to Agenus and the undisclosed target reverting to Incyte, each with a potential 15% royalty to the other party on any global net sales. The remaining three royalty-bearing programs in the collaboration targeting TIM-3, LAG-3 and one undisclosed target remain unchanged, and there are no more profit-share programs under the collaboration. For each program in the collaboration, we serve as the lead for pre-clinical development activities through the filing of an IND, and Incyte has exclusive rights and all decision-making authority for manufacturing, clinical development and commercialization. Accordingly, the timely and successful completion by Incyte of clinical development and commercialization activities will significantly affect the timing and amount of any royalties or milestones we may receive under the collaboration agreement. In addition, in March 2017 we transferred manufacturing responsibilities to Incyte for antibodies under that collaboration. Any delays or weaknesses in the ability of Incyte to successfully manufacture could have an adverse impact on those programs. Incyte's activities will be influenced by, among other things, the efforts and allocation of resources by Incyte, which we cannot control. If Incyte does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, manufacturing, regulatory approval, and commercialization efforts related to antibodies under the collaboration could be delayed or terminated. There can be no assurance that any of the development, regulatory or sales milestones will be achieved, or that we will receive any future milestone or royalty payments under the collaboration agreement. In September 2018, we sold to XOMA a portion of the royalties and milestones we are entitled to receive from Incyte.

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

- Incyte may terminate the agreement or any individual program for convenience upon 12 months' notice;
- Incyte has control over the development of assets in the collaboration;
- Incyte may change the focus of its development and commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to our collaboration;
- Incyte may choose not to develop and commercialize antibody products, if any, in all relevant markets or for one or more indications, if at all; and

- If Incyte is acquired during the term of our collaboration, the acquirer may have competing programs or different strategic priorities that could cause it to reduce its commitment to our collaboration.

If Incyte terminates our collaboration agreement, we may need to raise additional capital and may need to identify and come to agreement with another collaboration partner to advance certain of our antibody programs. Even if we are able to find another partner, this effort could cause delays in our timelines and/or additional expenses, which could adversely affect our business prospects and the future of our antibody product candidates under the collaboration.

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

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

Risks Related to Regulation of the Biopharmaceutical Industry

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

Drug development, including non-clinical testing and clinical development, and the process of obtaining regulatory approvals for new therapeutic products, is lengthy, expensive, and uncertain. For example, as of September 30, 2019, we had spent more than 20 years and \$940.7 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 landscapes in the fields of antibody, vaccine, adjuvant and adoptive cell therapy development, manufacture and commercialization are crowded. For example, we are aware of third party patents directed to methods for identifying and producing therapeutic products such as antibodies, vaccines, adjuvants and adoptive cell therapies. We are also aware of third party patents directed to products targeting numerous antigens for which we also seek to identify, develop, and commercialize products. For example, some patents claim products based on competitive binding with existing products, some claim products based on specifying sequence or other structural information, and some claim various methods of discovery, production, or use of such products.

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 products identified by us as therapeutic candidates. As we discover and develop our candidates, 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 30 issued United States patents and approximately 40 issued foreign patents. We also own, co-own or have exclusive rights to approximately 35 pending United States patent applications and approximately 250 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. 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. Notably, the Leahy-Smith America Invents Act, or the American Invents Act (“AIA”), introduced new procedures, including inter partes review and post grant review. These procedures may be used by competitors to challenge the scope and/or validity of our patents, including those patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges.

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

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

- we or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;
- third parties may initiate opposition proceedings, post-grant review, inter partes review, or reexamination proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and/or licensors or licensees to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us;
- the USPTO may initiate an interference or derivation proceeding between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our collaborators and/or licensors or licensees to participate in an interference or derivation proceeding to determine the priority of invention, which could jeopardize our patent rights; or

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

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

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

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

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- 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 landscapes around the discovery, development, manufacture and commercial use of our product candidates are 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 enacted and implemented wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection

available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, AIA was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and also affect patent litigation. The USPTO has developed 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 going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

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

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

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

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

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

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

Risks Related to Litigation

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

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

We maintain property and general commercial insurance coverage as well as errors and omissions insurance policies. This insurance coverage may not be sufficient to cover us for all potential claims or a claim may be made for which we are not covered by insurance, in which case the damages could have a material and adverse effect on the business.

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

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

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

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

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

We face an inherent risk of product liability exposure related to testing our product candidates in human clinical trials and manufacturing antibodies in our Berkeley, CA facility and may face even greater risks if we ever sell products commercially. An individual may bring a product liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. Product liability claims may result in:

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

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

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

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

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

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

Risks Related to our Common Stock

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

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us without the consent of our Board of Directors. Our certificate of incorporation provides for a staggered board and removal of directors only for cause. Accordingly, stockholders may elect only a minority of our Board at any annual meeting, which may have the effect of delaying or preventing changes in management. In addition, under our certificate of incorporation, our Board of Directors may issue additional shares of preferred stock and determine the terms of those shares of stock without any further action by our stockholders.

