UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2018

or

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

Commission File Number 001-35443

ARGOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**56-2110007**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4233 Technology Drive	
Durham, North Carolina	**27704**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (919) 287-6300

No changes
(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of May 8, 2018, there were 10,586,661 shares outstanding of the registrant's common stock, par value $0.001 per share.

ARGOS THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q
For the Quarterly Period Ended March 31, 2018

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Unless otherwise indicated, all information in this Quarterly Report on Form 10-Q gives effect to a 1-for-20 reverse stock split of Argos's outstanding common stock that became effective on January 18, 2018.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ARGOS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	December 31, 2017	March 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 15,188,838	$ 17,016,435
Assets held for sale	600,000	—
Prepaid expenses	1,252,134	1,341,941
Other receivables	143,449	457,237
Total current assets	17,184,421	18,815,613
Property and equipment, net	3,582,323	3,337,535
Other assets	11,020	11,020
Total assets	$ 20,777,764	$ 22,164,168
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 970,650	$ 1,001,649
Accrued expenses	1,263,867	2,916,674
Notes payable	4,972,649	4,976,269
Current portion of other convertible notes	2,350,000	2,130,000
Total current liabilities	9,557,166	11,024,592
Convertible note payable to related party	6,302,959	6,443,507
Long-term portion of other convertible notes	5,830,583	5,580,584
Deferred liabilities	8,153,500	2,276,000
Warrants	167,636	18,534
Commitments	—	—
Stockholders' deficit		
Preferred stock $0.001 par value; 5,000,000 shares authorized as of December 31, 2017 and March 31, 2018; 0 shares issued and outstanding as of December 31, 2017 and March 31, 2018	—	—
Common stock $0.001 par value; 200,000,000 shares authorized as of December 31, 2017 and March 31, 2018; 5,906,620 and 10,224,778 shares issued and outstanding as of December 31, 2017 and March 31, 2018	5,907	10,225
Accumulated other comprehensive loss	(125,864)	(128,826)
Additional paid-in capital	363,450,204	371,615,148
Accumulated deficit	(372,564,327)	(374,675,596)
Total stockholders' deficit	(9,234,080)	(3,179,049)
Total liabilities and stockholders' deficit	$ 20,777,764	$ 22,164,168

The accompanying notes are an integral part of these condensed consolidated financial statements.

ARGOS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended March 31,	
	2017	**2018**
Revenue	$ 105,259	$ 5,932,933
Operating expenses		
Research and development	7,913,829	5,545,065
General and administrative	3,962,891	2,499,002
Impairment of property and equipment	27,204,349	—
Restructuring costs	5,008,292	—
Total operating expenses	44,089,361	8,044,067
Operating loss	(43,984,102)	(2,111,134)
Other income (expense)		
Interest income	30,578	18,045
Interest expense	(728,433)	(148,937)
Gain on early extinguishment of debt	249,458	—
Change in fair value of warrant liability	20,357,323	149,102
Other expense	(4,905)	(18,345)
Other income (expense), net	19,904,021	(135)
Net loss	$ (24,080,081)	$ (2,111,269)
Net loss per share, basic and diluted	$ (11.66)	$ (0.28)
Weighted average common shares outstanding, basic and diluted	2,065,676	7,618,806

The accompanying notes are an integral part of these condensed consolidated financial statements.

ARGOS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended March 31,	
	2017	**2018**
Net loss	$ (24,080,081)	$ (2,111,269)
Other comprehensive gain		
Foreign currency translation gain (loss)	1,325	(2,962)
Total comprehensive loss	$ (24,078,756)	$ (2,114,231)

The accompanying notes are an integral part of these condensed consolidated financial statements.

ARGOS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Three Months Ended March 31,	
	2017	**2018**
Cash flows from operating activities		
Net loss	$ (24,080,081)	$ (2,111,269)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	244,495	220,815
Share-based compensation expense	3,647,671	715,734
Gain on early extinguishment of debt	(249,458)	—
Impairment loss on property and equipment	27,204,349	—
Decrease in fair value of warrant liability	(20,357,323)	(149,102)
Loss on disposal of equipment	13,347	18,345
Interest accrued on long-term debt	351,102	148,681
Changes in operating assets and liabilities:		
Prepaid expenses and other receivables	(594,525)	(103,596)
Accounts payable	75,197	30,998
Accrued expenses	(3,194,392)	1,652,807
Current portion of restructuring obligation	2,492,557	—
Long-term deferred liabilities	(27,500)	(5,877,500)
Long-term portion of manufacturing research and development obligation	90,340	—
Net cash used in operating activities	(14,384,221)	(5,454,087)
Cash flows from investing activities		
Purchase of property and equipment	(3,542,597)	—
Proceeds from sale of property and equipment	1,460,615	305,584
Net cash (used in) provided by investing activities	(2,081,982)	305,584
Cash flows from financing activities		
Net proceeds from sale of common stock and warrants	—	7,453,530
Proceeds from employee stock purchase plan	8,369	—
Payment on capital lease obligations	(33,514)	—
Payments on notes payable	(23,643,786)	(474,513)
Net cash (used in) provided by financing activities	(23,668,931)	6,979,017
Effect of exchange rates changes on cash	1,309	(2,917)
Net (decrease) increase in cash and cash equivalents	(40,133,825)	1,827,597
Cash, cash equivalents and restricted cash		
Beginning of period	53,713,376	15,188,838
End of period	$ 13,579,551	$ 17,016,435
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 468,839	$ 287
Supplemental disclosure of noncash investing and financing activities		
Issuance of warrants in exchange for early extinguishment of debt	$ 87,100	$ —
Purchases of property and equipment included in accounts payable and accrued expenses	$ 2,381,502	$ —
Sale of property and equipment included in other receivables	$ —	$ 300,000

The accompanying notes are an integral part of these condensed consolidated financial statements.

1. Organization and Basis of Presentation

Argos Therapeutics, Inc. (the "Company"), was incorporated in the State of Delaware on May 8, 1997. The Company is an immuno-oncology company focused on the development and commercialization of individualized immunotherapies for the treatment of cancer and infectious diseases based on its proprietary precision immunotherapy technology platform called Arcelis.

In April 2018 the Company terminated its development program for rocapuldencel-T, which it had been developing for the treatment of metastatic renal cell carcinoma, or mRCC, and other cancers. Based on a review of the status of its internal programs, resources and capabilities, the Company is exploring a wide range of strategic alternatives that may include a potential merger or sale of the Company, among other potential alternatives. The Company has retained Stifel, Nicolaus & Company, Incorporated ("Stifel") to serve as its financial advisor in the process. There can be no assurance that the Company will be able to enter into such a transaction or transactions on a timely basis, on terms that are favorable to the Company, or at all.

Prior to April 2018, the Company had been conducting a pivotal Phase 3 clinical trial of rocapuldencel-T in combination with sunitinib / standard of care for the treatment of newly diagnosed mRCC ("the ADAPT trial"). In February 2017, the independent data monitoring committee ("IDMC"), for the ADAPT trial recommended that the trial be discontinued for futility based on its planned interim data analysis. The IDMC concluded that the trial was unlikely to demonstrate a statistically significant improvement in overall survival in the combination treatment arm, utilizing the intent-to-treat population at the pre-specified number of 290 events (deaths), the original primary endpoint of the study. Notwithstanding the IDMC's recommendation, the Company determined to continue to conduct the trial while it analyzed interim data from the trial. Following a meeting with the U.S. Food and Drug Administration (the"FDA"), the Company determined to continue the ADAPT trial until at least the pre-specified number of 290 events occurred, and to submit to the FDA a protocol amendment to increase the pre-specified number of events for the primary analysis of overall survival in the trial beyond 290 events. In April 2018, the Company submitted a protocol amendment to the FDA that included an amended primary endpoint analysis with four co-primary endpoints. Subsequently in April 2018, the Company conducted another interim analysis of the data from the ADAPT trial, at which time 51 new events (deaths) had occurred subsequent to the February 2017 interim analysis. Based upon review of the interim data from this analysis, the Company determined that it was unlikely to achieve the endpoints if the trial were to be continued and decided to discontinue the ADAPT clinical trial. The Company does not expect to resume clinical development of rocapuldencel-T.

The Company is developing AGS-004, also an Arcelis-based product candidate, for the treatment of HIV. The Company has completed Phase 1 and Phase 2 trials funded by government grants and a Phase 2b trial that was funded in full by the National Institutes of Health ("NIH") and the National Institute of Allergy and Infectious Diseases ("NIAID"). The Company is currently supporting an ongoing investigator-initiated clinical trial of AGS-004 in adult HIV patients evaluating the use of AGS-004 in combination with a latency reversing drug, for HIV eradication, and plans to support an investigator-initiated Phase 2 clinical trial of AGS-004 evaluating AGS-004 for long-term viral control in pediatric patients provided that results from its ongoing trial in adult HIV patients are favorable and government funding is available.

Basis of Presentation and Going Concern

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and with the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial information. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. Accordingly, the statements do not include all information and footnotes required by U.S. GAAP for annual consolidated financial statements. In the opinion of management, such interim financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair statement of financial position, results of operations and cash flows for such periods. The results for the three months ended March 31, 2018 are not necessarily indicative of the results that may be expected for the year ended December 31, 2018 or future operating periods. The information included in these interim financial statements should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Quarterly Report on Form 10-Q and the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

The Company's consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has evaluated principal conditions and events that may raise substantial doubt about its ability to continue as a going concern within one year from the date that these financial statements are issued. The Company has incurred losses in each year since inception and as of March 31, 2018, had an accumulated deficit of $374.7 million. Also, as of March 31, 2018, the Company's current assets totaled $18.8 million compared with current liabilities of $11.0 million, and the Company had cash and cash equivalents of $17.0 million. The Company's primary use of cash is to fund its operating expenses, which consist principally of research and development expenditures necessary to advance its product candidates. The Company has evaluated its expected, probable future cash flow needs and has determined that it expects to incur substantial losses in the future as it conducts planned operating activities. Based upon its current and projected cash flow, the Company concluded there is substantial doubt about its ability to continue as a going concern within one year from the date that these financial statements are issued. The financial statements for the three months ended March 31, 2018 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

On March 3, 2017, the Company entered into a payoff letter with Horizon Technology Finance Corporation and Fortress Credit Co LLC (the "Lenders") under a venture loan and security agreement (the "Loan Agreement") pursuant to which the Company paid, on March 6, 2017, a total of $23.1 million to the Lenders, representing the principal balance and accrued interest outstanding under the Loan Agreement in repayment of the Company's outstanding obligations under the Loan Agreement. In addition, the Company issued to the Lenders five year warrants to purchase an aggregate of 5,000 shares of common stock at an exercise price of $26.00 per share in consideration of the Lenders acceptance of $23.1 million as payment in full. Upon the payment of the $23.1 million and the issuance of the warrants pursuant to the payoff letter, all of the Company's outstanding indebtedness and obligations to the Lenders under the Loan Agreement were paid in full, and the Loan Agreement and the notes thereunder were terminated.

In March 2017, the Company announced that its board of directors approved a workforce action plan designed to streamline operations and reduce operating expenses. The Company recognized $1.2 million in severance costs, all of which was paid as of December 31, 2017. The Company also recognized $3.2 million in stock-based compensation expense from the acceleration of vesting of stock options and restricted stock held by the terminated employees during the year ended December 31, 2017.

In June 2017, the Company raised net proceeds of $6.0 million through the issuance of a secured convertible note to Pharmstandard International S.A. ("Pharmstandard"), a collaborator and the Company's largest stockholder, in the aggregate principal amount of $6.0 million.

In August 2017, the Company entered into an agreement with Medpace, Inc. ("Medpace"), regarding $1.5 million in deferred fees that the Company owes Medpace for contract research and development services. Under the agreement, the Company paid $0.85 million of the amount during the third of quarter 2017 and paid the balance in April 2018.

In September 2017, the Company entered into a satisfaction and release agreement (the "Satisfaction and Release Agreement") with Invetech Pty Ltd ("Invetech"). Under the Invetech Satisfaction and Release Agreement, the Company agreed to make, issue and deliver to Invetech (i) a cash payment of $0.5 million, (ii) 57,142 shares of common stock and (iii) an unsecured convertible promissory note in the original principal amount of $5.2 million, on account of and in full satisfaction and release of all of the Company's payment obligations to Invetech arising under the Company's development agreement with Invetech (the "Invetech Development Agreement") prior to the date of the Invetech Satisfaction and Release Agreement, including the Company's obligation to pay Invetech up to a total of $8.3 million in deferred fees, bonus payments and accrued interest.

In November 2017, the Company entered into a satisfaction and release agreement (the "Saint-Gobain Satisfaction and Release Agreement") with Saint-Gobain Performance Plastics Corporation ("Saint-Gobain"). Under the Saint-Gobain Satisfaction and Release Agreement, the Company agreed to make, issue and deliver to Saint-Gobain (i) a cash payment of $0.5 million, (ii) 34,499 shares of common stock, (iii) an unsecured convertible promissory note in the original principal amount of $2.4 million, and (iv) certain specified equipment originally provided to the Company by Saint-Gobain under the development agreement with Saint-Gobain, or the ("Saint-Gobain Development Agreement"), on account of and in full satisfaction and release of all of the Company's payment obligations to Saint-Gobain arising under the Saint-Gobain Development Agreement, prior to the date of the Saint-Gobain Satisfaction and Release Agreement, including the development fees and charges. In connection with entering into the Saint-Gobain Satisfaction and Release Agreement, the Company and Saint-Gobain entered into an amendment to the Saint-Gobain Development Agreement to extend the term to December 31, 2019.

From June 2017 through December 31, 2017, the Company raised proceeds of $15.5 million through the issuance of common stock in an at-the-market offering under its sales agreement with Cowen & Company, LLC ("Cowen"). As of March 31, 2018, an additional $7.5 million of proceeds was raised subsequent to December 31, 2017. The Company raised an additional $21,000 of proceeds between April 1, 2018 and May 8, 2018. However, as a result of the delisting of its common stock from The Nasdaq Capital Market in April 2018, the Company does not expect to sell any additional shares under the sales agreement.

As of March 31, 2018, the Company had cash and cash equivalents of $17.0 million. The Company does not currently have sufficient cash resources to pay all of its accrued obligations in full or to continue its business operations beyond the end of 2018. As a result, in order to continue to operate its business beyond that time, the Company will need to raise additional funds. However, there can be no assurance that the Company will be able to generate funds on terms acceptable to the Company, on a timely basis, or at all.

In light of the termination of the ADAPT trial and the Company's cash resources, and based on a review of the status of its internal programs, resources and capabilities, the Company is exploring a wide range of strategic alternatives that may include a potential merger or sale of the Company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some of its assets or proprietary technologies. The Company has retained Stifel to serve as its financial advisor in the process. There can be no assurance that the Company will be able to enter into such a transaction or transactions on a timely basis, on terms that are favorable to the Company, or at all. If the Company is unable to successfully conclude a strategic transaction, the Company may determine to dissolve and liquidate its assets or seek protection under the bankruptcy laws. If the Company decides to dissolve and liquidate its assets or to seek protection under the bankruptcy laws, it is unclear to what extent the Company will be able to pay its obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to the Company's stockholders.

On April 23, 2018, the Company received a notification from The Nasdaq Stock Market LLC indicating that, because the Company had indicated that it would be unable to meet the stockholders' equity requirement for continued listing as of the April 24, 2018 deadline that had been set by the Nasdaq Hearing Panel, the Nasdaq Hearing Panel had determined to delist the Company's common stock from The Nasdaq Capital Market and to suspend trading in its common stock effective at the open of business on April 25, 2018. Following such delisting, the Company transferred its common stock to the OTCQB® Venture Market.

The condensed consolidated financial statements include the accounts of the Company and DC Bio Corp., the Company's Canadian wholly-owned subsidiary, an unlimited liability corporation incorporated in the Province of Nova Scotia and Argos Therapeutics (Europe) S.à.r.l., the Company's wholly-owned subsidiary, a société anonyme à responsabilité limitée incorporated in Luxembourg. Significant intercompany transactions and accounts have been eliminated.

On January 18, 2018, the Company effected a one-for-twenty reverse split of its common stock. All references to shares of common stock outstanding, average number of shares outstanding and per share amounts in these consolidated financial statements and notes to consolidated financial statements have been restated to reflect the reverse split on a retroactive basis.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Significant Accounting Policies

There have been no material changes in our significant accounting policies as of and for the three months ended March 31, 2018, as compared with the significant accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2017, except as described below under Revenue Recognition and Recently Adopted Accounting Standards.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less as of the date of purchase to be cash equivalents. Cash deposits are all in financial institutions in the United States of America, Canada and the European Union. The Company maintains cash in accounts which are in excess of federally insured limits. As of December 31, 2017 and March 31, 2018, $14.7 million and $16.5 million, respectively, in cash and cash equivalents was uninsured.

Revenue Recognition

An important part of the Company's business strategy has been to enter into arrangements with third parties both to assist in the development and commercialization of its product candidates, particularly in international markets, and to in-license product candidates in order to expand its pipeline. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development and regulatory objectives, and royalties on product sales. The Company has adopted the provisions of the Financial Accounting Standards Board ("FASB"), Codification Topic 606, Revenue from Contracts with Customers ("Topic 606"). This guidance supersedes the provisions of FASB Codification Topic 605, Revenue Recognition ("Topic 605").

Effective January 1, 2018, the Company adopted ASC 606, using the modified retrospective transition method. Under this method, results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with Topic 605. The Company applied the modified retrospective transition method to contracts that were not completed as of January 1, 2018, the effective date of adoption for ASC 606. The contracts to which the Company is a party that were not completed as of January 1, 2018 are the multi-year research contract with the NIH and NIAID (see Note 10) and the collaboration agreements included in Note 11. The Company assessed the potential effects to the consolidated financial statements and retained earnings of adoption of the modified retrospective transition method and has concluded that, upon adoption of the new standard, there was no impact on the Company's consolidated financial statements and there was no difference in what would have been recognized under Topic 605 or Topic 606 for the three months ended March 31, 2018.

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

If the Company is involved in a steering committee as part of a multiple element arrangement, the Company assesses whether its involvement constitutes a performance obligation or a right to participate. Steering committee services that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations.

If the Company cannot reasonably measure its progress toward complete satisfaction of a performance obligation because it lacks reliable information that would be required to apply an appropriate method of measuring progress, but the Company can reasonably estimate when the performance obligation ceases or the remaining obligations become inconsequential and perfunctory, then revenue is not recognized until the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

Development Milestone Payments. At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Reimbursement of Costs. Reimbursement of research and development costs by third party collaborators is recognized as revenue over time provided the Company has determined that it transfers control (i.e. performs the services) of a service over time and, therefore, satisfies a performance obligation according to the provisions outlined in the FASB Codification Topic 606-10-25-27, Revenue Recognition.

Royalty Revenue. For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue resulting from any of its collaboration agreements.

Deferred Revenue. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying condensed consolidated balance sheets. Short-term deferred revenue would consist of amounts that are expected to be recognized as revenue within the next fiscal year. Amounts that the Company expects will not be recognized in the next fiscal year would be classified as long-term deferred revenue.

Summary. During the three months ended March 31, 2017, the Company recognized $0.1 million of contract revenue under the contract with the NIH and NIAID and $27,500 of deferred revenue as revenue under the license agreement with Lummy (Hong Kong) Co. Ltd. (“Lummy HK”). During the three months ended March 31, 2018, the Company recognized $5.8 million of deferred milestone revenue as revenue under the license agreement with Medinet Co., Ltd and its wholly-owned subsidiary, MEDcell Co., Ltd. (together "Medinet"), $30,000 of contract revenue under the contract with the NIH and NIAID, $27,500 of deferred revenue as revenue and $14,000 in reimbursement of costs under the Lummy license agreement and $11,000 of grant revenue.

For additional discussion of accounting for collaboration revenues, see Note 11.

With respect to each of the foregoing areas of revenue recognition, the Company exercises significant judgment in determining whether an arrangement contains multiple elements, and, if so, how much revenue is allocable to each element. In addition, the Company exercises its judgment in determining when its significant obligations have been met under such agreements and the specific time periods over which it recognized revenue, such as non-refundable, up-front license fees. To the extent that actual facts and circumstances differ from the Company’s initial judgments, revenue recognition with respect to such transactions would change accordingly and any such change could affect the Company’s reported financial results.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). The provisions of ASU 2016-02 set out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). This new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted using guidance similar to existing guidance for operating leases. Topic 842 supersedes the previous lease standard, Topic 840 *Leases*. This guidance will be effective for annual periods and interim periods within those annual periods beginning after December 15, 2018, and will be effective for the Company on January 1, 2019. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's consolidated financial statements.

Recently Adopted Accounting Standards

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09*, Revenue from Contracts with Customers ("ASU 2014-09")* pertaining to revenue recognition. The primary objective of ASU 2014-09 is for entities to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which an entity expects to be entitled to in exchange for those goods or services. This new standard also requires enhanced disclosures about revenue, provides guidance for transactions that were not previously addressed comprehensively and improve guidance for multiple-element arrangements. Additionally, the FASB issued ASU 2016-10, *Identifying Performance Obligations and Licensing,* which provided additional guidance and clarity on this topic. This new standard is effective for the Company in first quarter of 2018.The two permitted transition methods under ASU 2014-09 are the full retrospective method, in which case the new standard would be applied to each prior period presented and the cumulative effect of applying the standard would be recognized as of the earliest period reported, or the modified retrospective method, in which case the cumulative effect of applying the new standard would be recognized as of the date of initial application. The Company elected the modified retrospective method and there was no impact upon adoption.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force).* This ASU requires changes in the presentation of certain items in the statement of cash flows including but not limited to debt prepayment or debt extinguishment costs; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies and distributions received from equity method investees. This guidance was effective for annual periods and interim periods within those annual periods beginning after December 15, 2017, requires adoption on a retrospective basis and was effective for the Company on January 1, 2018. The Company adopted this standard and there was no impact to the Company's consolidated financial statements upon adoption.

In November 2016, the FASB issued ASU 2016-18, *Restricted Cash* ("ASU 2016-18"). ASU 2016-18 requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and restricted cash. Accordingly, restricted cash will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted ASU 2016-18 during the first quarter of 2018, and the standard has been retrospectively applied to all periods presented. The following provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Condensed Consolidated Balance Sheet to the total of the same such amounts shown in the Condensed Consolidated Statement of Cash Flows as of March 31, 2017:

Cash and cash equivalents	$	11,137,799
Restricted cash included in current assets		2,441,752
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statement of Cash Flows	$	13,579,551

The following provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Condensed Consolidated Balance Sheet to the total of the same such amounts shown in the Condensed Consolidated Statement of Cash Flows as of December 31, 2016:

Cash and cash equivalents	$	52,973,376
Restricted cash included in current assets		740,000
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statement of Cash Flows	$	53,713,376

There was $0 of restricted cash as of December 31, 2017 and March 31, 2018.

2. Fair Value of Financial Instruments

The estimated fair values of all of the Company's financial instruments, excluding long-term debt, approximate their carrying amounts in the consolidated balance sheets as of December 31, 2017 and March 31, 2018.

As of December 31, 2017 and March 31, 2018, the Company held certain assets and liabilities that are required to be measured at fair value on a recurring basis. These assets include money market funds included in cash equivalents. Additionally, as of December 31, 2017 and March 31, 2018, the Company had outstanding warrants recorded as a liability and measured at fair value on a recurring basis. The valuation of these financial instruments uses a three-tiered approach, which requires that fair value measurements be classified and disclosed in one of three tiers. These tiers are: Level 1, defined as quoted prices in active markets for identical assets or liabilities; Level 2, defined as valuations based on observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets, or other inputs that are observable or can be corroborated by observable input data; and Level 3, defined as valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants.

The Company's Level 1 assets consist of money-market funds. The method used to estimate the fair value of the Level 1 assets is based on observable market data, as these money-market funds are publicly-traded. The Company has no Level 2 assets. As of each balance sheet date, observable market inputs may include trade information, broker or dealer quotes, bids, offers or a combination of these data sources.

The Company's warrant liability is classified as a Level 3 financial liability. The fair value of the warrant liability is measured using the Black-Scholes valuation model. Inherent in the Black-Scholes valuation model are assumptions related to expected stock price volatility, expected life, risk-free interest rate and dividend yield (see Note 9).

During the three months ended March 31, 2017 and 2018, there were no transfers between Levels 1, 2, and 3 assets or liabilities.

As of December 31, 2017 and March 31, 2018, these financial instruments and respective fair values were classified as follows:

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2017
Assets				
Money-market funds	$ 4,098,037	$ —	$ —	$ 4,098,037
Total assets at fair value	$ 4,098,037	$ —	$ —	$ 4,098,037
Liabilities				
Warrants	$ —	$ —	$ 167,636	$ 167,636
Total liabilities at fair value	$ —	$ —	$ 167,636	$ 167,636

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of March 31, 2018
Assets				
Money-market funds	$ 4,110,514	$ —	$ —	$ 4,110,514
Total assets at fair value	$ 4,110,514	$ —	$ —	$ 4,110,514
Liabilities				
Warrants	$ —	$ —	$ 18,534	$ 18,534
Total liabilities at fair value	$ —	$ —	$ 18,534	$ 18,534

Change in the fair value of the Company's Level 3 liability for warrants during the three months ended March 31, 2018 was as follows (see Note 9):

Balance as of December 31, 2017	$ 167,636
Change in fair value during the period	(149,102)
Balance as of March 31, 2018	$ 18,534

The amortized cost, gross unrealized holding gains, gross unrealized holding losses, and estimated fair value of money-market funds included in cash and cash equivalents as of December 31, 2017 and March 31, 2018 were as follows:

	As of December 31, 2017			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Money-market funds	$ 4,098,037	$ —	$ —	$ 4,098,037
	$ 4,098,037	$ —	$ —	$ 4,098,037

	As of March 31, 2018			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Money-market funds	$ 4,110,514	$ —	$ —	$ 4,110,514
	$ 4,110,514	$ —	$ —	$ 4,110,514

The fair value of the Company's debt was derived by evaluating the nature and terms of each note, considering the prevailing economic and market conditions as of each balance sheet date and based on the Level 2 valuation hierarchy of the fair value measurements standard using a present value methodology. The fair value of the Company's debt as of December 31, 2017 was approximately $19.1 million compared with its carrying value of $19.5 million (see Note 6). The fair value of the Company's debt as of March 31, 2018 was approximately $18.8 million compared with its carrying value of $19.1 million (see Note 6).

3. Restructuring Activities and Related Impairments of Property and Equipment and Leases

During the three months ended March 31, 2017, the Company had restructuring activities and impairments of property and equipment and leases. These activities were completed during the year ended December 31, 2017 and there were no such activities during the three months ended March 31, 2018. Following is a discussion of these activities during the three months ended March 31, 2017.

As discussed in Note 1, the Company's most advanced product candidate was rocapuldencel-T, which the Company was developing for the treatment of mRCC and other cancers. The Company was conducting a pivotal Phase 3 clinical trial of rocapuldencel-T in combination with sunitinib / standard of care for the treatment of newly diagnosed mRCC. In February 2017, the IDMC for the ADAPT trial recommended that the trial be discontinued for futility based on its planned interim data analysis. The IDMC concluded that the trial was unlikely to demonstrate a statistically significant improvement in overall survival in the combination treatment arm utilizing the intent-to-treat population at the pre-specified number of 290 events (deaths), the primary endpoint of the study. This development triggered a restructuring of the Company's operations and impairments of property and equipment and leases during the three months ended March 31, 2017. As set forth below and in Note 4, the Company recognized restructuring costs of $5.0 million and impairment loss of property and equipment of $27.2 million during the three months ended March 31, 2017.

Workforce Action Plan

On March 10, 2017, the Company enacted a workforce action plan designed to streamline operations and reduce the Company's operating expenses. Under this plan, the Company reduced its workforce by 46 employees (or 38%) from 122 employees to 76 employees in March 2017. The Company recognized $1.0 million in severance costs during the three months ended March 31, 2017. The Company also recognized $2.4 million in stock-based compensation costs from the acceleration of vesting of stock options held by the terminated employees.

CTI Lease Agreement

In January 2017, the Company entered into a ten-year lease agreement with two five-year renewal options for 40,000 square feet of manufacturing and office space at CTI on the Centennial Campus of North Carolina State University in Raleigh, North Carolina. The Company provided a security deposit in the amount of $2.4 million as security for obligations under the lease agreement, which was provided in the form of a letter of credit. In March 2017, the Company initiated discussions with the landlord of the CTI facility regarding the termination of this lease.

In March 2017 the landlord of the CTI facility notified the Company that it was terminating the lease due to nonpayment of invoices for up-fit costs, effective immediately. On March 31, 2017, the Company entered into a termination agreement with the landlord terminating the lease as of March 17, 2017. From the $2.4 million letter of credit, the landlord drew down $0.7 million to cover unpaid construction costs in March 2017 and $1.7 million in April 2017 for lease termination damages and agreed to return $0.1 million in consideration for being able to salvage some of the construction costs. Pursuant to the termination agreement, the Company has no further obligations under the lease. During the quarter ended March 31, 2017, the Company recorded a lease termination fee of $1.6 million which is included in Restructuring costs on the statement of operations and Current portion of restructuring liability on the balance sheet. The Company also recorded an impairment loss on Construction-in-progress on the property of $0.9 million during the three months ended March 31, 2017.

Impairment of Centerpoint Facility and Construction-in-Progress

During the three months ended March 31, 2017, the Company also determined that it would no longer need to develop its facility in Durham County, North Carolina ("Centerpoint"), which the Company intended to be built to house the Company's corporate headquarters and primary manufacturing facility. In November 2017, the Company and TKC Properties, the landlord of the Centerpoint facility, entered into a lease termination agreement in connection with the sale by TKC of the facility to a third party. In the statement of operations for the three months ended March 31, 2017, the Company recorded an impairment loss of $18.3 million for the Construction-in-progress on the property.

4. Property and Equipment and Assets Held for Sale

Property and equipment consist of the following as of December 31, 2017 and March 31, 2018:

	December 31, 2017	March 31, 2018
Office furniture and equipment	$ 639,603	$ 639,603
Computer equipment	989,137	981,661
Computer software	3,146,978	3,146,978
Laboratory equipment	6,050,640	5,914,448
Leasehold improvements	2,435,530	2,435,530
Total property and equipment, gross	13,261,888	13,118,220
Less: Accumulated depreciation and amortization	(9,679,565)	(9,780,685)
Property and equipment, net	$ 3,582,323	$ 3,337,535

The Company reviews its property and equipment for impairment whenever events or changes indicate its carrying value may not be recoverable.

5. Income Taxes

The Company has incurred net operating losses since inception and is forecasting additional losses through December 31, 2018. Therefore, no U.S. Federal, state or foreign income taxes are expected for 2018 and no provision for such taxes has been recorded as of March 31, 2018.

Due to the Company's history of losses since inception, there is not enough evidence at this time to support the conclusion that the Company will generate future income of a sufficient amount and nature to utilize the benefits of the Company's net deferred tax assets. Accordingly, as of December 31, 2017 and March 31, 2018, the Company provided a full valuation allowance against its net deferred tax assets since as of that time, the Company could not assert that it was more likely than not that these deferred tax assets would be realized.

On December 22, 2017, the U.S. government enacted the Tax Act. ASC 740 "Income Taxes" generally requires the effects of the tax law change to be recorded in the period of enactment. However, the SEC staff issued Staff Accounting Bulletin No. 118 to address situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. The Company has recognized the tax impacts in its consolidated financial statements for the year ended December 31, 2017, on a provisional basis. The ultimate impact may differ from these provisional amounts, possibly materially, due to among other things, additional analysis, changes in interpretations and assumptions the Company has made, and additional interpretive regulatory guidance that may be issued. The accounting is expected to be complete when the 2017 U.S. corporate income tax return is filed in 2018. The Company is continuing to evaluate the impact of the recently enacted tax law on its business and consolidated financial statements. For the first quarter of 2018, the Company has not made any measurement-period adjustments related to the provisional amounts recorded as of December 31, 2017.

6. Notes Payable and Gain on Early Extinguishment of Debt

Notes payable consist of the following as of December 31, 2017 and March 31, 2018:

	December 31, 2017	March 31, 2018
Convertible note payable to Pharmstandard, including accrued interest	$ 6,302,959	$ 6,443,507
Convertible note payable to Invetech, including accrued interest	5,845,655	5,645,656
Convertible note payable to Saint-Gobain, including accrued interest	2,334,929	2,064,929
Note payable to Medinet, including accrued interest	4,958,824	4,966,957
Other notes payable	13,825	9,311
Total debt	19,456,192	19,130,360
Less current portion of convertible note payable to Invetech, including accrued interest	(1,300,000)	(1,200,000)
Less current portion of convertible note payable to Saint-Gobain, including accrued interest	(1,050,000)	(930,000)
Less current portion of note payable to Medinet, including accrued interest	(4,958,824)	(4,966,958)
Less current portion of other notes payable	(13,825)	(9,311)
Long-term portion of notes payable and convertible notes payable	$ 12,133,543	$ 12,024,091

Convertible Note Payable to Invetech. On September 22, 2017, the Company entered into the Satisfaction and Release Agreement with Invetech. Under the Satisfaction and Release Agreement, the Company agreed to make, issue and deliver to Invetech (i) a cash payment of $0.5 million, (ii) 57,142 shares of the Company's common stock with a fair value of $0.2 million on the date of issuance and (iii) and unsecured convertible promissory note in the original principal amount of $5.2 million on account of and in full satisfaction and release of all of the Company's payment obligations to Invetech arising under the Invetech prior to the date of the Satisfaction and Release Agreement, including the Company's obligation to pay Invetech up to a total of $8.3 million in deferred fees, bonus payments and accrued interest. As a result, the Company recognized a gain on the early extinguishment of debt of $1.5 million in the Company's statement of operations during the year ended December 31, 2017. Following is a summary the terms of the convertible note payable to Invetech (the "Invetech Note").

The original principal amount of the Invetech Note is $5.2 million. The maturity date for the payment of principal and interest under the Invetech Note is September 30, 2020. The Invetech Note bears interest at a rate of 6.0% per annum, which interest will compound annually. The Invetech Note is not secured by any assets of the Company.

The Company was required to make quarterly installment payments under the Invetech Note for the fiscal quarters ending December 31, 2017 and March 31, 2018, each in an aggregate amount of up to $0.4 million, consisting of (i) cash in the amount of $0.2 million and (ii) if certain specified conditions are met as of the corresponding payment date, up to $0.2 million of shares of the Company's common stock. For the fiscal quarters ending June 30, 2018 through March 31, 2019, the Company is required to make quarterly installment payments, each in an aggregate amount of up to $0.3 million, consisting of (i) cash in the amount of $150,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to $150,000 of shares of the Company's common stock. For the fiscal quarters ending June 30, 2019 through June 30, 2020, the Company is required to make quarterly installment payments, each in an amount of $150,000, payable in cash. The Company made an installment payment of $0.2 million in cash to Invetech in each of the year ended December 31, 2017 and the three months ended March 31, 2018.

The Invetech Note also provides that on the anniversary of the issue date for each of the first three years following the issue date, the outstanding principal amount of the Invetech Note, if any, plus accrued and unpaid interest thereon shall automatically be deemed to be reduced by $250,000, if and only if the Company has paid all debt service payments due under the Invetech Note on or prior to the relevant anniversary date and no event of default, fundamental transaction or change of control, each as defined in the Invetech Note, has occurred on or prior to such anniversary date.

As detailed further below, Invetech may exercise its conversion rights upon: (i) maturity of the Invetech Note, (ii) certain change of control events, and (iii) certain events of default. In each case, the number of shares of common stock issuable upon such complete or partial conversion of the Invetech Note is determined by dividing the portion of the principal and accrued or unpaid interest to be converted by $10.00 per share (as adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction).

• *Maturity of the Invetech Note*. Upon maturity of the Invetech Note or at any time within 75 days of such maturity, Invetech may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.

• *Change of Control*. Upon a change of control pursuant to which Invetech has a redemption right, Invetech may, at its option, elect to convert any amount of the outstanding principal and accrued interest, less any remaining installment payments required to be made in cash, into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.

• *Default*. Upon the occurrence of certain events of default, Invetech may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.

Subject to the aforementioned conversion rights of Invetech, the Company may prepay the Invetech Note in whole or in part at any time without penalty or premium.

Convertible Note Payable to Saint-Gobain. On November 22, 2017, the Company entered into the Saint-Gobain Satisfaction and Release Agreement with Saint-Gobain. Under the Saint Gobain Satisfaction and Release Agreement, the Company agreed to make, issue and deliver to Saint-Gobain (i) a cash payment of $0.5 million, (ii) 34,499 shares of common stock, (iii) an unsecured convertible promissory note in the original principal amount of $2.4 million, and (iv) certain specified equipment originally provided to the Company by Saint-Gobain under the Saint-Gobain Development Agreement, on account of and in full satisfaction and release of all of the Company's payment obligations to Saint-Gobain arising under the Saint-Gobain Development Agreement, prior to the date of the Saint-Gobain Satisfaction and Release Agreement, including the development fees and charges. In connection with entering into the Saint-Gobain Satisfaction and Release Agreement, the Company and Saint-Gobain entered into an amendment to the Saint-Gobain Development Agreement to extend the term to December 31, 2019. Following is a summary the terms of the convertible note payable to Saint-Gobain (the "Saint-Gobain Note").

The original principal amount of the Saint-Gobain Note is $2.4 million. The maturity date for the payment of principal and interest under the Note is September 30, 2020. The Note bears interest at a rate of 6.0% per annum, which interest will compound quarterly. The Note is not secured by any assets of the Company.

The Company was required to make quarterly installment payments for the fiscal quarters ending December 31, 2017 and March 31, 2018, each in an aggregate amount of up to $340,000, consisting of (i) cash in the amount of $200,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to $140,000 of shares of the Company's common stock. For the fiscal quarters ending June 30, 2018 and September 30, 2018, the Company is required to make quarterly installment payments, each in an aggregate amount of up to $245,000, consisting of (i) cash in the amount of $125,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to $120,000 of shares of the Company's common stock. For the fiscal quarters ending December 31, 2018 and March 31, 2019, the Company is required to make quarterly installment payments, each in an aggregate amount of up to $220,000, consisting of (i) cash in the amount of $100,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to $120,000 of shares of the Company's common stock. For the fiscal quarter ending December 31, 2017, March 31, 2018, June 30, 2018, September 30, 2018, December 31, 2018 and March 31, 2019, if the conditions required for the issuance of common stock are not met solely because the stock price of the common stock at the time is less than $4.06 per share (as adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction), then the Company will be required to pay in each such quarter cash equal to 50% of the value of the common stock that would otherwise have been issued. For the fiscal quarters ending June 30, 2019 through June 30, 2020, the Company is required to make quarterly installment payments, each in an amount of $100,000, payable in cash. The Company made an installment payment of $0.3 million in cash to Saint-Gobain in each of the year ended December 31, 2017 and the three months ended March 31, 2018. The payments in common stock were not made in each of the year ended December 31, 2017 and the three months ended March 31, 2018 because the specified conditions were not met.

As detailed further below, Saint-Gobain may exercise its conversion rights upon: (i) maturity of the Saint-Gobain Note, (ii) certain change of control events, and (iii) certain events of default. In each case, the number of shares of common stock issuable upon such complete or partial conversion of the Saint-Gobain Note is determined by dividing the portion of the principal and accrued or unpaid interest to be converted by $10.00 per share (as adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction).

- *Maturity of the Note*. Upon maturity of the Saint-Gobain Note or at any time during the 75 day period prior to the maturity date of the note, Saint-Gobain may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.

- *Change of Control*. Upon a change of control pursuant to which Saint-Gobain has a redemption right, Saint-Gobain may, at its option, elect to convert any amount of the outstanding principal and accrued interest, less any remaining installment payments required to be made in cash, into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.

- *Default*. Upon the occurrence of certain events of default, Saint-Gobain may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.

Subject to the aforementioned conversion rights of Saint-Gobain, the Company may prepay the Saint-Gobain Note in whole or in part at any time without penalty or premium.

Convertible Note Payable to Pharmstandard. On June 15, 2017, the Company entered into a note purchase agreement (the "Note Purchase Agreement") with Pharmstandard, pursuant to which the Company agreed to issue and sell to Pharmstandard a secured convertible promissory note in the original principal amount of $6.0 million (the "Pharmstandard Note").

The Company issued the Pharmstandard Note on June 21, 2017, the closing date of the financing. Under the Pharmstandard Note, the maturity date for the payment of principal and interest is the fifth anniversary of the issue date. The Pharmstandard Note bears interest at a rate of 9.5% per annum, which interest compounds annually. The Pharmstandard Note is secured by a lien on and security interest in all of the Company's intellectual property. The Company may prepay the Pharmstandard Note in whole or in part at any time without penalty or premium. Upon the occurrence of certain events of default, Pharmstandard will have the option to require the Company to repay the unpaid principal amount of the Pharmstandard Note and any unpaid accrued interest.

In addition, at Pharmstandard's election, Pharmstandard may convert the entire principal and interest on the Pharmstandard Note into shares of the Company's common stock at a price per share equal to $10.00. However, Pharmstandard will not be permitted to convert the entire Pharmstandard Note if such conversion would result in Pharmstandard and its affiliates holding shares that exceed 39.9% of the total number of outstanding shares of common stock of the Company or 39.9% of the combined voting power of all outstanding securities of the Company. To the extent that conversion of the entire Pharmstandard Note would cause Pharmstandard and its affiliates to exceed these thresholds, Pharmstandard may convert a portion of the Pharmstandard Note to the extent these thresholds are not exceeded by such partial conversion.

Pharmstandard is the Company's largest stockholder, and beneficially owned, in the aggregate, shares representing approximately 14.23% of the Company's outstanding common stock as of May 8, 2018. In addition, two members of the Company's board of directors are closely associated with Pharmstandard.

Venture Loan Facility and Gain on Early Extinguishment of Debt. In September 2014, the Company entered into the Loan Agreement with the Lenders under which the Company could borrow up to $25.0 million in two tranches of $12.5 million each (the "Loan Facility").

The Company borrowed the first tranche of $12.5 million upon the closing of the Loan Facility in September 2014 and borrowed the second tranche of $12.5 million in August 2015. The per annum interest rate for each tranche was a floating rate equal to 9.25% plus the amount by which the one-month London Interbank Offered Rate ("LIBOR") exceeds 0.50% (effectively a floating rate equal to 8.75% plus the one-month LIBOR Rate). The total per annum interest rate was not to exceed 10.75%.

The Company incurred $0.4 million in debt issuance costs in connection with the closing of the Loan Facility. Debt issuance costs were presented in the Company's consolidated balance sheet as a direct deduction from the associated liability and amortized to interest expense over the terms of the related debt. Debt issuance costs were eliminated on the Company's consolidated balance sheet as of December 31, 2017 as a result of the early extinguishment of debt under the payoff letter discussed below.

The Company made payments with respect to the first tranche of $12.5 million on an interest-only basis monthly through October 31, 2016, and was obligated to make monthly payments of principal and accrued interest through the scheduled maturity date for the first tranche loan on September 30, 2018. In addition, a final payment for the first tranche loan equal to $0.6 million was due on September 30, 2018, or such earlier date specified in the Loan Agreement. The Company was recognizing the final payment of $0.6 million as accrued interest over the expected life of the first tranche loan. The Company agreed to repay the second tranche loan of $12.5 million in 18 monthly payments of interest only until February 7, 2017, followed by 24 monthly payments of principal and accrued interest through the scheduled maturity date for the second tranche loan on February 7, 2019. In addition, a final payment of $0.6 million was due on February 7, 2019, or such earlier date specified in the Loan Agreement. The Company was recognizing the final payment of $0.6 million as accrued interest over the expected life of the second tranche loan. In addition, the Company agreed that if the Company repaid all or a portion of the loan prior to the applicable maturity date, it would pay the Lenders a prepayment penalty fee based on a percentage of the then outstanding principal balance, equal to 3% if the prepayment occurs on or before 24 months after the funding date, 2% if the prepayment occurs more than 24 months after, but on or before 36 months after, the funding date thereof, or 1% if the prepayment occurs more than 36 months after the funding date thereof.

On March 3, 2017, the Company entered into a payoff letter with the Lenders, pursuant to which the Company paid on March 6, 2017, a total of $23.1 million to the Lenders, representing the principal balance and accrued interest outstanding under the Loan Agreement in repayment of the Company's outstanding obligations under the Loan Agreement. In addition, the Company issued to the Lenders five year warrants to purchase an aggregate of 5,000 shares of the Company's common stock at an exercise price of $26.00 per share in consideration of the Lenders accepting the $23.1 million. The Company recognized a gain on this early extinguishment of debt of $0.2 million during the year ended December 31, 2017 which is included in Other income (expense) on the statement of operations. The payoff of the debt was considered a troubled debt restructuring because of the doubt surrounding the Company's ability to continue as a going concern and the fact that the final payment of $1.25 million and the pre-payment penalty of $0.6 million were waived by the Lenders in exchange for the issuance of the warrants.

Upon the payment of the $23.1 million and the issuance of the warrants pursuant to the payoff letter, all outstanding indebtedness and obligations of the Company owing to the Lenders under the Loan Agreement were deemed paid in full, and the Loan Agreement and the notes thereunder were terminated.

In connection with the Loan Agreement, the Company issued to the Lenders and their affiliates warrants to purchase a total of 4,139 shares of the Company's common stock at a per share exercise price of $181.20 (the "Venture Loan Warrants"). Upon the Company's satisfaction of the conditions precedent to the making of the second tranche loan, the Venture Loan Warrants became exercisable in full. The Venture Loan Warrants will terminate on September 29, 2021 or such earlier date as specified in the Venture Loan Warrants. As of September 29, 2014, the Company recorded a debt discount of $0.3 million equal to the value of these Venture Loan Warrants. This debt discount was offset against the long-term portion of the note payable balance and included in additional paid-in capital on the Company's consolidated balance sheet. Debt discount was amortized to interest expense over the terms of the related debt. Debt discount was eliminated on the Company's balance sheet as of December 31, 2017 as a result of the early extinguishment of debt discussed above.