Our issuance of additional preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock and thereby effect a change in the composition of our Board of Directors. Our certificate of incorporation also provides that our stockholders may not take action by written consent. Our bylaws require advance notice of stockholder proposals and director nominations and permit only our president or a majority of the Board of Directors to call a special stockholder meeting. These provisions may have the effect of preventing or hindering attempts by our stockholders to replace our current management. In addition, Delaware law prohibits a corporation from engaging in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our Board of Directors may use this provision to prevent changes in our management. Also, under applicable Delaware law, our Board of Directors may adopt additional anti-takeover measures in the future.

Our stock has historically had low trading volume, and its public trading price has been volatile.

During the period from our initial public offering on February 4, 2000 to September 30, 2019, and the nine months ended September 30, 2019, the closing price of our common stock has fluctuated between \$1.59 (or \$0.27 pre-reverse stock split) and \$315.78 (or \$52.63 pre-reverse stock split) per share and \$2.17 and \$3.73 per share, respectively. The average daily trading volume for the nine months ended September 30, 2019 was approximately 1,189,006 shares, while the average daily trading volume for the year ended December 31, 2018 was approximately 1,538,510. 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 November 1, 2019, we had 137,361,477 shares of common stock outstanding. All of these shares, except 11,111,111 shares of common stock sold to Gilead in January 2019, 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 36,000,000 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 667,000 shares of common stock under our Employee Stock Purchase Plan, to permit the sale of 425,000 shares of common stock under our Directors' Deferred Compensation Plan, to permit the sale of approximately 31,100,319 shares of common stock pursuant to various private placement agreements and to permit the sale of up to 50,000,000 shares of our common stock pursuant to our At Market Issuance Sales Agreement. As of the date of filing, an aggregate of approximately 73,449,779 of these shares remained available for sale. In October 2018, we completed a private placement of 18,459 shares of Series C-1 convertible preferred stock, convertible into 18,459,000 shares of common stock. The resale of all 18,459,000 shares of common stock underlying the 18,459 shares of Series C-1 convertible preferred stock was registered with the SEC pursuant to a Registration Statement on Form S-3 filed with the SEC on November 8, 2018 and declared effective on December 10, 2018. As part of our collaboration with Gilead, we completed a private placement of 11,111,111 shares of common stock in January 2019, and on October 25, 2019, we filed a Registration Statement on Form S-3 to register the resale of these shares by Gilead, as required under our agreement. As of the date of this filing, such registration statement has not yet been declared effective by the SEC and Gilead is also prohibited from selling the shares before January 2020. In connection with our acquisition of 4-AB in February 2014, we are obligated to make contingent milestone payments to the former shareholders of 4-AB, payable in cash or shares of our common stock at our option, as follows (i) \$10.0 million upon our market capitalization exceeding \$750.0 million for 30 consecutive trading days prior to the earliest of (a) February 12, 2024, (b) the sale of 4-AB or (c) the sale of Agenus and (ii) \$10.0 million upon our market capitalization exceeding \$1.0 billion for 30 consecutive trading days prior to the earliest of (a) February 12, 2024, (b) the sale of 4-AB or (c) the sale of Agenus. In connection with our acquisition of PhosImmune in December 2015, we issued 1,631,521 shares of our common stock to the shareholders of PhosImmune and other third parties having a fair market value of approximately \$7.4 million at closing. In addition, we may be obligated in the future to pay certain contingent milestones payments, payable at our election in cash or shares of our common stock of up to \$35.0 million in the aggregate. If we elect to pay any of these contingent milestones in shares, we are obligated to file registration statements covering any such shares. The market price of our common stock may decrease based on the expectation of such sales.

As of September 30, 2019, warrants to purchase approximately 1,400,000 shares of our common stock with a weighted average exercise price per share of \$5.10 were outstanding.

As of September 30, 2019, options to purchase 24,890,137 shares of our common stock with a weighted average exercise price per share of \$3.62 were outstanding. These options are subject to vesting that occurs over a period of up to four years following the date of grant. As of September 30, 2019, we had 12,710,229 vested options and 2,117,285 non-vested shares outstanding.

As of September 30, 2019, our outstanding shares of Series A-1 Convertible Preferred Stock were convertible into 333,333 shares of our common stock.

As of September 30, 2019, our outstanding shares of Series C-1 Convertible Preferred Stock were convertible into 12,459,000 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, 2018, our procedures are subject to the risk that our controls may become inadequate because of changes in conditions or as a result of a deterioration in compliance with such procedures. No assurance is given that our procedures and processes for detecting weaknesses in our internal control over financial reporting will be effective.

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

Item 6. Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 31.1 | <u>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.</u> |
| 31.2 | <u>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.</u> |
| 32.1 | <u>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.</u> |
| 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 |

AGENUS INC.

SIGNATURES

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

Date: November 7, 2019

AGENUS INC.

/s/ CHRISTINE M. KLASKIN

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

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: November 7, 2019

/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: November 7, 2019

/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 September 30, 2019 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: November 7, 2019

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.