Medinet Loan. In December 2013, in connection with a license agreement currently with Medinet, as described in Note 11, the Company borrowed $9.0 million pursuant to an unsecured promissory note that bears interest at a rate of 3.0% per annum. The principal and interest under the note are due and payable on December 31, 2018. Under the terms of the note and the license agreement, any milestone payments related to the developmental and regulatory milestones that become due will be applied first to the repayment of the loan. The Company has the right to prepay the loan at any time. If the Company has not repaid the loan by December 31, 2018, then the Company has agreed to grant to Medinet a non-exclusive, royalty-bearing license to make and sell Arcelis products in Japan for the treatment of cancer. In such event, the amounts owing under the loan as of December 31, 2018 may constitute pre-paid royalties under the license or would be due and payable. Royalties under this license would be paid until the expiration of the licensed patent rights in Japan at a rate to be negotiated. If the Company and Medinet cannot agree on the royalty rate, they have agreed to submit the matter to arbitration. Because the $9.0 million promissory note was issued at a below market interest rate, the Company allocated the proceeds of the loan between the license agreement and the debt at the time of issuance. Accordingly, as of the borrowing date, December 31, 2013, the Company recorded $6.9 million to notes payable, based upon an effective interest rate of 8.0%, and $2.1 million as a deferred liability.

During the year ended December 31, 2015, the Company recorded a $1.0 million milestone payment as deferred revenue under the Medinet license agreement and reduced the related note payable by $0.8 million and the deferred liability by $0.2 million. During the year ended December 31, 2016, the Company recorded a $2.0 million milestone payment as deferred revenue under the Medinet license agreement and reduced the related note payable by $1.5 million and the deferred liability by $0.5 million. During the year ended December 31, 2017, the Company recorded an additional $2.0 million milestone payment as deferred revenue under the Medinet license agreement and reduced the related note payable by $1.5 million and the deferred liability by $0.5 million.

Under the agreement, the Company had the right to revoke both the manufacturing license and the sale license to be granted to Medinet or the sale license only. On February 14, 2018, the Company notified Medinet that it irrevocably agreed to have no further right to exercise its right under the license agreement to revoke the manufacturing and the sale license, or the sale license only. As a result of the Company's decision to forego these revocation rights, during the three months ended March 31, 2018, the Company recognized as revenue $5.8 million of milestone payments that had previously been received and recorded as deferred revenue.

As of December 31, 2017 and March 31, 2018, the amount of the note payable was $5.0 million, including $1.9 million of accrued interest. As of December 31, 2017 and March 31, 2018, the total deferred liability associated with the Medinet note was $6.9 million and $1.1 million, respectively (see Note 11).

Other Notes. During November 2013, the Company borrowed $77,832 from a lending institution to finance the purchase of computer equipment, of which $13,825 and $9,311 in principal was outstanding as of December 31, 2017 and March 31, 2018, respectively. Borrowings are collateralized by substantially all of the computer equipment financed under the agreement, bear interest at a rate of 8.31% per annum and are to be repaid in 60 equal monthly installments commencing on the date of borrowing.

7. Stockholders' Deficit

Issuance of Restricted Stock in Three Months Ended March 31, 2017

In lieu of paying certain annual cash bonuses for 2016, in January 2017 the Company granted restricted stock awards to certain of its executive officers and employees. The number of shares granted to each executive officer and employee was calculated by dividing 25% of the amount of the 2016 annual cash bonus that would otherwise have been paid by the closing price of the Company's common stock on January 13, 2017. A total of 4,005 restricted shares of common stock with an aggregate value of $394,534 were issued. Each of the restricted stock awards is subject to a lapsing right of repurchase in the Company's favor, which right lapsed with respect to 100% of the underlying shares of each award on April 17, 2017, for those executive officers and employees still providing services to the Company on such date.

Issuance of Common Stock in Three Months Ended March 31, 2018

At-the-Market Offering

In May 2015, the Company entered into a sales agreement with Cowen pursuant to which the Company could issue and sell shares of the Company's common stock from time to time having an aggregate offering price of up to $30 million through Cowen, acting as the Company's agent. In February 2018, the Company amended and restated the sales agreement with Cowen to increase the maximum aggregate offering price from $30 million to up to $45 million (the "Sales Agreement"). Sales of the Company's common stock through Cowen may be made by any method permitted that is deemed an "at-the-market offering" as defined in Rule 415 under the Securities Act of 1933, as amended. Cowen is not required to sell any specific number or dollar amount of securities, but acts as a sales agent using commercially reasonable efforts consistent with its normal trading and sales practices, and in accordance with the terms of the Sales Agreement. There is no arrangement for funds to be received in any escrow, trust or similar arrangement. Under the Sales Agreement, the Company has agreed to pay Cowen a commission of up to 3% of the gross proceeds of any sales made pursuant to the Sales Agreement. During the three months ended March 31, 2018, the Company sold 4,108,124 shares of common stock pursuant to the Sales Agreement, resulting in proceeds of $7.5 million, net of commissions and issuance costs. The Company sold an additional 27,869 shares resulting in net $21,000 of proceeds between April 1, 2018 and May 8, 2018. As of May 8, 2018, $15.7 million of stock remained to be sold under the Sales Agreement. However, as a result of the delisting of the Company's common stock from The Nasdaq Capital Market in April 2018, the Company does not expect to sell any additional shares under the Sales Agreement.

Issuance of Common Stock under Collaboration Agreements

On April 2, 2018, in consideration for the rights granted under an option agreement entered into with Pharmstandard and Actigen Limited ("Actigen") in February 2018, the Company issued 169,014 shares of its common stock to Pharmstandard, the value of which will be creditable against the upfront license fee payable under the option agreement if the Company enters into a license agreement. The option agreement is described further in Note 11.

In January 2018, the Company entered into a stock purchase agreement with Lummy HK under which the Company agreed to issue and sell to Lummy HK in a private financing 375,000 shares of the Company's common stock for an aggregate purchase price of $1.5 million. On March 23, 2018, the Company and Lummy HK amended the stock purchase agreement to reduce the aggregate price for the shares to $450,000. Concurrent with such amendment, the Company entered into a third amendment to its license agreement with Lummy HK pursuant to which Lummy HK agreed to pay the Company a $1.05 million milestone payment. In April 2018, the Company received from Lummy HK $450,000 for the purchase of the 375,000 shares and a $1.05 million milestone payment.

Issuance and Subsequent Cancellation of Restricted Stock

During March 2018, the Company issued 210,000 shares of restricted stock to employees and certain executives. These shares were canceled and returned to the Company on April 25, 2018 in connection with the delisting of the Company's common stock from The Nasdaq Capital Market.

8. Stock Incentive Plans

2014 Stock Incentive Plan and 2014 Employee Stock Purchase Plan

In January 2014, the Company's board of directors and stockholders approved, effective upon the closing of the Company's initial public offering, the 2014 Stock Incentive Plan (the "2014 Plan"). Under the 2014 Plan, the Company is authorized to grant incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards for 570,746 shares of common stock plus an annual increase in the number of shares of our common stock available for issuance under the plan on the first day of each fiscal year beginning with the fiscal year ending December 31, 2018 and continuing each fiscal year until, and including, the fiscal year ending December 31, 2024, equal to the lowest of 250,000 shares of common stock, four percent (4%) of the outstanding shares of common stock on such date or an amount determined by our board of directors.

At the July 28, 2017 stockholders' meeting, the stockholders approved an amendment to the 2014 Plan to increase the number of shares of common stock authorized for issuance under the 2014 Plan by 300,000 and to increase the maximum number of shares that automatically may be added to the 2014 Plan on the first day of each fiscal year until the fiscal year ending December 31, 2024 by 134,548 shares, such that the total number of shares of common stock authorized for issuance under the 2014 Plan is equal to the sum of 570,746 shares, plus an annual increase to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2018 and continuing each fiscal year until, and including, the fiscal year ending December 31, 2024, equal to the lowest of (i) 250,000 shares of Common Stock, (ii) four percent (4%) of the outstanding shares of Common Stock on such date or (iii) an amount determined by the Company's board of directors.

Also in January 2014, the Company's board of directors and stockholders approved, effective upon the closing of the Company's initial public offering, a 2014 Employee Stock Purchase Plan (the "2014 ESPP"). Under the 2014 ESPP, on the offering commencement date of each plan period (the "Purchase Plan Period"), the Company will grant to each eligible employee who is then a participant in the 2014 ESPP an option to purchase shares of common stock. The employee may authorize up to a maximum of 10% of his or her base pay to be deducted by the Company during each Purchase Plan Period. Each employee who continues to be a participant in the 2014 ESPP on the last business day of the Purchase Plan Period is deemed to have exercised the option, to the extent of accumulated payroll deductions within the 2014 ESPP ownership limits.

Under the terms of the 2014 ESPP, the option exercise price shall be determined by the Company's board of directors for each Purchase Plan Period and the option exercise price will be at least 85% of the applicable closing price of the common stock. The option exercise price will be 85% of the lower of the Company's closing stock price on the first and last business day of each Purchase Plan Period. The Company's first Purchase Plan Period commenced on September 2, 2014 and ended on February 27, 2015. For the first Purchase Plan Period, 652 shares were purchased with employee withholdings at an option exercise price based upon 85% of the closing price on February 27, 2015 of $180.40, resulting in the recognition of share-based compensation expense of $54,508. The Company's second Purchase Plan Period commenced on March 2, 2015 and ended on August 31, 2015. For the second Purchase Plan Period, 1,015 shares were purchased with employee withholdings at an option exercise price based upon 85% of the closing price on August 31, 2015 of $124.20, resulting in the recognition of share-based compensation expense of $72,800. The Company's third Purchase Plan Period commenced on September 1, 2015 and ended on February 29, 2016. For the third Purchase Plan Period, 1,814 shares were purchased with employee withholdings at an option exercise price based upon 85% of the closing price of $88.80 on February 29, 2016, resulting in the recognition of share-based compensation expense of $107,455. The Company's fourth Purchase Plan Period commenced on March 1, 2016 and ended on August 31, 2016. For the fourth Purchase Plan Period, 1,507 shares were purchased with employee withholdings at an option exercise price based upon 85% of the closing price at the beginning of the fourth Purchase Plan Period of $98.20, resulting in the recognition of share-based compensation expense of $63,788. The Company's fifth Purchase Plan Period commenced on September 1, 2016 and ended on February 28, 2017. For the fifth Purchase Plan Period, 428 shares were purchased with employee withholdings at an option exercise price based upon 85% of $23.00 on February 28, 2017, resulting in the recognition of share-based compensation expense of $30,064. The Company's sixth Purchase Plan Period commenced on March 1, 2017 and ended on August 31, 2017. For the sixth Purchase Plan Period, 999 shares were purchased with employee withholdings at an option exercise price based upon 85% of $4.00 on August 31, 2017, resulting in the recognition of share-based compensation expense of $17,711. The Company did not commence a new Purchase Plan Period after September 1, 2017.

Upon the exercise of stock options, vesting of other awards and purchase of shares through the 2014 ESPP or under the 2014 Plan, the Company issues new shares of common stock. All awards granted under the 2014 Plan that are canceled prior to vesting or expire unexercised are returned to the approved pool of reserved shares under the 2014 Plan and made available for future grants. As of March 31, 2018, there were 93,614 shares of common stock remaining available for future issuance under the 2014 Plan and 10,899 shares of common stock remaining available for future issuance under the 2014 ESPP.

The Company recorded the following share-based compensation expense:

	Three Months Ended March 31,	
	2017	2018
Research and development	$ 487,907	$ 259,793
General and administrative	748,160	455,941
Restructuring costs	2,411,604	—
Total stock-based compensation expense	$ 3,647,671	$ 715,734

Allocations to research and development and general and administrative expenses are based upon the department to which the associated employee reported. No related tax benefits of the stock-based compensation expense have been recognized. Stock-based payments issued to non-employees are recorded at their fair values and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period. As part of the restructuring costs discussed in Note 3, the Company recognized $2.4 million in stock-based compensation expense from the acceleration of stock option vesting for 46 employees who were terminated in March 2017.

During the three months ended March 31, 2017, the Company granted options to employees to purchase a total of 69,104 shares of the Company's common stock at exercise prices ranging from $27.00 to $101.00 per share, which, in each instance was the closing price of the Company's common stock on the grant date. No options were granted during the three months ended March 31, 2018.

The following table summarizes the Company's stock option activity during the three months ended March 31, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)
Outstanding as of December 31, 2017	269,514	$ 111.91	
Granted	—	$ —	
Exercised	—	$ —	
Cancelled	(64,562)	$ 116.43	
Outstanding as of March 31, 2018	204,952	$ 118.01	6.84
Exercisable as of March 31, 2018	136,132	$ 119.03	6.11
Vested and expected to vest as of March 31, 2018	199,653	$ 118.07	4.81

Valuation Assumptions for Stock Option Plans and Employee Stock Purchase Plan

The stock-based compensation expense was determined using the Black-Scholes option valuation model. Option valuation models require the input of subjective assumptions and these assumptions can vary over time. The weighted average assumptions used were as follows for the periods indicated:

	Stock Option Plans		Employee Stock Purchase Plan	
	Three Months Ended March 31,		Three Months Ended March 31,	
	2017	2018	2017	2018
Risk-free interest rate	2.27%	—	0.69%	—
Dividend yield	0%	—	0%	—
Expected term (in years)	7.0	—	0.5	—
Volatility	86%	—	165%	—

9. Warrants

In March 2016, the Company sold and certain investors purchased for a total purchase price of $19.9 million a total of 182,621 shares of common stock and warrants to purchase a total of 136,966 shares of common stock at a per share exercise price of $107.00. These warrants will terminate on March 14, 2021 or such earlier date as specified in the warrants. Additionally, in June 2016, the Company sold and such investors purchased for a total purchase price of $29.8 million a total of 273,933 shares of common stock and warrants to purchase a total of 205,450 shares of common stock at a per share exercise price of $107.00. These warrants will terminate on June 29, 2021 or such earlier date as specified in the warrants. In June 2016, warrants to purchase 2,803 shares of common stock were exercised for proceeds of $0.3 million to the Company.

In August 2016, the Company sold and certain investors purchased for a total purchase price of $50.0 million a total of 454,545 shares of common stock and warrants to purchase a total of 340,909 shares of common stock at a per share exercise price of $110.00 (the "August 2016 Warrants"). These warrants will terminate on August 2, 2021 or such earlier date as specified in the warrants.

As discussed in Note 6 regarding the Company's notes payable, in connection with the Loan Agreement in September 2014, the Company issued to the Lenders and their affiliates the Venture Loan Warrants. Upon the Company's satisfaction of the conditions precedent to the making of the second tranche loan, the Venture Loan Warrants became exercisable in full. The Venture Loan Warrants will terminate on September 29, 2021 or such earlier date as specified in the Venture Loan Warrants. In addition, in March 2017, the Company issued to the Lenders five year warrants to purchase an aggregate of 5,000 shares of the Company's common stock at an exercise price of $26.00 per share in consideration of the Lenders accepting the early pay-off of the indebtedness under the Loan Agreement. These warrants were recorded at a fair value of $87,100 and included in additional paid-in capital as of December 31, 2017 and March 31, 2018.

All outstanding warrants were issued with an original life of five years.

As of December 31, 2017 and March 31, 2018, outstanding warrants to purchase a total of 689,661 shares of the Company's common stock were as follows:

Type of Warrant and Classification	Date of Issuance	Number of Shares	Exercise Price	Expiration Date(s)
Common stock - Equity	9/29/14	4,139	$ 181.20	9/29/21
Common stock - Equity	3/4/16	134,163	$ 107.00	3/4/21
Common stock - Equity	6/29/16	205,450	$ 107.00	6/29/21
Common stock - Liability	8/2/16	340,909	$ 110.00	8/02/21
Common stock - Equity	3/6/17	5,000	$ 26.00	3/06/22

The following warrants were issued in August 2016 and remained outstanding as of December 31, 2017 and March 31, 2018, and include provisions that could require cash settlement. The August 2016 Warrants were therefore recorded as liabilities of the Company at the estimated fair value as of the date of issuance. The August 2016 Warrants are required to be recorded at fair value as of the end of each subsequent reporting period, with changes in fair value recorded as other income or expense in the Company's condensed consolidated statement of operations in each subsequent period:

	August 2016 Warrants
Exercise price	$ 110.00
Expiration date	August 2, 2021
Total shares issuable on exercise	340,909

The fair value of the August 2016 Warrants is measured using the Black-Scholes valuation model. Inherent in the Black-Scholes valuation model are assumptions related to expected stock price volatility, expected life, risk-free interest rate and dividend yield. The risk-free interest rate is based on the U.S. Treasury five-year maturity yield curve in effect on the date of valuation. The dividend yield percentage is zero because the Company neither currently pays dividends nor intends to do so during the expected term of the August 2016 Warrants. Expected stock price volatility is based on the weighted average of the Company's historical common stock volatility and the volatility of several peer public companies. The expected life of the August 2016 Warrants is assumed to be equivalent to their remaining contractual term.

The assumptions used by the Company to determine the fair value of the August 2016 Warrants are summarized in the following table as of December 31, 2017 and March 31, 2018:

	December 31, 2017	March 31, 2018
Exercise price of warrants	$ 110.00	$ 110.00
Closing underlying stock price on date of valuation	$ 3.00	$ 0.90
Expected stock price volatility	112%	115%
Expected life (in years)	3.58	3.33
Risk-free interest rate	2.04%	2.39%
Expected dividend yield	0.0%	0.0%
Valuation per common share underlying each warrant	$ 0.49	$ 0.05
Total liability for warrants on the consolidated balance sheet	$ 167,636	$ 18,534
Decrease in fair value during the period	20,758,425	$ 149,102

In 2013, the Company agreed to enter into a manufacturing rights agreement for the manufacturing of rocapuldencel-T in the European market with Pharmstandard, which also provided for the issuance of warrants to Pharmstandard to purchase 24,989 shares of the Company's common stock at an exercise price of $116.40 per share. As of March 31, 2018, the Company had not entered into this manufacturing rights agreement or issued such warrants.

10. Contract with the NIH and NIAID

In September 2006, the Company entered into a multi-year research contract with the NIH and NIAID to design, develop and clinically test an autologous HIV immunotherapy capable of eliciting therapeutic immune responses. The Company is using funds from this contract to develop AGS-004. Under this contract, as amended, the NIH and NIAID have committed to fund up to a total of $39.8 million, including reimbursement of direct expenses and allocated overhead and general and administrative expenses of up to $38.4 million and payment of other specified amounts totaling up to $1.4 million upon the Company's achievement of specified development milestones. Since September 2010, the Company has received reimbursement of its allocated overhead and general and administrative expenses at provisional indirect cost rates equal to negotiated provisional indirect cost rates agreed to with the NIH and NIAID in September 2010. These provisional indirect cost rates are subject to adjustment based on the Company's actual costs pursuant to the agreement with the NIH and NIAID. This commitment originally extended until May 2013. The Company agreed to an additional modification of the Company's contract with the NIH and NIAID under which the NIH and NIAID agreed to increase their funding commitment to the Company by an additional $5.4 million in connection with the extension of the contract from May 2013 to September 2015. Additionally, a contract modification for a $0.5 million increase was agreed to by the NIH on September 18, 2014 to cover a portion of the manufacturing costs of the planned Phase 2 clinical trial of AGS-004 for long-term viral control in pediatric patients. On June 29, 2016, a contract modification was agreed to that extended the NIH and NIAID's commitment under the contract to July 31, 2018. The Company has agreed to a statement of work under the contract, and is obligated to furnish all the services, qualified personnel, material, equipment, and facilities, not otherwise provided by the U.S. government, needed to perform the statement of work.

The Company recognizes revenue from reimbursements earned in connection with the contract as reimbursable costs are incurred and revenues from the achievement of milestones under the NIH and NIAID contract upon the accomplishment of any such milestone.

For the three months ended March 31, 2017 and 2018, the Company recorded revenue under the NIH and NIAID agreement of $77,759 and $30,318, respectively. The Company has recorded total revenue of $38.1 million through March 31, 2018 under this agreement. As of March 31, 2018, there was up to $1.7 million of potential revenue remaining to be earned under the agreement with the NIH and NIAID. As of December 31, 2017 and March 31, 2018, the Company recorded a receivable from the NIH and NIAID of $31,977 and $30,318, respectively. The concentration of credit risk is equal to the outstanding accounts receivable and such risk is subject to the credit worthiness of the NIH and NIAID. There have been no credit losses under this arrangement.

11. Collaboration Agreements

Pharmstandard License Agreement

In August 2013, Pharmstandard purchased shares of the Company's series E preferred stock. Concurrent with such purchase, the Company entered into an exclusive royalty-bearing license agreement with Pharmstandard. Under this license agreement, the Company granted Pharmstandard and its affiliates a license, with the right to sublicense, develop, manufacture and commercialize rocapuldencel-T and other products for the treatment of human diseases, which are developed by Pharmstandard using the Company's individualized immunotherapy platform, in the Russian Federation, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan, which the Company refers to as the Pharmstandard Territory. The Company also provided Pharmstandard with a right of first negotiation for development and commercialization rights in the Pharmstandard Territory to specified additional products the Company may develop.

Under the terms of the license agreement, Pharmstandard licensed the Company rights to clinical data generated by Pharmstandard under the agreement and granted the Company an option to obtain an exclusive license outside of the Pharmstandard Territory to develop and commercialize improvements to the Company's Arcelis technology generated by Pharmstandard under the agreement, a non-exclusive worldwide royalty-free license to Pharmstandard improvements to manufacture products using the Company's Arcelis technology and a license to specified follow-on licensed products generated by Pharmstandard outside of the Pharmstandard Territory, each on terms to be negotiated upon the Company's request for a license. In addition, Pharmstandard agreed to pay the Company pass-through royalties on net sales of all licensed products in the low single digits until it has generated a specified amount of aggregate net sales. Once the net sales threshold is achieved, Pharmstandard will pay the Company royalties on net sales of specified licensed products, including rocapuldencel-T, in the low double digits below 20%. These royalty obligations last until the later of the expiration of specified licensed patent rights in a country or the twelfth anniversary of the first commercial sale in such country on a country by country basis and no further royalties on specified other licensed products. After the net sales threshold is achieved, Pharmstandard has the right to offset a portion of the royalties Pharmstandard pays to third parties for licenses to necessary third party intellectual property against the royalties that Pharmstandard pays to the Company.

The agreement will terminate upon expiration of the royalty term, upon which all licenses will become fully paid-up perpetual exclusive licenses. Either party may terminate the agreement for the other party's uncured material breach or if specified conditions occur relating to the other party's insolvency or bankruptcy and the Company may terminate the agreement if Pharmstandard challenges or assists a third party in challenging specified patent rights of the Company. If Pharmstandard terminates the agreement upon the Company's material breach or bankruptcy, Pharmstandard is entitled to terminate the Company's licenses to improvements generated by Pharmstandard, upon which the Company may come to rely for the development and commercialization of rocapuldencel-T and other licensed products outside of the Pharmstandard Territory, and to retain its licenses from the Company and to pay the Company substantially reduced royalty payments following such termination.

In November 2013, the Company entered into an agreement with Pharmstandard under which Pharmstandard purchased shares of the Company's series E preferred stock. Under this agreement, the Company agreed to enter into a manufacturing rights agreement for the European market with Pharmstandard, which also provided for the issuance of warrants to Pharmstandard to purchase 24,989 shares of the Company's common stock at an exercise price of $116.40 per share. The Company has not entered into this manufacturing rights agreement or issued the warrants. All outstanding shares of the Company's preferred stock converted into shares of the Company's common stock upon the closing of its initial public offering in February 2014.

Pharmstandard and Actigen Option Agreement

On February 1, 2018, the Company entered into an option agreement with Pharmstandard and Actigen to evaluate, with an option to license, certain patent rights and know-how related to a group of fully human PD1 monoclonal antibodies and related technology held by Actigen. Actigen previously granted Pharmstandard an option to exclusively license these patent rights. Under the option agreement, Pharmstandard granted to the Company (i) an exclusive license for evaluation purposes only to make, have made, use and import the PD1 monoclonal antibodies covered by these patent rights (but not offer to sell or sell products and processes covered by or incorporating the patent rights) for a period of one year from the date of the agreement and (ii) an option exercisable during the one-year period to obtain an exclusive license (with the right to sublicense) under the patent rights to make, have made, use, offer for sale, sell and import (with a right to grant sublicenses) the PD1 monoclonal antibodies for all prophylactic, therapeutic and diagnostic uses and for all human diseases and conditions in the United States and Canada. The parties have agreed that, if the Company exercises the option during the option exercise period, the parties will negotiate in good faith a license agreement on the terms and conditions outlined in the option agreement, including payments by us to Pharmstandard of (i) an upfront license fee of $3.6 million, payable upon execution of the license agreement in our common stock of the Company, (ii) various development and regulatory milestone payments totaling $8.5 million, and (iii) upper single digit percentage royalties on net sales of any pharmaceutical product or therapeutic regimen incorporating the licensed PD1 monoclonal antibodies that will apply on a country-by-country basis until the later of the last to expire patent or ten years from the date of first commercial sale, against which the first $5.0 million of our development expenditures will be credited as prepaid royalties.

In consideration for the rights granted under the option agreement, the Company issued 169,014 shares of its common stock to Pharmstandard, the value of which will be creditable against the upfront license fee payable under the option agreement if the Company enters into a license agreement. Unless earlier terminated by any party for uncured material breach or by us without cause upon thirty days prior written notice, the option agreement will terminate upon the later of the end of the option exercise period if the Company decides not to exercise the option or sixty days after the Company exercises the option.

Green Cross License Agreement

In July 2013, the Company entered into an exclusive royalty-bearing license agreement with Green Cross Corp. ("Green Cross"). Under this agreement, the Company granted Green Cross a license to develop, manufacture and commercialize rocapuldencel-T for mRCC in South Korea. The Company also provided Green Cross with a right of first negotiation for development and commercialization rights in South Korea to specified additional products the Company may develop.

Under the terms of the license, Green Cross has agreed to pay the Company $0.5 million upon the initial submission of an application for regulatory approval of a licensed product in South Korea, $0.5 million upon the initial regulatory approval of a licensed product in South Korea and royalties ranging from the mid-single digits to low double digits below 20% on net sales until the fifteenth anniversary of the first commercial sale in South Korea. In addition, Green Cross has granted the Company an exclusive royalty free license to develop and commercialize all Green Cross improvements to the Company's licensed intellectual property in the rest of the world, excluding South Korea, except that, as to such improvements for which Green Cross makes a significant financial investment and that generate significant commercial benefit in the rest of the world, the Company is required to negotiate in good faith a reasonable royalty that the Company will be obligated to pay to Green Cross for such license. Under the terms of the agreement, the Company is required to continue to develop and to use commercially reasonable efforts to obtain regulatory approval for rocapuldencel-T in the United States.

The agreement will terminate upon expiration of the royalty term, which is 15 years from the first commercial sale, upon which all licenses will become fully paid up perpetual non-exclusive licenses. Either party may terminate the agreement for the other party's uncured material breach or if specified conditions occur relating to the other party's insolvency or bankruptcy and the Company may terminate the agreement if Green Cross challenges or assists a third party in challenging specified patent rights of the Company. If Green Cross terminates the agreement upon the Company's material breach or bankruptcy, Green Cross is entitled to terminate the Company's licenses to improvements and retain its licenses from the Company and to pay the Company substantially reduced milestone and royalty payments following such termination.

Medinet License Agreement

In December 2013, the Company entered into a license agreement with Medinet Co., Ltd. This agreement was subsequently novated, amended and restated among the Company, Medinet Co., Ltd. and MEDcell Co., Ltd. in October 2014. Pursuant to the novation, Medinet Co., Ltd. assigned and transferred all of its rights and obligations under the original license agreement, including the rights to receive payments under the $9.0 million note in favor of Medinet Co., Ltd., to MEDcell Co., Ltd. without any substantive change in the underlying rights or obligations. Medinet Co., Ltd. and MEDcell Co., Ltd. together are referred to herein as "Medinet." Under this agreement, the Company granted Medinet an exclusive, royalty-free license to manufacture in Japan rocapuldencel-T and other products using the Company's Arcelis technology solely for the purpose of the development and commercialization of rocapuldencel-T and these other products for the treatment of mRCC. The Company refers to this license as the manufacturing license.

In addition, under this agreement, the Company granted Medinet an option to acquire a nonexclusive, royalty-bearing license under the Company's Arcelis technology to sell in Japan rocapuldencel-T and other products for the treatment of mRCC. The Company refers to the option as the sale option and the license as the sale license. This option expired on April 30, 2016. As a result, Medinet may only manufacture rocapuldencel-T and these other products for the Company or its designee. The Company and Medinet have agreed to negotiate in good faith a supply agreement under which Medinet would supply the Company or its designee with rocapuldencel-T and these other products for development and sale for the treatment of mRCC in Japan. During the term of the manufacturing license, the Company may not manufacture rocapuldencel-T or these other products for the Company or any designee for development or sale for the treatment of mRCC in Japan.

In consideration for the manufacturing license, Medinet paid the Company $1.0 million. Medinet also loaned the Company $9.0 million in connection with the Company entering into the agreement. The Company has agreed to use these funds in the development and manufacturing of rocapuldencel-T and the other products. Medinet also agreed to pay the Company milestone payments of up to a total of $9.0 million upon the achievement of developmental and regulatory milestones and $5.0 million upon the achievement of a sales milestone related to rocapuldencel-T and these products. Under the terms of the note and the manufacturing license agreement, any milestone payments related to the developmental and regulatory milestones that become due will be applied first to the repayment of the loan. The first milestone was achieved in July 2015 and resulted in a $1.0 million payment. The second milestone was achieved in June 2016 and resulted in a $2.0 million payment. The third milestone was achieved in March 2017 and resulted in a $2.0 million payment. Together, these milestone payments reduced the outstanding principal under the loan as of December 31, 2017 to $4.0 million.

In December 2013, in connection with the manufacturing license agreement with Medinet, the Company borrowed $9.0 million pursuant to an unsecured promissory note that bears interest at a rate of 3.0% per annum. The principal and interest under the note are due and payable on December 31, 2018. The Company has the right to prepay the loan at any time. If the Company has not repaid the loan by December 31, 2018, then the Company has agreed to grant to Medinet a non-exclusive, royalty-bearing license to make and sell Arcelis products in Japan for the treatment of cancer. In such event, the amounts owing under the loan as of December 31, 2018 may constitute pre-paid royalties under the license or would be due and payable. Royalties under this license would be paid until the expiration of the licensed patent rights in Japan at a rate to be negotiated. If the Company and Medinet cannot agree on the royalty rate, the Company and Medinet have agreed to submit the matter to arbitration.

The Company recorded the initial $1.0 million payment from Medinet as a deferred liability. In addition, because the $9.0 million promissory note was issued at a below market interest rate, the Company allocated the proceeds of the loan between the manufacturing license agreement and the debt at the time of issuance. Accordingly, as of December 31, 2013, the date of borrowing, the Company recorded $6.9 million to notes payable, based upon an effective interest rate of 8.0%, and $2.1 million as a deferred liability. During the year ended December 31, 2015, the Company recorded a $1.0 million milestone payment as deferred revenue under the license agreement and reduced the related note payable by $0.8 million and the deferred liability by $0.2 million.

During the year ended December 31, 2016, the Company recorded a $2.0 million milestone payment as deferred revenue under this license agreement and reduced the related note payable by $1.5 million and the deferred liability by $0.5 million. As of December 31, 2016, the amount of the note payable was $6.4 million, including $1.8 million accrued interest, and the total deferred liability associated with the Medinet note was $5.4 million.

During the year ended December 31, 2017, the Company recorded an additional $2.0 million milestone payment as deferred revenue under this license agreement and reduced the related note payable by $1.5 million and the deferred liability by $0.5 million. As of December 31, 2017, the amount of the note payable was $5.0 million, including $1.9 million of accrued interest, and the total deferred liability associated with the Medinet note was $6.9 million of which $6.0 million was deferred revenue.

On February 14, 2018, the Company notified Medinet that the Company irrevocably agreed to have no further right to exercise its right under the license agreement to revoke the manufacturing and sale license, or the sale license only. In all other respects, the Medinet license agreement remains in full force and effect. As a result of the revocation right no longer being of force and effect, the Company recognized $5.8 million of deferred milestone revenue as revenue under ASC 606 during the first quarter of 2018. As of March 31, 2018, the amount of the note payable was $5.0 million, including $1.9 million of accrued interest, and the total deferred liability associated with the Medinet note was $1.1 million of which $150,000 was deferred revenue. As of March 31, 2018, there are performance obligations related to the Medinet license agreement of $150,000 that are unsatisfied. The remaining performance obligations are expected to be satisfied over time throughout the remainder of 2018 such that the $150,000 of deferred revenue is expected to be recognized as revenue by December 31, 2018.

The agreement will terminate upon expiration of the royalty term, upon which all licenses will become fully paid up, perpetual non-exclusive licenses. Either party may terminate the agreement for the other party's uncured material breach or if specified conditions occur relating to the other party's insolvency or bankruptcy, and the Company may terminate the agreement if Medinet challenges or assists a third party in challenging specified patent rights of the Company. If Medinet terminates the agreement upon the Company's material breach or bankruptcy, Medinet is entitled to terminate the Company's licenses to improvements and retain its royalty-bearing licenses from the Company.

Lummy License Agreement

On April 7, 2015, the Company and Lummy HK, a wholly owned subsidiary of Chongqing Lummy Pharmaceutical Co. Ltd., entered into a license agreement (the "License Agreement") whereby the Company granted to Lummy HK an exclusive license under the Arcelis technology, including patents, know-how and improvements to manufacture, develop and commercialize products for the treatment of cancer ("Licensed Product") in China, Hong Kong, Taiwan and Macau (the "Territory"). Under the License Agreement, Lummy HK also has a right of first negotiation with respect to a license under the Arcelis technology for the treatment of infectious diseases in the Territory. This agreement was subsequently amended in December 2016 and also in October 2017.

Under the terms of the License Agreement, the parties will share relevant data, and the Company will have a right to reference Lummy HK data for purposes of its development programs under the Arcelis technology. In addition, Lummy HK has granted to the Company an exclusive, royalty-free license under and to any and all Lummy HK improvements to the Arcelis technology conceived or reduced to practice by Lummy HK ("Lummy HK Improvements") and Lummy HK data to develop and/or commercialize products ("Arcelis-Based Products") outside the Territory, an exclusive, royalty-free license under and to any and all investigational new drug applications ("INDs") and other regulatory approvals and Lummy HK trademarks used for an Arcelis-Based Product to develop and/or commercialize an Arcelis-Based Product outside the Territory and a non-exclusive, worldwide, royalty-free license under any Lummy HK Improvements and Lummy HK data to manufacture Arcelis-Based Products anywhere in the world. Lummy HK has the right to reference the Company's data, INDs and other regulatory filings and submissions for the purpose of developing and obtaining regulatory approval of Licensed Products in the Territory.

Pursuant to the License Agreement, Lummy HK will pay the Company royalties on net sales and an aggregate of up to $22.3 million upon the achievement of manufacturing, regulatory and commercial milestones. The License Agreement will terminate upon expiration of the last to expire royalty term for all Arcelis-Based Products, with each royalty term being the longer of the expiration of the last valid patent claim covering the applicable Arcelis-Based Product and 10 years from the first commercial sale of such Arcelis-Based Product. Either party may terminate the License Agreement for the other party's uncured material breach or if specified conditions occur relating to the other party's insolvency or bankruptcy. The Company may terminate the License Agreement if Lummy HK challenges or assists a third party in challenging specified patent rights of the Company. If Lummy HK terminates the License Agreement upon the Company's material breach or bankruptcy, Lummy HK is entitled to terminate the licenses it granted to the Company and retain its licenses from the Company with respect to Arcelis-Based Products then in development or being commercialized, subject to Lummy HK's continued obligation to pay royalties and milestones with respect to such Arcelis-Based Products.

Pursuant to the License Agreement, Lummy HK paid the Company a $1.5 million milestone payment upon the achievement of a manufacturing milestone in October 2017. The milestone payment was made in consideration of the successful initiation of transfer of technology related to the manufacturing of rocapuldencel-T, to which Lummy HK has a license for commercialization in China and other Asian territories. The Company recorded this $1.5 million payment from Lummy HK as revenue.

In January 2018, the Company entered into a stock purchase agreement with Lummy HK under which the Company agreed to issue and sell to Lummy HK in a private financing 375,000 shares of the Company's common stock for an aggregate purchase price of $1.5 million. In March 2018, the Company and Lummy HK amended the stock purchase agreement to reduce the aggregate price for the shares to $450,000. Concurrent with such amendment, the Company entered into a third amendment to its license agreement with Lummy HK pursuant to which Lummy HK agreed to pay the Company a $1.05 million milestone payment. In April 2018, the Company received from Lummy HK $450,000 for the purchase of the 375,000 shares and a $1.05 million milestone payment.

As of March 31, 2018, there are performance obligations related to the Lummy HK License Agreement of $2.3 million that are unsatisfied of which $1.1 million are expected to be met in the second quarter of 2018 and recognized as revenue. The remaining $1.2 million in performance obligations are expected to be satisfied and recognized as revenue on a straight-line basis over the estimated remaining license period from July 1, 2018 to December 31, 2029. As of December 31, 2017 and March 31, 2018, the Company had deferred revenue from the Lummy license agreement of $1.2 million and $2.3 million, respectively.

12. Net Loss Per Share

Basic and diluted net loss per share of common stock was determined by dividing net loss by the weighted average of shares of common stock outstanding during the period. The Company's potentially dilutive shares, which include options to purchase common stock and warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be antidilutive.

The following table presents the computation of basic and diluted net loss per share of common stock:

	Three Months Ended March 31,	
	2017	2018
Net loss	$ (24,080,081)	$ (2,111,269)
Weighted average shares outstanding, basic and diluted	2,065,676	7,618,806
Net loss per share, basic and diluted	$ (11.66)	$ (0.28)

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	Three Months Ended March 31,	
	2017	2018
Stock options outstanding	292,903	267,987
Warrants outstanding	686,050	689,661
Convertible notes outstanding	—	1,448,352

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes appearing in "Item 1. Financial Statements" in this Quarterly Report on Form 10-Q. In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, future financial performance, expense levels and liquidity sources, includes forward-looking statements that involve risks and uncertainties. You should read "Item 1A. Risk Factors" in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

We are an immuno-oncology company focused on the development and commercialization of individualized immunotherapies for the treatment of cancer and infectious diseases based on our proprietary precision immunotherapy technology platform called Arcelis.

In April 2018, we terminated our development program for rocapuldencel-T, which we had been developing for the treatment of metastatic renal cell carcinoma, or mRCC, and other cancers. Based on a review of the status of our internal programs, resources and capabilities, we are exploring a wide range of strategic alternatives that may include a potential merger or sale of the Company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some of our assets or proprietary technologies, among other potential alternatives. We have retained Stifel, Nicolaus & Company, Incorporated, or Stifel, to serve as our financial advisor in the process. There can be no assurance that we will be able to enter into such a transaction or transactions on a timely basis, on terms that are favorable to us, or at all. If we are unable to successfully conclude a strategic transaction, we may determine to dissolve and liquidate our assets or seek protection under the bankruptcy laws. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

Prior to April 2018, we had been conducting a pivotal Phase 3 clinical trial of rocapuldencel-T in combination with sunitinib / standard of care for the treatment of newly diagnosed mRCC, or the ADAPT trial. In February 2017, the independent data monitoring committee, or the IDMC, for the ADAPT trial recommended that the trial be discontinued for futility based on its planned interim data analysis. The IDMC concluded that the trial was unlikely to demonstrate a statistically significant improvement in overall survival in the combination treatment arm, utilizing the intent-to-treat population at the pre-specified number of 290 events (deaths), the original primary endpoint of the study.

Notwithstanding the IDMC's recommendation, we determined to continue to conduct the trial while we analyzed interim data from the trial. Following a meeting with the U.S. Food and Drug Administration, or FDA, we determined to continue the ADAPT trial until at least the pre-specified number of 290 events occurred, and to submit to the FDA a protocol amendment to increase the pre-specified number of events for the primary analysis of overall survival in the trial beyond 290 events. In April 2018, we submitted a protocol amendment to the FDA that included an amended primary endpoint analysis with four co-primary endpoints. Subsequently in April 2018,we conducted another interim analysis of the data from the ADAPT trial, at which time 51 new events (deaths) had occurred subsequent to the February 2017 interim analysis. Based upon review of the interim data from this analysis, we determined that the endpoints were unlikely to be achieved if the trial were to be continued and decided to discontinue the ADAPT clinical trial. We do not expect to resume clinical development of rocapuldencel-T.

We are developing AGS-004, also an Arcelis-based product candidate, for the treatment of HIV. We have completed Phase 1 and Phase 2 trials funded by government grants and a Phase 2b trial that was funded in full by the National Institutes of Health, or NIH, and the National Institute of Allergy and Infectious Diseases, or NIAID. We are currently supporting an ongoing investigator-initiated clinical trial of AGS-004 in adult HIV patients evaluating the use of AGS-004 in combination with vorinostat, a latency reversing drug, for HIV eradication, and plan to support an investigator-initiated Phase 2 clinical trial of AGS-004 evaluating AGS-004 for long-term viral control in pediatric patients provided that results from the investigator-initiated trial in adult HIV patients are favorable and government funding is available.

On March 3, 2017, we entered into a payoff letter with Horizon Technology Finance Corporation and Fortress Credit Co LLC, or the Lenders, under our venture loan and security agreement, or the Loan Agreement, pursuant to which we paid, on March 6, 2017, a total of $23.1 million to the Lenders, representing the principal balance and accrued interest outstanding under the Loan Agreement in repayment of our outstanding obligations under the Loan Agreement. In addition, we issued to the Lenders five year warrants to purchase an aggregate of 5,000 shares of common stock at an exercise price of $26.00 per share in consideration of the Lenders acceptance of $23.1 million as payment in full. Upon the payment of the $23.1 million and the issuance of the warrants pursuant to the payoff letter, all of our outstanding indebtedness and obligations to the Lenders under the Loan Agreement were paid in full, and the Loan Agreement and the notes thereunder were terminated.

In March 2017, we announced that our board of directors approved a workforce action plan designed to streamline operations and reduce operating expenses. During the year ended December 31, 2017, we recognized $1.2 million in severance costs, all of which was paid as of December 31, 2017. We also recognized $3.2 million in stock-based compensation expense from the acceleration of vesting of stock options and restricted stock held by the terminated employees during the year ended December 31, 2017.

In June 2017, we raised net proceeds of $6.0 million through the issuance of a secured convertible note to Pharmstandard International S.A., or Pharmstandard, a collaborator and our largest stockholder, in the aggregate principal amount of $6.0 million.

In August 2017, we entered into an agreement with Medpace, Inc., or Medpace, regarding $1.5 million in deferred fees that we owed Medpace for contract research and development services. Under the agreement we paid $0.85 million of the amount during the third quarter of 2017 and paid the balance in April 2018.

In September 2017, we entered into a satisfaction and release agreement, or the Invetech Satisfaction and Release Agreement, with Invetech Pty Ltd, or Invetech. Under the Invetech Satisfaction and Release Agreement, we agreed to make, issue and deliver to Invetech (i) a cash payment of $0.5 million, (ii) 57,142 shares of our common stock and (iii) an unsecured convertible promissory note in the original principal amount of $5.2 million on account of and in full satisfaction and release of all of our payment obligations to Invetech arising under our development agreement with Invetech, or the Invetech Development Agreement, prior to the date of the Invetech Satisfaction and Release Agreement, including our obligation to pay Invetech up to a total of $8.3 million in deferred fees, bonus payments and accrued interest.

In November 2017, we entered into a satisfaction and release agreement, or the Saint-Gobain Satisfaction and Release Agreement, with Saint-Gobain Performance Plastics Corporation, or Saint-Gobain. Under the Saint Gobain Satisfaction and Release Agreement, we agreed to make, issue and deliver to Saint-Gobain (i) a cash payment of $0.5 million, (ii) 34,499 shares of our common stock, (iii) an unsecured convertible promissory note in the original principal amount of $2.4 million, and (iv) certain specified equipment originally provided to us by Saint-Gobain under the development agreement with Saint-Gobain, or the Saint-Gobain Development Agreement, on account of and in full satisfaction and release of all of our payment obligations to Saint-Gobain arising under the Saint-Gobain Development Agreement, prior to the date of the Saint-Gobain Satisfaction and Release Agreement, including the development fees and charges. In connection with entering into the Saint-Gobain Satisfaction and Release Agreement, we and Saint-Gobain entered into an amendment to the Saint-Gobain Development Agreement to extend the term to December 31, 2019.

From June 2017 through December 31, 2017, we raised proceeds of $15.5 million through the issuance of common stock in an at-the-market offering under our original sales agreement with Cowen & Company, LLC, or Cowen. In February 2018, we amended and restated the original sales agreement with Cowen to increase the maximum aggregate offering price of the shares of our common stock which we may sell under the agreement from $30 million to up to $45 million. During the three months ended March 31, 2018, we raised proceeds of $7.5 million, net of commissions and issuance costs. As of May 8, 2018, we raised an additional $21,000 of proceeds through the sale of our common stock subsequent to March 31, 2018 under the amended and restated sales agreement and $15.7 million remained available for sale under the amended and restated sales agreement. However, as a result of the delisting of our common stock from The Nasdaq Capital Market in April 2018, we do not expect to sell any additional shares under our amended and restated sales agreement.

In January 2018, we entered into a stock purchase agreement with Lummy (Hong Kong), Ltd., or Lummy, under which we agreed to issue and sell to Lummy in a private financing 375,000 shares of common stock for an aggregate purchase price of $1.5 million. In March 2018, we and Lummy amended the stock purchase agreement to reduce the aggregate price for the shares to $450,000. Concurrent with such amendment, we entered into a third amendment to our license agreement with Lummy pursuant to which Lummy agreed to pay us a $1.05 million milestone payment. The $450,000 payment for the shares of common stock and the $1.05 million milestone payment were received in April 2018.

As of March 31, 2018, we had cash and cash equivalents of $17.0 million. We do not currently have sufficient cash resources to pay all of our accrued obligations in full or to continue our business operations beyond the end of 2018. As a result, in order to continue to operate our business beyond that time, we will need to raise additional funds. However, there can be no assurance that we will be able to generate funds on terms acceptable to us, on a timely basis, or at all.

On April 23, 2018, we received a notification from The Nasdaq Stock Market LLC indicating that, because we had indicated that we would be unable to meet the stockholders' equity requirement for continued listing as of the April 24, 2018 deadline that had been set by the Nasdaq Hearing Panel, the Nasdaq Hearing Panel determined to delist our common stock from The Nasdaq Capital Market and to suspend trading in our common stock effective at the open of business on April 25, 2018. Following such delisting, we transferred our common stock to the OTCQB® Venture Market.

Our consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As of March 31, 2018, our current assets totaled $18.8 million compared with current liabilities of $11.0 million, and we had cash and cash equivalents of $17.0 million. Based upon our current and projected cash flow, we note there is substantial doubt about our ability to continue as a going concern within one year after the date that these financial statements are issued. The financial statements for the quarter ended March 31, 2018 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern.

We have devoted substantially all of our resources to our drug development efforts, including advancing our Arcelis precision immunotherapy technology platform, conducting clinical trials of our product candidates, protecting our intellectual property and providing general and administrative support for these operations. We have not generated any revenue from product sales and, to date, have funded our operations primarily through public offerings of our common stock and warrants, a venture loan, private placements of common stock, preferred stock and warrants, convertible debt financings, government contracts, government and other third party grants and license and collaboration agreements. From inception in May 1997 through March 31, 2018, we have raised a total of $525.9 million in cash, including:

- $360.7 million from the sale of our common stock, convertible debt, warrants and preferred stock;
- $32.9 million from the licensing of our technology;
- $107.3 million from government contracts, grants and license and collaboration agreements; and
- $25.0 million from the Loan Agreement with the Lenders.

We have incurred losses in each year since our inception in May 1997. Our net loss was $53.0 million and $40.6 million for the years ended December 31, 2016, and 2017, respectively and $2.1 million for the three months ended March 31 2018. As of March 31, 2018, we had an accumulated deficit of $374.7 million. Substantially all of our operating losses have resulted from costs incurred in connection with our development programs and from general and administrative costs associated with our operations.

In light of the termination of the ADAPT trial and the Company's cash resources, and based on a review of the status of our internal programs, resources and capabilities, we are exploring a wide range of strategic alternatives that may include a potential merger or sale of the Company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some of our assets or proprietary technologies. We have retained Stifel to serve as our financial advisor in the process. There can be no assurance that we will be able to enter into such a transaction or transactions on a timely basis, on terms that are favorable to us, or at all. If we are unable to successfully conclude a strategic transaction, we may determine to dissolve and liquidate our assets or seek protection under the bankruptcy laws. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders. Alternatively, if we determine to continue our business operations, we will need to raise additional capital prior to the commercialization of AGS-004 or any other product candidates. If we seek to and are able to raise the capital necessary to continue the development of our product candidates, including AGS-004, we anticipate that our expenses will increase substantially if and as we:

- continue to support the ongoing investigator-initiated clinical trial of AGS-004, support any future investigator-initiated clinical trials of AGS-004 and initiate and conduct additional clinical trials of AGS-004 for the treatment of HIV;
- establish a facility for the commercial manufacture of our products based on our Arcelis-based precision immunotherapy technology platform;
- establish a sales, marketing and distribution infrastructure to commercialize products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- hire additional clinical, quality control, scientific and management personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts.

We have no external committed sources of funds other than our contract with the NIH and NIAID, as described under the section entitled NIH Funding below. We do not expect to generate significant additional funds or product revenue unless and until we successfully complete development, obtain marketing approval and commercialize our product candidates, either alone or in collaboration with third parties, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to the commercialization of AGS-004 or any other product candidates if we determine to continue our business operations. Until such time, if ever, as we can generate substantial product revenues, we expect to seek to finance our operating activities through a combination of equity offerings, debt financings, government contracts, government and other third party grants or other third party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds through these means when needed, on favorable terms or at all.

NIH Funding

In September 2006, we entered into a multi-year research contract with the NIH and NIAID to design, develop and clinically test an autologous HIV immunotherapy capable of eliciting therapeutic immune responses. We have used funds from this contract to develop AGS-004, including to fund in full our Phase 2b clinical trial of AGS-004. On June 29, 2016, a contract modification was agreed to that extended the NIH and NIAID's commitment under the contract to July 31, 2018. We have agreed to a statement of work under the contract, and are obligated to furnish all the services, qualified personnel, material, equipment, and facilities not otherwise provided by the U.S. government needed to perform the statement of work.

Under this contract, as amended, the NIH and NIAID have committed to fund up to a total of $39.8 million, including reimbursement of direct expenses and allocated overhead and general and administrative expenses of up to $38.4 million and payment of other specified amounts totaling up to $1.4 million upon our achievement of specified development milestones. This amount includes a September 2014 modification of the contract under which the NIH and NIAID agreed to fund up to an additional $0.5 million to cover a portion of the manufacturing costs of the planned Phase 2 clinical trial of AGS-004 for long-term viral control in pediatric patients. The NIH's commitment under the contract extends to July 31, 2018. Since September 2010, we have received reimbursement of our allocated overhead and general and administrative expenses at provisional indirect cost rates equal to negotiated provisional indirect cost rates agreed to with the NIH and NIAID in September 2010. These provisional indirect cost rates are subject to adjustment based on our actual costs pursuant to the agreement with the NIH and NIAID and may result in additional payments to us from the NIH and NIAID to reflect our actual costs since September 2010.

We have recorded revenue of $38.1 million through March 31, 2018 under the NIH and NIAID contract. This contract is the only arrangement under which we have generated substantial revenue. As of March 31, 2018, there was up to $1.7 million of potential revenue remaining to be earned under the agreement with the NIH and NIAID.

Development and Commercialization Agreements

An important part of our business strategy has been to enter into arrangements with third parties both to assist in the development and commercialization of our product candidates, particularly in international markets, and to in-license product candidates in order to expand our pipeline.

Pharmstandard. In August 2013, in connection with the purchase of shares of our series E preferred stock by Pharmstandard, we entered into an exclusive royalty-bearing license agreement with Pharmstandard. Under this license agreement, we granted Pharmstandard and its affiliates a license, with the right to sublicense, to develop, manufacture and commercialize rocapuldencel-T and other products for the treatment of human diseases, which are developed by Pharmstandard using our individualized immunotherapy platform, in the Russian Federation, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan, which we refer to as the Pharmstandard Territory. We also provided Pharmstandard with a right of first negotiation for development and commercialization rights in the Pharmstandard Territory to specified additional products we may develop.

Under the terms of the license agreement, Pharmstandard licensed us rights to clinical data generated by Pharmstandard under the agreement and granted us an option to obtain an exclusive license outside of the Pharmstandard Territory to develop and commercialize improvements to our Arcelis technology generated by Pharmstandard under the agreement, a non-exclusive worldwide royalty-free license to Pharmstandard improvements to manufacture products using our Arcelis technology and a license to specified follow-on licensed products generated by Pharmstandard outside of the Pharmstandard Territory, each on terms to be negotiated upon our request for a license. In addition, Pharmstandard agreed to pay us pass-through royalties on net sales of all licensed products in the low single digits until it has generated a specified amount of aggregate net sales. Once the net sales threshold is achieved, Pharmstandard will pay us royalties on net sales of specified licensed products, including rocapuldencel-T, in the low double digits below 20%. These royalty obligations last until the later of the expiration of specified licensed patent rights in a country or the twelfth anniversary of the first commercial sale in such country on a country by country basis and no further royalties on specified other licensed products. After the net sales threshold is achieved, Pharmstandard has the right to offset a portion of the royalties Pharmstandard pays to third parties for licenses to necessary third party intellectual property against the royalties that Pharmstandard pays to us.

The agreement will terminate upon expiration of the royalty term, upon which all licenses will become fully paid up perpetual exclusive licenses. Either party may terminate the agreement for the other party's uncured material breach or if specified conditions occur relating to the other party's insolvency or bankruptcy and we may terminate the agreement if Pharmstandard challenges or assists a third party in challenging specified patent rights of ours. If Pharmstandard terminates the agreement upon our material breach or bankruptcy, Pharmstandard is entitled to terminate our licenses to improvements generated by Pharmstandard, upon which we may come to rely for the development and commercialization of rocapuldencel-T and other licensed products outside of the Pharmstandard Territory, and Pharmstandard is entitled to retain its licenses from us and to pay us substantially reduced royalty payments following such termination.

In November 2013, we entered into an agreement with Pharmstandard under which Pharmstandard purchased shares of our series E preferred stock. Under this agreement, we agreed to enter into a manufacturing rights agreement for the European market with Pharmstandard and that the manufacturing rights agreement would provide for the issuance of warrants to Pharmstandard to purchase 24,989 shares of our common stock at an exercise price of $116.40 per share. As of May 8, 2018, we had not entered into this manufacturing rights agreement or issued the warrants.

Pharmstandard and Actigen. On February 1, 2018, we entered into an option agreement with Pharmstandard and Actigen Limited, or Actigen, under which we obtained an exclusive option to license certain patent rights and know-how related to a group of fully human PD1 monoclonal antibodies and related technology held by Actigen. Actigen previously granted Pharmstandard an option to exclusively license these patent rights. Under the option agreement, Pharmstandard granted to us an exclusive license for evaluation purposes only to make, have made, use and import the PD1 monoclonal antibodies covered by these patent rights (but not offer to sell or sell products and processes covered by or incorporating the patent rights) for a period of one year from the date of the agreement and an option exercisable during the option exercise period to obtain an exclusive license (with the right to sublicense) under the patent rights to make, have made, use, offer for sale, sell and import (with a right to grant sublicenses) the PD1 monoclonal antibodies for all prophylactic, therapeutic and diagnostic uses and for all human diseases and conditions in the United States and Canada. The parties have agreed that, if we exercise the option during the option exercise period, the parties will negotiate in good faith a license agreement, on the terms and conditions outlined in the option agreement, including payments by us to Pharmstandard of an upfront license fee of $3.6 million, payable upon execution of the license agreement in our common stock, various development and regulatory milestone payments totaling $8.5 million, and upper single digit percentage royalties on net sales of any pharmaceutical product or therapeutic regimen incorporating the licensed PD1 monoclonal antibodies that will apply on a country-by-country basis until the later of the last to expire patent or ten years from the date of first commercial sale, against which the first $5.0 million of our development expenditures will be credited as prepaid royalties.

In consideration for the rights granted under the option agreement, we issued 169,014 shares of our common stock to Pharmstandard the value of which will be creditable against the upfront license fee of $3.6 million payable under the option agreement if we enter into a license agreement. Unless earlier terminated by any party for uncured material breach or by us without cause upon thirty days prior written notice, the option agreement will terminate upon the later of the end of the option exercise period if we decide not to exercise the option or sixty days after we exercise the option.

Green Cross. In July 2013, in connection with the purchase of our series E preferred stock by Green Cross Corp., or Green Cross, we entered into an exclusive royalty-bearing license agreement with Green Cross. Under this agreement we granted Green Cross a license to develop, manufacture and commercialize rocapuldencel-T for mRCC in South Korea. We also provided Green Cross with a right of first negotiation for development and commercialization rights in South Korea to specified additional products we may develop.

Under the terms of the license, Green Cross has agreed to pay us $0.5 million upon the initial submission of an application for regulatory approval of a licensed product in South Korea, $0.5 million upon the initial regulatory approval of a licensed product in South Korea and royalties ranging from the mid-single digits to low double digits below 20% on net sales until the fifteenth anniversary of the first commercial sale in South Korea. In addition, Green Cross has granted us an exclusive royalty free license to develop and commercialize all Green Cross improvements to our licensed intellectual property in the rest of the world, excluding South Korea, except that, as to such improvements for which Green Cross makes a significant financial investment and that generate significant commercial benefit in the rest of the world, we are required to negotiate in good faith a reasonable royalty that we will be obligated to pay to Green Cross for such license. Under the terms of the agreement, we are required to continue to develop and to use commercially reasonable efforts to obtain regulatory approval for rocapuldencel-T in the United States.

The agreement will terminate upon expiration of the royalty term, which is 15 years from the first commercial sale, upon which all licenses will become fully paid up perpetual non-exclusive licenses. Either party may terminate the agreement for the other party's uncured material breach or if specified conditions occur relating to the other party's insolvency or bankruptcy and we may terminate the agreement if Green Cross challenges or assists a third party in challenging specified patent rights of ours. If Green Cross terminates the agreement upon our material breach or bankruptcy, Green Cross is entitled to terminate our licenses to improvements and retain its licenses from us and to pay us substantially reduced milestone and royalty payments following such termination.

Medinet. In December 2013, we entered into a license agreement with Medinet. Under this agreement, we granted Medinet an exclusive, royalty-free license to manufacture in Japan rocapuldencel-T and other products using our Arcelis technology solely for the purpose of the development and commercialization of rocapuldencel-T and these other products for the treatment of mRCC. We refer to this license as the manufacturing license. In addition, under this agreement, we granted Medinet an option to acquire a nonexclusive, royalty-bearing license under our Arcelis technology to sell in Japan rocapuldencel-T and other products for the treatment of mRCC. We refer to the option as the sale option and the license as the sale license.

The sale option expired on April 30, 2016. As a result, Medinet has only retained the manufacturing license and may only manufacture rocapuldencel-T and these other products for us or our designee. We have agreed to negotiate in good faith a supply agreement under which Medinet would supply us or our designee with rocapuldencel-T and these other products for development and sale for the treatment of mRCC in Japan. During the term of the manufacturing license, we may not manufacture rocapuldencel-T or these other products for us or any designee for development or sale for the treatment of mRCC in Japan.

In consideration for the manufacturing license, Medinet paid us $1.0 million. Medinet also loaned us $9.0 million in connection with us entering into the agreement. We have agreed to use these funds in the development and manufacturing of rocapuldencel-T and the other products. Medinet also agreed to pay us milestone payments of up to a total of $9.0 million upon the achievement of developmental and regulatory milestones and $5.0 million upon the achievement of a sales milestone related to rocapuldencel-T and these products.

We borrowed the $9.0 million pursuant to an unsecured promissory note that bears interest at a rate of 3.0 % per annum. The principal and interest under the note are due and payable on December 31, 2018. Under the terms of the note and the manufacturing license agreement, any milestone payments related to the developmental and regulatory milestones that become due will be applied first to the repayment of the loan. We have achieved $5.0 million in milestones. As a result, the outstanding principal of the loan as of February 1, 2018 has been reduced to $4.0 million. We have the right to prepay the loan at any time. If we have not repaid the loan by December 31, 2018, then we have agreed to grant to Medinet a non-exclusive, royalty-bearing license to make and sell Arcelis products in Japan for the treatment of cancer. In such event, the amounts owing under the loan as of December 31, 2018 may constitute pre-paid royalties under the license or would be due and payable. We do not expect to pay the amounts owing under the loan by December 31, 2018. Royalties under this license would be paid until the expiration of the licensed patent rights in Japan at a rate to be negotiated. If we cannot agree on the royalty rate, we have agreed to submit the matter to arbitration.

Under the agreement, we had the right to revoke both the manufacturing license and the sale license to be granted to Medinet or the sale license only. In February 2018, we notified Medinet that we irrevocably agreed to have no further right to exercise our right under the license agreement to revoke the manufacturing and the sale license, or the sale license only. As a result of our decision to forego these revocation rights, during the three months ended March 31, 2018, we recognized as revenue $5.8 million of milestone payments that had previously been received and recorded as deferred revenue.

The agreement will terminate upon expiration of the royalty term, upon which all licenses will become fully paid up, perpetual non-exclusive licenses. Either party may terminate the agreement for the other party's uncured material breach or if specified conditions occur relating to the other party's insolvency or bankruptcy, and we may terminate the agreement if Medinet challenges or assists a third party in challenging specified patent rights of ours. If Medinet terminates the agreement upon our material breach or bankruptcy, Medinet is entitled to terminate our licenses to improvements and retain its royalty-bearing licenses from us.

Lummy. On April 7, 2015, we and Lummy (Hong Kong) Co. Ltd., or Lummy HK, entered into a license agreement pursuant to which we granted to Lummy HK an exclusive license under the Arcelis technology, including patents, know-how and improvements to manufacture, develop and commercialize products for the treatment of cancer in China, Hong Kong, Taiwan and Macau. Lummy HK also has a right of first negotiation with respect to a license under the Arcelis technology for the treatment of infectious diseases in China, Hong Kong, Taiwan and Macau. This agreement was subsequently amended in December 2016, October 2017 and March 2018.

Under the terms of the license agreement, the parties will share relevant data, and we will have a right to reference Lummy HK data for purposes of its development programs under the Arcelis technology. In addition, Lummy HK has granted to us an exclusive, royalty-free license under and to any and all Lummy HK improvements to the Arcelis technology conceived or reduced to practice by Lummy HK and Lummy HK data to develop and/or commercialize products outside China, Hong Kong, Taiwan and Macau, an exclusive, royalty-free license under and to any and all investigational new drugs, or INDs, and other regulatory approvals and Lummy HK trademarks used for an Arcelis-based product to develop and/or commercialize an Arcelis-based product outside China, Hong Kong, Taiwan and Macau and a non-exclusive, worldwide, royalty-free license under any Lummy HK improvements and Lummy HK data to manufacture Arcelis-based products anywhere in the world. Lummy HK has the right to reference our data, INDs and other regulatory filings and submissions for the purpose of developing and obtaining regulatory approval of licensed products in China, Hong Kong, Taiwan and Macau.

Pursuant to the license agreement, Lummy HK will pay us royalties on net sales and an aggregate of up to $22.3 million upon the achievement of manufacturing, regulatory and commercial milestones. On October 18, 2017, we entered into a second amendment to the license agreement and Lummy HK paid us $1.5 million upon the achievement of a manufacturing milestone in October 2017. On March 23, 2018, we entered into a third amendment to the license agreement pursuant to which Lummy agreed to pay us a $1.05 million milestone. Lummy also agreed to purchase 375,000 shares of our common stock for a purchase price of $450,000 pursuant to an amended stock purchase agreement. We received payments for the achievement of this milestone and for the purchase of these shares of common stock in April 2018.

Of the potential $22.3 million in milestone payments, to date we have earned $2.55 million, of which we received $1.5 million as of March 31, 2018, and $1.05 million in April 2018. The license agreement will terminate upon expiration of the last to expire royalty term for all Arcelis-based products, with each royalty term being the longer of the expiration of the last valid patent claim covering the applicable Arcelis-based product and 10 years from the first commercial sale of such Arcelis-based product. Either party may terminate the license agreement for the other party's uncured material breach or if specified conditions occur relating to the other party's insolvency or bankruptcy. We may terminate the license agreement if Lummy HK challenges or assists a third party in challenging specified patent rights of ours. If Lummy HK terminates the license agreement upon our material breach or bankruptcy, Lummy HK is entitled to terminate the licenses it granted to us and retain its licenses from us with respect to Arcelis-based products then in development or being commercialized, subject to Lummy HK's continued obligation to pay royalties and milestones with respect to such Arcelis-based products.

Invetech. In October 2014, we entered into the Invetech Development Agreement. Under the Invetech Development Agreement, Invetech had agreed to continue to develop and provide prototypes of the automated production system to be used for the manufacture of our Arcelis-based products. Subsequent to signing the Invetech Development Agreement, Invetech agreed to defer 30% of its fees, up to $5.0 million subject to payments by us in installments over 2017 and 2018.

On September 22, 2017, we entered into the Invetech Satisfaction and Release Agreement. Under the Invetech Satisfaction and Release Agreement, we agreed to make, issue and deliver to Invetech (i) a cash payment of $0.5 million (ii) 57,142 shares of our common stock and (iii) an unsecured convertible promissory note in the original principal amount of $5.2 million on account of and in full satisfaction and release of all of our payment obligations to Invetech arising under the Invetech Development Agreement prior to the date of the Invetech Satisfaction and Release Agreement, including our obligation to pay Invetech up to a total of $8.3 million in deferred fees, bonus payments and accrued interest.

Although we currently have no ongoing activities under the Invetech Development Agreement, the term of the Invetech Development Agreement will continue until the completion of the development of the production systems. The Invetech Development Agreement can be terminated early by either party because of a technical failure or by us without cause. We own all intellectual property arising from the development services with the exception of existing Invetech intellectual property incorporated therein-under which we have a license.

Saint-Gobain. In January 2015, we entered into the Saint-Gobain Development Agreement, that was subsequently amended in 2015, 2016 and 2017. Under the Saint-Gobain Development Agreement, Saint-Gobain agreed to develop a range of disposables for use in our automated production systems to be used for the manufacture of our Arcelis-based products. The Saint-Gobain agreement requires the parties to execute a commercial supply agreement under which Saint-Gobain would become the exclusive supplier of disposables for the manufacture of our products treating solid tumors for no less than fifteen years. The Saint-Gobain agreement will continue until December 31, 2019, but can be terminated by written agreement of the parties because of a material default, including the failure to execute the commercial supply agreement, or a failure to achieve a performance milestone.

On November 22, 2017, we entered into the Saint-Gobain Satisfaction and Release Agreement. Under the Saint-Gobain Satisfaction and Release Agreement, we agreed to make, issue and deliver to Saint-Gobain (i) a cash payment of $0.5 million, (ii) 34,499 shares of our common stock (iii) an unsecured convertible promissory note in the original principal amount of $2.4 million, and (iv) certain specified equipment originally provided to us under the development agreement, on account of and in full satisfaction and release of all payment obligations to Saint-Gobain arising under the development agreement, including the development fees and charges owed by us to Saint-Gobain.

Cellscript. In December 2015, we entered into a development and supply agreement with Cellscript, LLC, or Cellscript. Under the agreement, Cellscript has agreed to develop cGMP processes for the manufacture and production of CD40L RNA, a ribonucleic acid used in the production of our Arcelis-based products, and to manufacture and produce CD40L RNA.

In consideration for these development and production services, we have agreed to pay Cellscript total fees of $4.6 million. Upon the execution of the agreement, we made an initial payment to Cellscript of $2.1 million through the issuance to Cellscript of 45,309 shares of our common stock. The balance of these fees is payable to Cellscript, at our option, in cash, common stock or a combination of cash and common stock upon the achievement of development milestones. Any shares of common stock issued pursuant to the agreement are subject to a lock-up period of 180 days from the date of issuance of such shares to Cellscript.

Under the terms of the agreement, Cellscript shall be the sole and exclusive manufacturer and supplier to us of CD40L RNA, and we will make agreed upon cash payments to Cellscript for CD40L RNA produced for us during the term of the agreement. Under the agreement, Cellscript shall also be our sole and exclusive supplier of enzymes and various kits comprising enzymes for transcription, capping and/or polyadenylation of RNA. We will make agreed upon cash payments to Cellscript for each kit that is purchased under the agreement.

The agreement will continue until the earlier of June 30, 2018 or the effective date of a commercial supply agreement negotiated in good faith by the parties, but can be earlier terminated by either party due to a material breach or upon bankruptcy of the other party. As of March 31, 2018, we accrued $2.0 million for development and production services performed by Cellscript under the development and supply agreement .

Manufacturing

We currently have manufacturing suites located at our Technology Drive and Patriot Center leased facilities in Durham, North Carolina. We manufacture Arcelis-based product candidates for research and development purposes and for clinical trials at these facilities.

In January 2017, we entered into a ten-year lease agreement with two five-year renewal options for 40,000 square feet of manufacturing and office space at the Center for Technology Innovation, or CTI, on the Centennial Campus of North Carolina State University in Raleigh, North Carolina. We provided a security deposit in the amount of $2.4 million as security for obligations under the lease agreement, which was provided in the form of a letter of credit. We had intended to utilize this facility to manufacture rocapuldencel-T to support submission of a biologics license application, or BLA, to the FDA and to support initial commercialization of rocapuldencel-T.

To provide for capacity expansion beyond the initial few years following potential launch of rocapuldencel-T, we also had planned to build-out and equip a second facility, which we refer to as the Centerpoint facility. In August 2014, we entered into a ten-year lease agreement with renewal options. Under the lease agreement, we agreed to lease certain land and an approximately 125,000 square-foot building to be constructed in Durham County, North Carolina. We initially intended this facility to house our corporate headquarters and commercial manufacturing before we entered into the lease for the Center for Technology Innovation, or CTI, facility. The shell of the new facility was constructed on a build-to-suit basis in accordance with agreed upon specifications and plans and was completed in June 2015. However, the build-out and equipping of the interior of the facility was suspended as we pursued financing arrangements to support the further build out of the facility.

Due to the recommendation of the IDMC in February 2017 to discontinue the ADAPT study, we reassessed our manufacturing plans. In March 2017, we entered into a lease termination agreement with the landlord of our CTI facility terminating the lease as of March 17, 2017. From the $2.4 million letter of credit, the landlord drew down $0.7 million to cover unpaid construction costs in March 2017 and $1.7 million in April 2017 for lease termination damages and agreed to return $0.1 million in consideration for being able to salvage some of the construction costs. Pursuant to the lease termination agreement, we have no further obligations under the lease. During the year ended December 31, 2017, we recorded a lease termination fee of $1.6 million that is included in restructuring costs on the statement of operations and Current portion of restructuring liability on the balance sheet. We also recorded an impairment loss on Construction-in-progress on the property of $0.9 million during the year ended December 31, 2017.

In November 2017, we and TKC Properties, the landlord of the Centerpoint facility, entered into a lease termination agreement terminating the lease agreement as of November 21, 2017. In addition, TKC Properties completed the sale of the facility to a third party and we received cash proceeds of approximately $1.8 million. As of December 31, 2017, we recorded $0 for the Centerpoint facility and $0 for the lease liability. Additionally, we are no longer required to maintain restricted cash of approximately $0.7 million as a security deposit.

Results of Operations

Comparison of the Three Months Ended March 31, 2017 with the Three Months Ended March 31, 2018

The following table summarizes the results of our operations for each of the three month periods ended March 31, 2017 and 2018, together with the changes in those items in dollars and as a percentage:

	Three Months Ended March 31,		$	%
	2017	2018	Change	Change
	(in thousands)			
Revenue	$ 105	$ 5,933	$ 5,828	*
Operating expenses				
Research and development	7,914	5,545	(2,369)	(29.9%)
General and administrative	3,963	2,499	(1,464)	(36.9%)
Impairment of property and equipment	27,204	—	(27,204)	*
Restructuring costs	5,008	—	(5,008)	*
Total operating expenses	44,089	8,044	(36,045)	(81.8%)
Loss from operations	(43,984)	(2,111)	41,873	95.2%
Interest income	31	18	(13)	(41.0%)
Interest expense	(728)	(149)	579	79.6%
Gain on early extinguishment of debt	249	—	(249)	*
Change in fair value of warrant liability	20,357	149	(20,208)	*
Other expense	(5)	(18)	(13)	(274.0%)
Net loss	$ (24,080)	$ (2,111)	$ 21,969	91.2%

* Not meaningful

Revenue

To date, we have not generated revenue from the sale of any products. Substantially all of our revenue has been derived from our NIH and NIAID contract and our license agreements with Medinet and Lummy. We may generate revenue in the future from government contracts and grants, payments from future license or collaboration agreements and product sales. We expect that any revenue we generate will fluctuate from quarter to quarter.

Revenue was $0.1 million for the three months ended March 31, 2017, compared with $5.9 million for the three months ended March 31, 2018, an increase of $5.8 million. The $5.8 million increase for the three months ended March 31, 2018 resulted from the recognition of $5.8 million of revenue from milestone payments from Medinet that had previously been recorded as deferred revenue as a result of our decision to irrevocably forego our revocation right under our license agreement with Medinet.

Research and Development Expenses

Since our inception in 1997, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. We recognize our research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related expenses for personnel in research and development functions;
- fees paid to consultants and clinical research organizations, or CROs, including in connection with our clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work and statistical compilation and analysis;
- commercial manufacturing development consisting of costs incurred under our development agreement with Invetech under which Invetech has agreed to develop and provide prototypes of the automated production system to be used for the manufacture of our Arcelis-based products;
- allocation of facility lease and maintenance costs;
- costs incurred under our development agreement with Saint-Gobain to develop a range of disposables for use in the automated production system;
- depreciation of leasehold improvements, laboratory equipment and computers;
- costs related to production of product candidates for clinical trials;
- costs related to compliance with regulatory requirements;
- consulting fees paid to third parties related to non-clinical research and development;
- costs related to stock options or other share-based compensation granted to personnel in research and development functions; and
- acquisition fees, license fees and milestone payments related to acquired and in-licensed technologies.

The table below summarizes our direct research and development expenses by program for the periods indicated. Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, including in connection with our clinical trials, and related clinical trial fees. Research and development expenses also include commercial manufacturing development costs consisting primarily of costs incurred under our Invetech Development Agreement to develop and provide prototypes of the automated production system to be used for the manufacture of our Arcelis-based products and our Saint-Gobain Development Agreement to develop a range of disposables to be used in both our manual and automated manufacturing processes. We have been developing rocapuldencel-T and AGS-004 in parallel, and typically use our employee and infrastructure resources across multiple research and development programs. We do not allocate salaries, share-based compensation, employee benefit or other indirect costs related to our research and development function to specific product candidates. Those expenses are included in "Indirect research and development expense" in the table below.

	Three Months Ended March 31,	
	2017	2018
	(in thousands)	
Direct research and development expense by program:		
Rocapuldencel-T	$ 2,403	$ 3,123
AGS-004	56	13
Total direct research and development program expense	2,459	3,136
Commercial manufacturing development expense	(373)	-
Indirect research and development expense	5,828	2,409
Total research and development expense	$ 7,914	$ 5,545

Research and development expenses were $7.9 million for the three months ended March 31, 2017, compared with $5.5 million for the three months ended March 31, 2018, a decrease of $2.4 million, or 29.9%. The decrease in research and development expense reflects a $3.4 million decrease in indirect research and development expense partially offset by a $0.7 million increase in direct research and development expense and a $0.4 million increase in commercial manufacturing development expense. The increase in direct research and development expenses resulted primarily from the following:

- Direct research and development expense for rocapuldencel-T increased from $2.4 million for the three months ended March 31, 2017 to $3.1 million in the three months ended March 31, 2018. This increase is primarily related to $2.0 million in accrued contract services payable to Cellscript partially offset by a reduction of costs related to the ADAPT trial of rocapuldencel-T.

- Direct research and development expense with respect to AGS-004 was not significantly different in the three months ended March 31, 2017 compared with the three months ended March 31, 2018.

During the three months ended March 31, 2017, we recorded a credit of $0.4 million related to amounts owed under our agreement with Saint-Gobain, which we recorded as a reduction of research and development expense. No commercial manufacturing development expense was recorded for the three months ended March 31, 2018.

The decrease in indirect research and development expense was primarily due to decreased compensation expense associated with our decision to significantly reduce the size of our workforce engaged in research and development activities in March 2017. As of March 31, 2018, we had 28 employees engaged in such activities, compared with 56 employees engaged in such activities as of March 31, 2017.

The successful development of AGS-004 or any other product candidate we may develop is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the development of AGS-004 or any other product candidate we may develop, or the period, if any, in which material net cash inflows from such product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress, expense and results of our ongoing clinical trials;
- the scope, rate of progress, expense and results of additional clinical trials that we may conduct;
- the scope, rate of progress, expense and results of our commercial manufacturing development efforts;
- other research and development activities; and
- the timing of regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. If the FDA or another regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses were $4.0 million for the three months ended March 31, 2017, compared with $2.5 million for the three months ended March 31, 2018, a decrease of $1.5 million or 36.9%. This decrease was primarily due to a decrease of $1.2 million in personnel costs, including salaries, benefits and stock-based compensation, a decrease of $0.5 million in consulting costs and a decrease of $0.1 million in marketing expense, partially offset by an increase of $0.3 million in legal expenses.

General and administrative expenses consist primarily of salaries and related costs for employees in executive, operational and finance, information technology and human resources functions. Other significant general and administrative expenses include allocation of facilities costs, professional fees for accounting and legal services and expenses associated with obtaining and maintaining patents.

Impairment Loss on Property and Equipment

We recognized an impairment loss on property and equipment of $27.2 million for the three months ended March 31, 2017, compared with $0 for the three months ended March 31, 2018. We review our property and equipment for impairment whenever events or changes indicate its carrying value may not be recoverable.

Impairment of Centerpoint Facility and Construction-in-Progress

We determined during the three months ended March 31, 2017 that we no longer planned to develop our Centerpoint facility. Accordingly, we recorded an impairment loss of $18.3 million for the Construction-in-progress on the property.

Additionally, we determined during the three months ended March 31, 2017 that we would no longer need to develop various equipment included in Construction-in-progress under our current manufacturing plans. As such, we entered into agreements and understandings with various vendors to attempt to sell or dispose this equipment at prices less than our carrying value. Accordingly, we determined that the fair value of this equipment held for sale was $0.7 million as of March 31, 2017 and recorded an impairment loss of $1.1 million. Additionally, we recorded a $6.1 million impairment loss on other equipment included in Construction-in-progress that had to be abandoned or had no net realizable value. Finally, we recorded an impairment loss of $0.9 million on Construction-in-progress that was abandoned at the CTI facility.

Impairment of Capital Leases

In August 2016, we entered into two agreements, or the Power Generation Agreements, with an electric utility company. The Power Generation Agreements were accounted for as capital leases for financial reporting purposes. Under the lease agreements, the electric utility company agreed to design, procure, install, own and maintain electrical equipment at Centerpoint to provide required electrical loads. Property, plant and equipment included $2.4 million as of December 31, 2016 under the Power Generation Agreements in the Construction-in-progress account. As of March 31, 2017, $2.2 million of these assets were classified as Assets held for sale on our Balance Sheet. Since the capital leases are for electrical equipment held for sale on the Centerpoint property, we recorded an impairment loss of $0.1 million during the three months ended March 31, 2017.

Restructuring Costs

We recognized restructuring costs of $5.0 million during the three months ended March 31, 2017 compared with $0 during the three months ended March 31, 2018. The restructuring costs and impairment charges during the three months ended March 31, 2017 were related to the restructuring of our operations following the recommendation by the IDMC to discontinue the ADAPT study in February 2017.

Workforce Action Plan

On March 10, 2017, we enacted a workforce action plan designed to streamline operations and reduce our operating expenses. Under this plan, we reduced our workforce by 46 employees (or 38%) from 122 employees to 76 employees in March 2017. We recognized $1.0 million in severance costs during the three months ended March 31, 2017, of which $0.9 million was unpaid as of March 31, 2017. We also recognized $2.4 million in stock compensation costs from the acceleration of vesting of stock options held by the terminated employees.

CTI Lease Agreement

In January 2017, we entered into a ten-year lease agreement with two five-year renewal options for 40,000 square feet of manufacturing and office space at CTI on the Centennial Campus of North Carolina State University in Raleigh, North Carolina. We provided a security deposit in the amount of $2.4 million as security for obligations under the lease agreement, which was provided in the form of a letter of credit. In March 2017, we initiated discussions with the landlord of the CTI facility regarding the termination of this lease.

In March 2017 the landlord of our CTI facility notified us that it was terminating the lease due to nonpayment of invoices for up-fit costs, effective immediately. On March 31, 2017, we entered into a termination agreement with the landlord terminating the lease as of March 17, 2017. From the $2.4 million letter of credit, the landlord drew down $0.7 million to cover unpaid construction costs in March 2017 and $1.7 million in April 2017 for lease termination damages and agreed to return $0.1 million in consideration for being able to salvage some of the construction costs. Pursuant to the termination agreement, we have no further obligations under the lease. During the quarter ended March 31, 2017, we recorded a lease termination fee of $1.6 million which is included in Restructuring costs on the statement of operations and Current portion of restructuring liability on the balance sheet. We also recorded an impairment loss on Construction-in-progress on the property of $0.9 million during the three months ended March 31, 2017.

Interest Expense

Interest expense was $0.7 million for the three months ended March 31, 2017, compared with $0.1 million for the three months ended March 31, 2018, resulting in a decrease of $0.6 million. The decrease primarily resulted from the extinguishment of our Loan Agreement in March 2017, which included the write off of the remaining debt discount.

Gain on Early Extinguishment of Debt

We recognized a gain on early extinguishment of debt of $0.2 million for the three months ended March 31, 2017, compared with $0 for the three months ended March 31, 2018. On March 3, 2017, we entered into a payoff letter with the Lenders, pursuant to which we paid on March 6, 2017, a total of $23.1 million to the Lenders, representing the principal balance and accrued interest outstanding under the Loan Agreement in repayment of our outstanding obligations under the Loan Agreement. In addition, we issued to the Lenders five year warrants to purchase an aggregate of 5,000 shares of our common stock at an exercise price of $26.00 per share in consideration of the Lenders accepting the $23.1 million as repayment in full. We recognized a gain on this early extinguishment of debt of $0.2 million during the three months ended March 31, 2017 which is included in Other income (expense) on the statement of operations.

Change in Fair Value of Warrant Liability

Gain from the change in fair value of the warrant liability was $20.4 million for the three months ended March 31, 2017, compared with $0.1 million for the three months ended March 31, 2018. The 2017 amount represents the decrease in the fair value of our warrant liability during the three months ended March 31, 2017 for the warrants issued in August 2016. The August 2016 warrants contain provisions that could require cash settlement and are recorded as a liability at fair value on the date of issuance and as of the end of each reporting period. The fair value of the August 2016 warrants declined by $20.4 million from $20.9 million to $0.6 million during the three months ended March 31, 2017 primarily due to a significant decline in the price of our common stock and a shorter expected life of the August 2016 warrants.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2018, we had cash and cash equivalents of $17.0 million.

Since our inception in May 1997 through March 31, 2018, we have funded our operations principally with $360.7 million from the sale of common stock, convertible debt, warrants and preferred stock, $32.9 million from the licensing of our technology, $107.3 million from government contracts, grants and license and collaboration agreements, and $25.0 million from the Loan Agreement.

Troubled Debt Restructuring with Invetech. As of June 30, 2017, we had recorded a manufacturing research and development obligation payable to Invetech on our consolidated balance sheet of $8.3 million, representing $5.2 million in deferred fees, $2.3 million in estimated bonus payments and $0.7 million in accrued interest. On September 22, 2017, we entered into the Invetech Satisfaction and Release Agreement. Under the Invetech Satisfaction and Release Agreement, we agreed to make, issue and deliver to Invetech (i) a cash payment of $0.5 million, (ii) 57,142 shares of our common stock and (iii) an unsecured convertible promissory note in the original principal amount of $5.2 million on account of and in full satisfaction and release of all of our payment obligations to Invetech arising under the Invetech Development Agreement prior to the date of the Invetech Satisfaction and Release Agreement, including our obligation to pay Invetech up to a total of $8.3 million in deferred fees, bonus payments and accrued interest.

The maturity date for the payment of principal and interest under the note is September 30, 2020. The note bears interest at a rate of 6.0% per annum, which interest will compound annually. For each of the quarterly periods ended December 31, 2017 and March 31, 2018, we paid Invetech $200,000 in cash under the note. For the fiscal quarters ending June 30, 2018 through March 31, 2019, we are required to make quarterly installment payments under the note, each in an aggregate amount of up to $0.3 million, consisting of (i) cash in the amount of $150,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to $150,000 of shares of our common stock. For the fiscal quarters ending June 30, 2019 through June 30, 2020, we are required to make quarterly installment payments under the note, each in an amount of $150,000, payable in cash. Subject to Invetech's conversion rights, we may prepay the note in full or in part at any time without penalty or premium.

The note also provides that on the anniversary of the issue date of the note for each of the first three years following the issue date, the outstanding principal amount of the note, if any, plus accrued and unpaid interest thereon shall automatically be deemed to be reduced by $250,000, if and only if we have paid all debt service payments due under the note on or prior to the relevant anniversary date and no event of default, fundamental transaction or change of control, each as defined in the note, has occurred on or prior to such anniversary date.

Upon maturity of the note or at any time within 75 days of such maturity, or upon the occurrence of certain events of default, Invetech may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of our common stock. Upon a change of control pursuant to which Invetech has a redemption right, Invetech may, at its option, elect to convert any amount of the outstanding principal and accrued interest, less any remaining installment payments required to be made in cash, into shares of our common stock. We will be required to pay any amount not so converted in cash. Upon the occurrence of certain events of default, Invetech may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of our common stock. We will be required to pay any amount not so converted in cash. In each case, the number of shares of common stock issuable upon such complete or partial conversion of the note is determined by dividing the portion of the principal and accrued or unpaid interest to be converted by $10.00 per share (as adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction). Unless Invetech has elected to exercise these conversion rights, we, subject to specified exceptions, may prepay the note in whole or in part, in cash, at any time without penalty or premium.

Troubled Debt Restructuring with Saint-Gobain. As of September 30, 2017, we had recorded accrued expenses of $4.8 million payable to Saint-Gobain. On November 22, 2017, we entered into the Saint-Gobain Satisfaction and Release Agreement. Under the Saint Gobain Satisfaction and Release Agreement, we agreed to make, issue and deliver to Saint-Gobain (i) a cash payment of $0.5 million, (ii) 34,499 shares of common stock, (iii) an unsecured convertible promissory note in the original principal amount of $2.4 million, and (iv) certain specified equipment originally provided to us by Saint-Gobain under the Saint-Gobain Development Agreement, on account of and in full satisfaction and release of all of our payment obligations to Saint-Gobain arising under the Saint-Gobain Development Agreement, prior to the date of the Saint-Gobain Satisfaction and Release Agreement, including the development fees and charges. As a result, we recognized a gain on the early extinguishment of debt of $0.6 million during the year ended December 31, 2017.

The maturity date for the payment of principal and interest under the note is September 30, 2020. The note bears interest at a rate of 6.0% per annum, which interest will compound quarterly. For each of the quarterly periods ended December 31, 2017 and March 31, 2018, we paid Saint-Gobain $270,000 in cash under the note. For the fiscal quarters ending June 30, 2018 and September 30, 2018, we are required to make quarterly installment payments under the note, each in an aggregate amount of up to $245,000, consisting of (i) cash in the amount of $125,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to $120,000 of shares of our common stock. For the fiscal quarters ending December 31, 2018 and March 31, 2019, we are required to make quarterly installment payments under the note, each in an aggregate amount of up to $220,000, consisting of (i) cash in the amount of $100,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to $120,000 of shares of our common stock. For the fiscal quarter ending December 31, 2017, March 31, 2018, June 30, 2018, September 30, 2018, December 31, 2018 and March 31, 2019, if the conditions required for the issuance of common stock are not met solely because the stock price of the common stock at the time is less than $4.058 per share (as adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction), then we will be required to pay in each such quarter cash equal to 50% of the value of the common stock that would otherwise have been issued. For the fiscal quarters ending June 30, 2019 through June 30, 2020, we are required to make quarterly installment payments under the note, each in an amount of $100,000, payable in cash.

Upon maturity of the note or at any time during the 75-day period prior to the maturity date of the note, Saint-Gobain may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of our common stock. Upon a change of control pursuant to which Saint-Gobain has a redemption right, Saint-Gobain may, at its option, elect to convert any amount of the outstanding principal and accrued interest, less any remaining installment payments required to be made in cash, into shares of our common stock. We will be required to pay any amount not so converted in cash. Upon the occurrence of certain events of default, Saint-Gobain may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of our common stock. We will be required to pay any amount not so converted in cash. In each case, the number of shares of common stock issuable upon such complete or partial conversion of the note is determined by dividing the portion of the principal and accrued or unpaid interest to be converted by $10.00 per share (as adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction). Unless Saint-Gobain has elected to exercise these conversion rights, we, subject to specified exceptions, may prepay the note in whole or in part, in cash, at any time without penalty or premium.

Venture Loan and Security Agreement. In September 2014, we entered into the Loan Agreement with the Lenders, under which we borrowed $25.0 million in two tranches of $12.5 million each. The per annum interest rate for each tranche was a floating rate equal to 9.25% plus the amount by which the one-month LIBOR exceeds 0.50% (effectively a floating rate equal to 8.75% plus the one-month LIBOR Rate). The total per annum interest rate could not exceed 10.75%.

On March 3, 2017, we entered into a payoff letter with the Lenders, pursuant to which we paid, on March 6, 2017, a total of $23.1 million to the Lenders, representing the principal balance and accrued interest outstanding under the Loan Agreement in repayment of our outstanding obligations under the Loan Agreement. In addition, we issued to the Lenders five year warrants to purchase an aggregate of 5,000 shares of common stock at an exercise price of $26.00 per share in consideration of the Lenders acceptance of $23.1 million as payment in full. Upon the payment of the $23.1 million and the issuance of the warrants pursuant to the payoff letter, all of our outstanding indebtedness and obligations to the Lenders under the Loan Agreement were deemed paid in full, and the Loan Agreement and the notes thereunder were terminated.

At-the-Market Offering. On May 8, 2015, we filed a shelf registration statement on Form S-3, or the 2015 Shelf, with the SEC, which covers the offering, issuance and sale of up to $125.0 million of our common stock, preferred stock, debt securities, depositary shares, purchase contracts, purchase units and warrants. We simultaneously entered into a sales agreement, or the Original Sales Agreement, with Cowen and Company LLC, or Cowen, to provide for the offering, issuance and sale of up to $30.0 million of our common stock from time to time in "at-the-market" offerings under the 2015 Shelf. The 2015 Shelf was declared effective by the SEC on May 14, 2015.

On January 9, 2017, we filed a shelf registration statement on Form S-3, or the 2017 Shelf, with the SEC, which covers the offering, issuance and sale of up to $200.0 million of our common stock, preferred stock, debt securities, depositary shares, purchase contracts, purchase units and warrants and which became effective on January 24, 2017. On February 2, 2018, we amended and restated the Original Sales Agreement with Cowen, or the Amended and Restated Sales Agreement, in order to increase the maximum aggregate offering price of our shares of common stock that may be offered from time to time in "at-the-market offerings" by $15.0 million from $30.0 million to $45.0 million. On February 2, 2018, we filed a prospectus supplement with the SEC in connection with the issuance and sale of the additional shares available under the 2017 Shelf. We refer to the Original Sales Agreement and the Amended and Restated Sales Agreement collectively as the Sales Agreement.

Under the Sales Agreement, we pay Cowen a commission of up to 3% of the gross proceeds. During the three months ended March 31, 2018, we sold 4,108,124 shares of common stock pursuant to the Sales Agreement, resulting in proceeds of $7.5 million, net of commissions and issuance costs. As of May 8, 2018, we had sold an additional 27,869 shares of our common stock resulting in $21,000 of proceeds subsequent to March 31, 2018 under the Sales Agreement and $15.7 million remained available for sale under the Sales Agreement. However, as a result of the delisting of our common stock from The Nasdaq Capital Market in April 2018, we do not expect to sell any additional shares under the Sales Agreement.

Follow-On Public Offering . On August 2, 2016, we issued and sold 454,545 shares of common stock and warrants to purchase an aggregate of 340,909 shares of common stock, in an underwritten public offering at a price to the public of $110.00 per share and accompanying warrant. The shares of common stock and warrants were sold in combination, with one warrant to purchase up to 0.75 of a share of common stock accompanying each share of common stock sold. The warrants have an exercise price of $110.00 per share, became immediately exercisable upon issuance and will expire on August 2, 2021. The aggregate net proceeds to us of the offering were approximately $48.2 million after deducting underwriting discounts and commissions and offering expenses.

Convertible Note Issued to Pharmstandard. On June 15, 2017, we entered into a convertible note purchase agreement with Pharmstandard, pursuant to which we agreed to issue and sell to Pharmstandard a convertible secured promissory note in the original principal amount of $6.0 million in a private placement. We issued the note to Pharmstandard on June 21, 2017, the closing date of the financing. Under the note, the maturity date for the payment of principal and interest is the fifth anniversary of the issue date. The note bears interest at a rate of 9.5% per annum, which interest compounds annually. The note is secured by a lien on and security interest in all of our intellectual property. We may prepay the note in whole or in part at any time without penalty or premium. Upon the occurrence of certain events of default, Pharmstandard will have the option to require us to repay the unpaid principal amount of the note and any unpaid accrued interest.

In addition, at Pharmstandard's election, Pharmstandard may convert the entire principal and interest of the note into shares of our common stock at a price per share equal to $10.00. However, Pharmstandard will not be permitted to convert the entire note if such conversion would result in Pharmstandard and its affiliates holding shares that exceed 39.9% of the total number of outstanding shares of our common stock or 39.9% of the combined voting power of all of our outstanding securities. To the extent that conversion of the entire note would cause Pharmstandard and its affiliates to exceed these thresholds, Pharmstandard may convert a portion of the note to the extent these thresholds are not exceeded by such partial conversion.

Pharmstandard is our largest stockholder, and beneficially owned, in the aggregate, shares representing approximately 14.23% of our outstanding common stock as of May 8, 2018. In addition, two members of our board of directors are closely associated with Pharmstandard.

We paid $23,000 in legal expenses of Pharmstandard, including legal expenses incurred in connection with our resale registration obligations set forth in a registration rights agreement that we entered into with Pharmstandard. We have granted Pharmstandard, and Pharmstandard has granted us, indemnification rights with respect to each parties' respective representations, warranties, covenants and agreements under the note purchase agreement.

Cash Flows

The following table sets forth the major sources and uses of cash for the periods set forth below:

	Three Months Ended March 31,	
	2017	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (14,384)	$ (5,454)
Investing activities	(2,082)	306
Financing activities	(23,669)	6,979
Effect of exchange rate changes on cash	1	(3)
Net increase (decrease) in cash and cash equivalents	$ (40,134)	$ 1,828

Operating Activities. Net cash used in operating activities of $14.4 million during the three months ended March 31, 2017 was primarily a result of our $24.1 million net loss and a net increase in operating assets and liabilities of $1.2 million, partially offset by non-cash items of $10.9 million. Changes in operating assets and liabilities primarily included a decrease in accrued expenses of $3.2 million and an increase in prepaid expenses of $0.6 million, partially offset by an increase in restructuring liability of $2.5 million, an increase in accounts payable of $0.1 million, and an increase in the long-term portion of the manufacturing research and development obligation of $0.1 million. Non-cash items primarily include impairment charges on property and equipment of $27.2 million, share-based compensation expense of $3.6 million, interest accrued on long-term debt of $0.4 million, and depreciation and amortization expense of $0.2 million, partially offset by a decrease in the fair value of the warrant liability of $20.4 million and a gain on the early extinguishment of debt of $0.2 million.

Net cash used in operating activities of $5.5 million during the three months ended March 31, 2018 was primarily a result of our $2.1 million net loss and a net decrease in operating assets and liabilities of $4.3 million, partially offset by non-cash items of $1.0 million. Changes in operating assets and liabilities primarily included a decrease in long-term deferred liabilities of $5.8 million related to the recognition of deferred revenue in connection with our license agreement with Medinet and an increase in prepaid expenses and other receivables of $0.1 million, partially offset by an increase in accrued expenses of $1.7 million primarily related to our agreement with Cellscript. Non-cash items primarily include share-based compensation expense of $0.7 million, depreciation and amortization expense of $0.2 million, and interest accrued on long-term debt of $0.1 million, partially offset by a decrease in the fair value of the warrant liability of $0.1 million.

Investing Activities. Net cash used in investing activities was $2.1 million for the three months ended March 31, 2017. Cash used in investment activities during the three months ended March 31, 2017 consisted of $3.5 million of purchases of property and equipment, partially offset by proceeds of $1.5 million from the sale of impaired equipment held for sale and previously included in Construction-in-progress.

Net cash provided by investing activities was $0.3 million for the three months ended March 31, 2018. Cash provided by investment activities during the three months ended March 31, 2018 consisted of proceeds of $0.3 million from the sale of impaired equipment held for sale and previously included in Construction-in-progress.

Financing Activities. Net cash used in financing activities was $23.7 million for the three months ended March 31, 2017, consisting primarily of the pay-off of our Loan Agreement with $23.1 million in cash.

Net cash provided by financing activities was $7.0 million for the three months ended March 31, 2018, consisting primarily of $7.5 million of proceeds from the issuance of common stock through our at-the-market facility, partially offset by $0.5 million of payments on our notes payable**.**

Funding Requirements

To date, we have not generated any product revenue from our development stage product candidates. We do not know when, or if, we will generate any product revenue. We do not expect to generate significant product revenue unless or until we obtain marketing approval of, and commercialize, AGS-004. Despite our cost containment measures, including the March 2017 workforce reduction and the termination of development of rocapuldencel-T, we expect that our ongoing expenses will be substantial and may increase in connection with our ongoing activities, particularly if we initiate additional clinical trials of AGS-004, and seek regulatory approval for any product candidate we may develop or establish a commercial manufacturing facility or otherwise arrange for commercial manufacturing. In addition, if we obtain regulatory approval of any product candidate, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. Furthermore, we would expect to continue to incur additional costs associated with operating as a public company. We will need substantial additional funding in connection with our continuing operations.

As of March 31, 2018, we had cash and cash equivalents of $17.0 million. We do not currently have sufficient cash resources to pay all of our accrued obligations in full or to continue our business operations beyond the end of 2018. As a result, in order to continue to operate our business beyond that time, we will need to raise additional funds. However, there can be no assurance that we will be able to generate funds on terms acceptable to us, on a timely basis, or at all.

In light of the termination of the ADAPT trial and our cash resources, and based on a review of the status of our internal programs, resources and capabilities, we are exploring a wide range of strategic alternatives that may include a potential merger or sale of the Company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some of our assets or proprietary technologies. We have retained Stifel to serve as our financial advisor in the process. There can be no assurance that we will be able to enter into such a transaction or transactions on a timely basis, on terms that are favorable to us, or at all. If we are unable to successfully conclude a strategic transaction, we may determine to dissolve and liquidate our assets or seek protection under the bankruptcy laws. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

On April 23, 2018, we received a notification from The Nasdaq Stock Market LLC indicating that, because we had indicated that we would be unable to meet the stockholders' equity requirement for continued listing as of the April 24, 2018 deadline that had been set by the Nasdaq Hearing Panel, the Nasdaq Hearing Panel had determined to delist our common stock from The Nasdaq Capital Market and to suspend trading in our common stock effective at the open of business on April 25, 2018. Following such delisting, we transferred our common stock to the OTCQB® Venture Market. Because our common stock is not listed for trading on a national securities exchange, our ability to raise capital to continue to fund our operations by selling shares and our ability to acquire other companies or technologies by using our shares as consideration has been impaired.

We have based our estimates as to our cash needs on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of any product candidate we may develop, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of such product candidates.

Our future capital requirements will depend on many factors, including:

- our ability to enter into a strategic transaction and the timing and the terms of such transaction;
- the progress and results of the ongoing investigator-initiated clinical trial of AGS-004 in combination with vorinostat for HIV eradication, the planned investigator-initiated clinical trial of AGS-004 that we may support, the development, initiation and support of any additional clinical trials of AGS-004, and our ability to obtain additional funding under our NIH and NIAID contract for our AGS-004 program;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates or for the PD1 monoclonal antibodies which we have an option to in-license, should we decide to exercise our option;
- the costs and timing of establishing a commercial manufacturing facility or of alternative arrangements for commercial manufacturing and any costs and liabilities associated with financing arrangements entered into to fund the costs of these activities;
- the costs, timing and outcome of regulatory submissions and review of our product candidates;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive regulatory approval;
- the potential need to repay the $4.0 million in principal remaining outstanding under the loan under our license agreement with Medinet;
- payments due under our agreement with Medpace for the conduct of the ADAPT clinical trial;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates be approved by the FDA or a similar regulatory authority outside the United States;
- the extent to which we acquire or invest in other businesses, products and technologies;
- our ability to obtain government or other third party funding for the development of our product candidates; and
- our ability to establish collaborations on favorable terms, if at all, particularly arrangements for the development and commercialization of AGS-004.

Until such time, if ever, as we can generate substantial product revenue or enter into a strategic transaction, we expect to finance our cash needs through a combination of equity offerings, debt financings, government contracts, government and other third party grants or other third party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholder ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect stockholder rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through government or other third party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. We are seeking government or other third party funding for the continued development of AGS-004. In January 2014, CARE agreed that it would fund all patient clinical costs of Stage 1 of our adult eradication clinical trial of AGS-004, except for the associated manufacturing costs for which we were responsible. NIAID's Division of AIDS has approved $6.6 million in funding for Stage 2 of this Phase 2 clinical trial to be provided directly to the University of North Carolina. If we are unable to raise additional government or other third party funding when needed, we may be required to delay, limit, reduce or terminate our development of AGS-004 or to grant rights to develop and market AGS-004 that we would otherwise prefer to keep for ourselves.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 1 of the notes to our financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017. Other than as described below, there have been no significant changes to our critical accounting policies since December 31, 2017.

Revenue Recognition. An important part of our business strategy has been to enter into arrangements with third parties both to assist in the development and commercialization of our product candidates, particularly in international markets, and to in-license product candidates in order to expand our pipeline. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development and regulatory objectives, and royalties on product sales. We have adopted the provisions of the Financial Accounting Standards Board, or FASB, Codification Topic 606, Revenue from Contracts with Customers, or Topic 606, effective January 1, 2018. This guidance supersedes the provisions of FASB Codification Topic 605, Revenue Recognition.

License Fees and Multiple Element Arrangements. If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license at such time as the license is transferred to the licensee and the licensee is able to use, and benefit from, the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress in each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

If we are involved in a steering committee as part of a multiple element arrangement, we assess whether our involvement constitutes a performance obligation or a right to participate. Steering committee services that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which we expect to complete our aggregate performance obligations.

If we cannot reasonably measure its progress toward complete satisfaction of a performance obligation because it lacks reliable information that would be required to apply an appropriate method of measuring progress, but we can reasonably estimate when the performance obligation ceases or the remaining obligations become inconsequential and perfunctory, then revenue is not recognized until we can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement.

Development Milestone Payments. At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the control of the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, we reevaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjusts our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Reimbursement of Costs. Reimbursement of research and development costs by third party collaborators is recognized as revenue over time provided we have determined that it transfers control (for example, performs the services) of a service over time and, therefore, satisfies a performance obligation according to the provisions outlined in the FASB Codification Topic 606-10-25-27, Revenue Recognition.

Royalty Revenue. For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any royalty revenue resulting from any of its collaboration agreements.

Deferred Revenue. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying condensed consolidated balance sheets. Short-term deferred revenue would consist of amounts that are expected to be recognized as revenue within the next fiscal year. Amounts that the we expect will not be recognized in the next fiscal year would be classified as long-term deferred revenue.

With respect to each of the foregoing areas of revenue recognition, we exercise significant judgment in determining whether an arrangement contains multiple elements, and, if so, how much revenue is allocable to each element. In addition, we exercise our judgment in determining when its significant obligations have been met under such agreements and the specific time periods over which we recognized revenue, such as non-refundable, up-front license fees. To the extent that actual facts and circumstances differ from our initial judgments, revenue recognition with respect to such transactions would change accordingly and any such change could affect our reported financial results.

Contractual Obligations

During the three months ended March 31, 2018, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our primary exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of three months or less. The related interest income sensitivity is affected by changes in the general level of short-term U.S. interest rates. We primarily invest in high quality, short-term marketable debt securities issued by high quality financial and industrial companies.

Due to the short-term duration and low risk profile of our cash, cash equivalents and short-term investments, an immediate 10.0% change in interest rates would not have a material effect on the fair value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our cash, cash equivalents and short-term investments.

We do not believe that our cash and cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in fair value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

All of our other debt instruments and liabilities that incur interest charges do so at fixed rates. We incur interest expense at fixed rates under the promissory note payable to Medinet (3% per annum), the convertible note payable to Pharmstandard (9.5% per annum), the convertible note payable to Invetech (6% per annum), the convertible note payable to Saint-Gobain (6% per annum) and other notes payable (8.31% per annum).

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of and with the participation of our management, including our chief executive officer, who is our principal executive officer, and our chief financial officer, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of March 31, 2018. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2018, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not a party to any legal proceedings and are not aware of any claims or actions pending or threatened against us. In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing business environment that involves multiple risks and substantial uncertainty. The following discussion addresses risks and uncertainties that could cause, or contribute to causing, actual results to differ from expectations in material ways. In evaluating our business, investors should pay particular attention to the risks and uncertainties described below and in other sections of this Quarterly Report on Form 10-Q and in our subsequent filings with the SEC. These risks and uncertainties, or other events that we do not currently anticipate or that we currently deem immaterial also may affect our results of operations, cash flows and financial condition. The trading price of our common stock could also decline due to any of these risks, and you could lose all or part of your investment.

Risks Related to the Development and Regulatory Approval of Our Product Candidates

We have depended heavily on the success of our two lead Arcelis-based product candidates, rocapuldencel-T and AGS-004. Clinical trials of our product candidates may not be successful. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for sale. We have invested a significant portion of our efforts and financial resources in the development of our two lead Arcelis-based product candidates, rocapuldencel-T for the treatment of metastatic renal cell carcinoma, or mRCC, and other cancers and AGS-004 for the treatment of HIV. However, after reviewing the data from an interim analysis of our pivotal Phase 3 ADAPT clinical trial of rocapuldencel-T in combination with sunitinib / standard-of-care for the treatment of mRCC, we terminated the development of rocapuldencel-T in April 2018.

Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and commercialization of AGS-004 and any other product candidates we develop, if we determine to proceed with such development. The success of our product candidates will depend on several factors, including the following:

- successful completion of clinical trials, including clinical results that are statistically significant as well as clinically meaningful in the context of the indications for which we are developing our product candidates;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States;
- establishing a facility for the commercial manufacture of products based on our Arcelis precision immunotherapy technology platform;
- maintaining patent and trade secret protection and regulatory exclusivity for our product candidates, both in the United States and internationally;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- commercial acceptance of our products, if and when approved, by patients, the medical community and third party payors;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- effectively competing with other therapies; and
- a continued acceptable safety profile of the products following any marketing approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

In February 2017, we announced that the Independent Data Monitoring Committee, or IDMC, for our pivotal Phase 3 ADAPT clinical trial of rocapuldencel-T in combination with sunitinib / standard-of-care for the treatment of mRCC recommended that the trial be discontinued for futility based on its planned interim data analysis. The IDMC concluded that the trial was unlikely to demonstrate a statistically significant improvement in overall survival in the combination treatment arm, utilizing the intent-to-treat population at the pre-specified number of 290 events (deaths), the original primary endpoint of the study. Notwithstanding the IDMC's recommendation, we determined to continue to conduct the trial while we analyzed interim data from the trial. Following a meeting with the U.S. Food and Drug Administration, or FDA, we determined to continue the ADAPT trial until at least the pre-specified number of 290 events occurred and to submit to the FDA a protocol amendment to increase the pre-specified number of events for the primary analysis of overall survival in the trial beyond 290 events. In April 2018, we submitted a protocol amendment to the FDA that included an amended primary endpoint analysis with four co-primary endpoints. Subsequently in April 2018 we conducted another interim analysis of the data from the ADAPT trial, at which time 51 new events (deaths) had occurred subsequent to the February 2017 interim analysis. Based upon review of the interim data from this analysis, we determined that we were unlikely to achieve the endpoints if the trial were to be continued and decided to discontinue the ADAPT clinical trial. We do not expect to resume clinical development of rocapuldencel-T.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials, such as the failure of our Phase 3 ADAPT trial, can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

As a general matter, if we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the product is distributed or used; or
- have the product removed from the market after obtaining marketing approval.

If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing or commercialization of our product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. For example, based upon review of interim data from our ADAPT trial, in April 2018, we determined that we were unlikely to achieve the endpoints of the ADAPT clinical trial and terminated the development of rocapuldencel-T. Unforeseen events that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates include:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate; for example, in our Phase 2b clinical trial of AGS-004, we experienced a higher dropout rate than we anticipated due to the higher than expected number of patients who did not complete the full 12 week antiretroviral treatment interruption required by the protocol for the trial;
- our third party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may decide, or regulators or institutional review boards may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

In addition, the patients recruited for clinical trials of our product candidates may have a disease profile or other characteristics that are different than we expect and different than the clinical trials were designed for, which could adversely impact the results of the clinical trials. For instance, our Phase 2 combination therapy clinical trial of rocapuldencel-T in combination with sunitinib was originally designed to enroll patients with favorable disease risk profiles and intermediate disease risk profiles and with a primary endpoint of complete response rate. However, the actual trial population consisted entirely of patients with intermediate disease risk profiles and poor disease risk profiles.

Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. For example, in response to our submission of an investigational new drug application, or IND, for AGS-004, the FDA raised safety concerns regarding the analytical treatment interruption contemplated by our protocol for our Phase 2 clinical trial of AGS-004, and required a one-year safety follow-up after the final dose for each patient. This resulted in the need for an amendment to the trial protocol and a four-month delay prior to initiating the Phase 2 clinical trial in the United States.

In addition to additional costs, significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates and may harm our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States.

Our competitors may have ongoing clinical trials for product candidates that could be competitive with our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. For example, during the Phase 1/2 monotherapy clinical trial of rocapuldencel-T that we conducted, our ability to enroll patients in the trial was adversely affected by the FDA's approval of sorafenib and sunitinib, because patients did not want to receive, and physicians were reluctant to administer, rocapuldencel-T as an experimental monotherapy once new therapies that showed efficacy in clinical trials were introduced to the market and became widely available. In addition, patient enrollment in our trials may be adversely impacted by uncertainties regarding our Arcelis-based products linked to the termination of the ADAPT trial and the rocapuldencel-T development program.

Patient enrollment is affected by other factors including:

- severity of the disease under investigation;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;

- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

The actual amount of time for full enrollment of our clinical trials could be longer than planned. Enrollment delays in any of our clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our other clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

We are developing AGS-004 for use in combination with latency reversing drugs to eradicate HIV. If latency reversing drugs are not successfully developed for HIV on a timely basis or at all, we will be unable to develop AGS-004 for this use or will be delayed in doing so. In addition, because there are currently no products approved for HIV eradication, we cannot be certain of the clinical trials that we will need to conduct or the regulatory requirements that we will need to satisfy in order to obtain marketing approval of AGS-004 for this purpose.

We are focusing our development program for AGS-004 on the use of AGS-004 in combination with latency reversing drugs, including vorinostat, to eradicate HIV. We plan to rely on these latency reversing drugs because we recognize that the ultimate objective of virus eradication is unlikely to be achieved with immunotherapy alone because the immune system is not able to recognize the HIV virus in latently infected cells with a low level or lack of expression of HIV antigens.

Several companies and academic groups are evaluating latency reversing drugs that can potentially activate latently infected cells to increase viral antigen expression and make the cells vulnerable to elimination by the immune system. We are not a party to any arrangements with these companies or academic groups. If these companies or academic groups determine not to develop latency reversing drugs for this purpose because the drugs do not sufficiently increase viral antigen expression or have unacceptable toxicities, or these companies or academic groups otherwise determine to collaborate with other developers of immunotherapies on a combination therapy for complete virus eradication, we will not be able to complete our AGS-004 development program. In addition, if these companies or academic groups do not proceed with such development on a timely basis, our AGS-004 program correspondingly would be delayed.

A number of the latency reversing drugs being evaluated for use in HIV patients are currently approved in the United States and elsewhere for use in the treatment of specified cancer indications. For instance, vorinostat is approved for cutaneous T-cell lymphoma. If these drugs are not approved by the FDA or equivalent foreign regulatory authorities for use in HIV, the FDA and these other regulatory authorities may not approve AGS-004 without the latency reversing drug having received marketing approval for HIV. If the FDA and these other regulatory authorities approve AGS-004 without the approval of the latency reversing drug for HIV, the use of AGS-004 in combination with the latency reversing drug for virus eradication would require sales of the latency reversing drug for off-label use. In such event, the success of the combination of AGS-004 and the latency reversing drug would be subject to the willingness of physicians, patients, healthcare payors and others in the medical community to use the latency reversing drug for off-label use and of government authorities and third party payors to pay for the combination therapy. In addition, we would be limited in our ability to market the combination for its intended use if the latency reversing drug were to be used off-label. Furthermore, we are not currently conducting a clinical trial for AGS-004 as a monotherapy for HIV that could serve as a basis for approval of AGS-004 without the combination of a latency reversing drug.

Currently, there are no products approved for the eradication of HIV. As a result, we cannot be certain as to the clinical trials we will need to conduct or the regulatory requirements that we will need to satisfy in order to obtain marketing approval of AGS-004 for the eradication of HIV.

If serious adverse or inappropriate side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

Our only product candidate, AGS-004, is still in clinical development and its risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In addition, such effects or characteristics could cause an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates, require us to conduct additional clinical trials or other tests or studies, and could result in a more restrictive label, or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities.

Our Arcelis-based product candidates are immunotherapies that are based on a novel technology utilizing a patient's own tissue. This may raise development issues that we may not have anticipated or be able to resolve, regulatory issues that could delay or prevent approval or personnel issues that may prevent us from further developing and commercializing our product candidates.

Rocapuldencel-T and AGS-004 are based on our novel Arcelis precision immunotherapy technology platform. In the course of developing this platform and these product candidates, we have encountered difficulties in the development process. For example, we terminated the development of MB-002, the predecessor to rocapuldencel-T, when the results from the initial clinical trial of MB-002 indicated that the product candidate only corrected defects in the production of one of two critical cytokines required for effective immune response. In addition, based upon review of interim data, in April 2018, we determined that we were unlikely to achieve the endpoints of the ADAPT clinical trial and terminated the development of rocapuldencel-T. There can be no assurance that additional development problems will not arise in the future which we may not have anticipated or be able to resolve or which may cause significant delays in development.

In addition, regulatory approval of novel product candidates such as our Arcelis-based product candidates manufactured using novel manufacturing processes such as ours can be more expensive and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical products, due to our and regulatory agencies' lack of experience with them. The FDA has only approved a few individualized immunotherapy products to date. This lack of experience may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions.

The novel nature of our product candidates also means that fewer people are trained in or experienced with product candidates of this type, which may make it difficult to find, hire and retain capable personnel for research, development and manufacturing positions.

Development of our individualized Arcelis-based product candidates is subject to significant uncertainty because each product candidate is derived from source material that is inherently variable. This variability could reduce the effectiveness of our Arcelis-based product candidates, delay any FDA approval of any of our Arcelis-based product candidates, cause us to change our manufacturing methods and adversely affect the commercial success of any approved Arcelis-based products.

The disease samples from the patients to be treated with our Arcelis-based products vary from patient to patient. This inherent variability may adversely affect our ability to manufacture our products because each tumor or virus sample that we receive and process will yield a different product. As a result, we may not be able to consistently produce a product for every patient and we may not be able to treat all patients effectively. Such inconsistency could delay FDA or other regulatory approval of our Arcelis-based product candidates or, if approved, adversely affect market acceptance and use of our Arcelis-based products. If we have to change our manufacturing methods to address any inconsistency, we may have to perform additional clinical trials, which would delay FDA or other regulatory approval of our Arcelis-based product candidates and increase the costs of development of our Arcelis-based product candidates.

The inherent variability of the disease samples from the patients to be treated with our Arcelis-based products may further adversely affect our ability to manufacture our products because variability in the source material for our product candidates, such as tumor cells or viruses, may cause variability in the composition of other cells in our product candidates. Such variability in composition or purity could adversely affect our ability to establish acceptable release specifications and the development and regulatory approval processes for our product candidates may be delayed, which would increase the costs of development of our Arcelis-based product candidates.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Failure to obtain regulatory approval for any of our product candidates will prevent us from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third party contract research organizations to assist us in this process. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each therapeutic indication to establish the product candidate's safety and efficacy. Securing FDA approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. To date, the FDA has only approved a few individualized immunotherapy products. Changes in clinical guidelines or regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.

We are a party to arrangements with third parties, and intend to enter into additional arrangements with third parties, under which they would market our products outside the United States. In order to market and sell our products in the European Union and many other jurisdictions, we or such third parties must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

The efforts of the Trump Administration to pursue regulatory reform may limit the FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.

The Trump Administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. On January 30, 2017, President Trump issued an executive order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This executive order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage 0in oversight and implementation activities in the normal course, our business may be negatively impacted.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $53.0 million for the year ended December 31, 2016, $40.6 million for the year ended December 31, 2017 and $2.1 million for the three months ended March 31, 2018. As of March 31, 2018, we had an accumulated deficit of $374.7 million. As a result of our historical operating losses and expected future negative cash flows from operations, we have concluded that there is substantial doubt about our ability to continue as a going concern. To date, we have financed our operations primarily through public offerings of common stock, private placements of common stock, preferred stock and warrants, convertible debt financings, debt from financial institutions, government contracts, government and other third party grants and license and collaboration agreements. We have devoted substantially all of our efforts to research and development, including clinical trials. Specifically, we have devoted a significant portion of our financial resources to the development of rocapuldencel-T. We have not completed development of any product candidates, and do not expect to resume clinical development of rocapuldencel-T.

As we proceed with the development of our product candidates, provided we are able to raise the capital necessary to fund such development, we anticipate that our expenses will increase substantially if and as we:

- continue to support the ongoing investigator-initiated clinical trial of AGS-004 and initiate and support or conduct any additional trials of AGS-004 for the treatment of HIV;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a facility for the commercial manufacture of products based on our Arcelis precision immunotherapy technology platform;
- establish a sales, marketing and distribution infrastructure to commercialize products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- hire additional clinical, quality control, scientific and management personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned commercialization efforts.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This development and commercialization will require us to be successful in a range of challenging activities, including successfully completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval for these product candidates, building out and equipping a commercial manufacturing facility and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We are only in the preliminary stages of some of these activities. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have recently terminated the rocapuldencel-T clinical program and are evaluating potential strategic alternatives that could significantly impact our future operations and financial position.

Based on a review of the status of our internal programs, resources and capabilities, we plan to explore a wide range of strategic alternatives that may include a potential merger or sale of the Company, among other potential alternatives that could maximize both near and long-term value for our shareholders. We have retained Stifel, Nicolaus & Company, Incorporated to serve as our financial advisor in the process. We do not have a defined timeline for the exploration of strategic alternatives and are not confirming that the process will result in any strategic alternative being announced or consummated. We do not intend to discuss or disclose further developments during this process unless and until our Board of Directors has approved a specific action or otherwise determined that further disclosure is appropriate.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce, terminate or eliminate our product development programs, including establishing a commercial manufacturing facility or our commercialization efforts and to take other actions to reduce our operating expenses.

We have no external sources of funds other than our contract with the NIH and NIAID for the development of AGS-004, and we expect our expenses may increase in connection with our ongoing activities, particularly if we continue the clinical development of AGS-004 or if we undertake development of the group of PD1 monoclonal antibodies which we secured an exclusive option to in-license, if we decide to exercise that option; seek regulatory approval for our product candidates; and establish a commercial manufacturing facility or otherwise arrange for commercial manufacturing. In addition, if we obtain regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding if we wish to continue our operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, terminate or eliminate our product development programs or our commercialization efforts and to take other actions to reduce our operating expenses.

We have outstanding debt payable to Pharmstandard International S.A., or Pharmstandard, a collaborator and our largest stockholder, in the aggregate principal plus accrued interest amount of $6.4 million; Invetech Pty Ltd, or Invetech, in the aggregate principal plus accrued interest amount of $5.0 million; Saint-Gobain Performance Plastics Corporation, or Saint-Gobain, in the aggregate principal plus accrued interest amount of $1.9 million; and Medinet Co. Ltd., or Medinet, in the aggregate principal plus accrued interest amount of $5.0 million.

We do not currently have sufficient cash resources to pay all of our accrued obligations in full or to continue our business operations beyond the end of 2018. Therefore, we will need to raise additional capital prior to such time in order to continue to operate our business beyond that time. Alternatively, we may seek to engage in one or more potential transactions, such as the sale of our company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some of our assets or proprietary technologies, but there can be no assurance that we will be able to enter into such a transaction or transactions on a timely basis or on terms that are favorable to us, or at all. Under these circumstances, we may instead determine to dissolve and liquidate our assets or seek protection under the bankruptcy laws. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

On April 23, 2018, we received a notification from The Nasdaq Stock Market LLC indicating that, because we had indicated that we would be unable to meet the stockholders' equity requirement for continued listing as of the April 24, 2018 deadline that had been set by the Nasdaq Hearing Panel, the Nasdaq Hearing Panel determined to delist our common stock from The Nasdaq Capital Market and to suspend trading in our common stock effective at the open of business on April 25, 2018. Following such delisting, we transferred our common stock to the OTCQB® Venture Market, operated by OTC Markets Group Inc. Because our common stock is not listed for trading on a national securities exchange, our ability to raise capital to continue to fund our operations by selling shares and our ability to acquire other companies or technologies by using our shares as consideration has been impaired.

Our future capital requirements will depend on many factors, including:

- our ability to enter into a strategic transaction and the timing and the terms of such transaction;
- the progress and results of the ongoing investigator-initiated clinical trial of AGS-004 in combination with vorinostat for HIV eradication, the planned investigator-initiated clinical trial of AGS-004 that we may support, any additional clinical trial of AGS-004 that we initiate and support, and our ability to obtain additional funding under our NIH and NIAID contract for our AGS-004 program;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates or for the PD1 monoclonal antibodies which we have an option to in-license, should we decide to exercise our option;
- the costs and timing of establishing a commercial manufacturing facility or of alternative arrangements for commercial manufacturing and any costs and liabilities associated with financing arrangements entered into to fund the costs of these activities;
- the costs, timing and outcome of regulatory submissions and review of our product candidates;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive regulatory approval;
- the potential need to repay the $4.0 million in principal currently remaining outstanding under the loan under our license agreement with Medinet Co. Ltd. and its wholly-owned subsidiary, MEDcell Co., LTD, which we refer to together as Medinet;
- payments due under our agreement with Medpace for the close-out of the ADAPT clinical trial;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates be approved by the FDA or a similar regulatory authority outside the United States;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or invest in other businesses, products and technologies;
- our ability to obtain government or other third party funding for the development of our product candidates; and
- our ability to establish collaborations on favorable terms, if at all, particularly arrangements to develop, market and distribute any product candidates that we may develop, including AGS-004.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Additional financing may not be available to us on acceptable terms, or at all.

Our independent registered public accounting firm included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Our report from our independent registered public accounting firm for the year ended December 31, 2017 includes an explanatory paragraph stating that our losses from operations and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, government contracts, government and other third party grants or other third party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. For example, since 2016 we have issued and sold securities in several PIPE financings, under a sales agreement with Cowen, and in a public follow-on offering, each of which have resulted in dilution to our existing stockholders. Additionally, during 2017 we issued both secured and unsecured convertible debt and raised equity capital under our sales agreement with Cowen, which have resulted in further dilution to our stockholders.

Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We also may seek government or other third party funding for the continued development of AGS-004 and to collaborate with third parties for the development and commercialization of AGS-004. If we raise additional funds through government or other third party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If the loan from Medinet becomes due and we do not repay it, we have agreed to grant Medinet a non-exclusive, royalty-bearing license to make and sell Arcelis products in Japan for the treatment of cancer.

Our ability to use our net operating loss carry-forwards and tax credit carryforwards may be limited.

The utilization of the net operating loss and tax credit carryforwards may be subject to limitation under the rules regarding a change in stock ownership as determined by the Internal Revenue Code, and state and foreign tax laws. Section 382 of the Internal Revenue Code of 1986, as amended, imposes annual limitations on the utilization of net operating loss carryforwards, other tax carryforwards, and certain built-in losses upon an ownership change as defined under that section. In general terms, an ownership change may result from transactions that increase the aggregate ownership of certain of our stockholders by more than 50 percentage points over a three-year testing period. If we have undergone a Section 382 ownership change, an annual limitation would be imposed on certain of our tax attributes, including net operating loss and capital loss carryforwards, and certain other losses, credits, deductions or tax basis. We believe that we experienced an ownership change during 2014 under Section 382. Due to the Section 382 limitation resulting from the ownership change, $28.2 million of our U.S. federal net operating losses are expected to expire unused. Additionally, our U.S. federal tax credits and state net operating losses may be limited. The amount of U.S. federal net operating losses expected to expire due to the Section 382 limitation has not been recognized in our consolidated financial statements as of December 31, 2017. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carry-forwards and other tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which potentially could result in increased future tax liability to us. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal tax law.

Risks Related to the Commercialization of our Product Candidates

We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

Our operations to date have been limited to financing and staffing our company, developing our technology and product candidates and establishing collaborations. We have not yet demonstrated an ability to successfully complete a pivotal clinical trial, compile an acceptable regulatory submission, obtain marketing approvals, manufacture a commercial scale product or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Even if AGS-004 or any future product candidate receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

We have never commercialized a product candidate. Even if AGS-004 or any future product candidate receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. Gaining market acceptance for our Arcelis-based products may be particularly difficult as, to date, the FDA has only approved a few individualized immunotherapies and our Arcelis-based products are based on a novel technology. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of sales, marketing and distribution support;
- the approval of other new products for the same indications;
- the ability of our product to be combined with emerging standards of care;
- availability and amount of reimbursement from government payors, managed care plans and other third party payors;
- adverse publicity about the product or favorable publicity about competitive products;
- clinical indications for which the product is approved; and
- the prevalence and severity of any side effects.

If any of our product candidates receives marketing approval and we, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the product could be compromised.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, in a broader patient population or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered;

- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- additional restrictions may be imposed on the distribution or use of the product via a risk evaluation and mitigation strategy, or REMS;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We have only limited commercial capabilities and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization, outsource these functions to third parties or enter into collaborations or other arrangements with third parties for the distribution or marketing of our product candidates should such candidates receive marketing approval.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- inability to establish customer service and access services, including potential supply chain and specialty pharmacy arrangements.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidate, and will face competition with respect to any products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Many marketed therapies for the indication that we are currently pursuing, or indications that we may in the future seek to address using our Arcelis precision immunotherapy technology platform, are widely accepted by physicians, patients and payors, which may make it difficult for us to replace them with any products that we successfully develop and are permitted to market.

There are numerous FDA-approved treatments for HIV, primarily antiretroviral therapies marketed by large pharmaceutical companies. Generic competition has developed in this market as patent exclusivity periods for older drugs have expired, with more than 15 generic drugs currently on the market. The presence of these generic drugs is resulting in price pressure in the HIV therapeutics market and could affect the pricing of AGS-004. Currently, there are no approved therapies for the eradication of HIV. We expect that major pharmaceutical companies that currently market antiretroviral therapy products or other companies that are developing HIV product candidates may seek to develop products for the eradication of HIV.

Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and device industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, recently passed legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. These risks may be even greater with respect to our Arcelis-based products which are manufactured using a novel technology. None of our product candidates has been widely used over an extended period of time, and therefore our safety data are limited. We derive the raw materials for manufacturing of our Arcelis-based product candidates from human cell sources, and therefore the manufacturing process and handling requirements are extensive and stringent, which increases the risk of quality failures and subsequent product liability claims.

If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold $10.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage when we begin commercializing our product candidates, if ever. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

We have based our research and development efforts on our Arcelis precision immunotherapy technology platform. Notwithstanding our large investment to date and potential future expenditures in our Arcelis precision immunotherapy technology platform, we have not yet developed, and may never successfully develop, any marketed drugs using this approach. As a result of pursuing the development of product candidates using our Arcelis precision immunotherapy technology platform, we may fail to develop product candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success.

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Risks Related to Our Dependence on Third Parties

Our reliance on government funding adds uncertainty to our research and commercialization efforts and may impose requirements that increase the costs of commercialization and production of our government-funded product candidates.

Our current development of AGS-004 for HIV is primarily funded by the NIH. This funding is currently expected to expire in July 2018. We will be dependent upon additional government funding for continued development of AGS-004. However, increased pressure on governmental budgets may reduce the availability of government funding for programs such as AGS-004. In addition, contracts and grants from the U.S. government and its agencies include provisions that give the government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the government to:

- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including intellectual property rights, in products and data developed under such agreements;

- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government or a specific government agency;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

Government agreements normally contain additional terms and conditions that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These include, for example:

- specialized accounting systems unique to government contracts and grants;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract and grant information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

We expect to depend on collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We have entered into an exclusive license agreement with Pharmstandard for the development and commercialization of rocapuldencel-T in Russia and the other states comprising the Commonwealth of Independent States and an exclusive license agreement with Green Cross Corp., or Green Cross, for the development and commercialization of rocapuldencel-T for the treatment of mRCC in South Korea and an exclusive license agreement with Lummy (Hong Kong) Co. Ltd., or Lummy HK, for the development, manufacture and commercialization of rocapuldencel-T in China, Hong Kong, Taiwan and Macau. We have also entered into a license agreement with Medinet under which we granted Medinet an exclusive license to manufacture in Japan rocapuldencel-T for the purpose of development and commercialization for the treatment of mRCC. As a result, we are dependent on our third party collaborators for any further development of rocapuldencel-T. However, we do not expect that any of our collaborators will continue the development of rocapuldencel-T.

We also plan to seek government or other third party funding for continued development of AGS-004 and to collaborate with third parties to develop and commercialize AGS-004. Our likely collaborators for any development, distribution, marketing, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

Under our existing arrangements we have limited control, and under any additional arrangements we may enter into with third parties we will likely have limited control, over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or, require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may have the right to conduct clinical trials of our product candidates without our consent and could conduct trials with flawed designs that result in data that adversely affect our clinical trials, our ability to obtain marketing approval for our product candidates or market acceptance of our product candidates;
- collaborators may hold rights that could preclude us from commercializing our products in certain territories;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. For example, in 2009, our collaboration with Kyowa Hakko Kirin Co., Ltd. with respect to rocapuldencel-T and AGS-004 was terminated by our collaborator.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we are not able to establish additional collaborations, we may have to alter any development and commercialization plans.

Our drug development programs and any potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may collaborate with pharmaceutical and biotechnology companies for the development and commercialization of those product candidates. For example, we have entered into license agreements with third parties to develop, manufacture and/or commercialize rocapuldencel-T in Russia and the other states comprising the Commonwealth of Independent States, South Korea, Japan, China, Hong Kong, Taiwan and Macau. In light of our decision to terminate the ADAPT trial, we do not expect that any of these collaborators will continue the development of rocapuldencel-T. We also intend to collaborate with third parties to develop and commercialize AGS-004.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

If we are not able to obtain such funding or enter into collaborations for our product candidates, we may have to curtail the development of such product candidates, reduce or delay a candidate's development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop these product candidates or bring these product candidates to market and generate product revenue.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We do not independently conduct clinical trials of our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our oversight responsibilities as sponsor of the trial. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other regulatory authorities require us to comply with standards, commonly referred to as Good Clinical Practice, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

For instance, in December 2015 we received a notice from Health Canada that one of the sites at which we were conducting our Phase 3 ADAPT trial in Canada had been found to be non-compliant with Good Clinical Practice in Canada and that if the issues raised in the notice were not corrected, Health Canada could suspend our authorization to conduct the ADAPT trial at all sites in Canada. We submitted a response to Health Canada and subsequently received a Completion of Response notice from Health Canada stating that our corrective actions were satisfactory and that the matter was officially closed.

We also rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

Risks Related to the Manufacturing of Our Product Candidates

We will need to establish a facility to manufacture our Arcelis-based products on a commercial scale. We do not have experience in manufacturing Arcelis-based products on a commercial scale. If, due to our lack of manufacturing experience, we cannot manufacture our Arcelis-based products on a commercial scale successfully or manufacture sufficient product to meet our expected commercial requirements, our business may be materially harmed.

We currently have manufacturing suites in our Technology Drive and Patriot Center leased facilities in Durham, North Carolina. We manufacture Arcelis-based product candidates for research and development purposes and for clinical trials at these facilities.

We believe these facilities are sufficient for the manufacture of AGS-004 to support our ongoing clinical trial and any likely near-term clinical trials that we may initiate.

We expect that we would establish both manual and automated manufacturing processes in any commercial manufacturing facility if we determine to establish such facility. Prior to implementing commercial manufacturing of any Arcelis-based product, we would be required to demonstrate that our commercial manufacturing facility is constructed and operated in accordance with current good manufacturing practice. We would also be required to show the comparability between any Arcelis-based product that we produce using the manual processes in our current facility and the same product produced using the manual process in the commercial manufacturing facility.

If we transition to automated manufacturing processes, we expect our automated manufacturing processes will be based on existing functioning prototypes of automated devices for the production of commercial quantities of our Arcelis-based product candidates. These devices can be used to perform substantially all steps required for the manufacture of our Arcelis-based product candidates.

We do not have experience in manufacturing products on a commercial scale. In addition, because we are aware of only a few companies that have manufactured an individualized immunotherapy product for commercial sale, there are limited precedents from which we can learn. We may encounter difficulties in the manufacture of our Arcelis-based products due to our limited manufacturing experience. These difficulties could delay the build-out and equipping of a commercial manufacturing facility and regulatory approval of the manufacture of our Arcelis-based products using the facility, increase our costs or cause production delays or result in us not manufacturing sufficient product to meet our expected commercial requirements, any of which could damage our reputation and hurt our profitability. If we are unable to successfully increase our manufacturing capacity to commercial scale, our business may be materially adversely affected.

If we fail to establish commercial manufacturing operations in compliance with regulatory requirements, or augment our manufacturing personnel, we may not be able to initiate commercial operations or produce sufficient product to meet our expected commercial requirements. We have delayed the implementation of our automated manufacturing process and may not be able to use such process on a timely basis or at all.

In order to meet our business plan, which contemplated manufacturing our product first using manual processes and later using automated processes for the commercial requirements of any Arcelis-based product candidates that might be approved, we planned to build out and equip a leased commercial manufacturing facility and add manufacturing personnel in advance of any regulatory submission for approval. If we determine to continue our plan to establish a commercial manufacturing facility, we will require substantial capital expenditures and additional regulatory approvals. In addition, it will be costly and time consuming to recruit necessary additional personnel.

If we are unable to successfully build out and equip a commercial manufacturing facility in compliance with regulatory requirements or hire and train additional necessary manufacturing personnel appropriately, our filing for regulatory approval of our product candidates may be delayed or denied.

We plan to delay the implementation of our automated manufacturing process until we complete the clinical development of an Arcelis-based product and secure additional funding. Thus, if we are able to successfully complete the clinical development of an Arcelis-based product and obtain marketing approval, we plan to initially commercially supply such product using manual manufacturing processes. Prior to implementing commercial manufacturing of an Arcelis-based product, we will be required to demonstrate that the commercial manufacturing facility is constructed and operated in accordance with current Good Manufacturing Practice, or cGMP. If we continue the development of any Arcelis-based product, we will also be required to show the comparability between such product that we produce using the manual processes in our current facility and that product produced using the manual process in the new facility.

Our implementation of automated processes could take longer, particularly if we are unable to achieve any of the required tasks on a timely basis, or at all. Work under our collaboration with Invetech and Saint-Gobain to develop the equipment and disposables necessary to implement the automated manufacturing processes for Arcelis-based products is not expected to resume until we are able to successfully complete the clinical development of an Arcelis-based product and obtain marketing approval. If Invetech or Saint-Gobain are delayed in resumption of the projects or do not perform as expected under the agreements or the projects with Invetech or Saint-Gobain are unsuccessful for any other reason, our timelines for the implementation of our automated manufacturing processes could be further delayed and our business could be adversely affected.

Prior to implementing the automated manufacturing processes for Arcelis-based products, we will be required to:

- demonstrate that the disposable components and sterilization and packaging methods used in the manufacturing process are suitable for use in manufacturing in accordance with current good manufacturing practice, or cGMP, and current Good Tissue Practices, or cGTP;
- build and validate processing equipment that complies with cGMP and cGTP;
- equip a commercial manufacturing facility to accommodate the automated manufacturing process;
- perform process testing with final equipment, disposable components and reagents to demonstrate that the methods are suitable for use in cGMP and cGTP manufacturing;
- demonstrate consistency and repeatability of the automated manufacturing processes in the production of any Arcelis-based product in our new facility to fully validate the manufacturing and control process using the actual automated cGMP processing equipment; and
- demonstrate comparability between any Arcelis-based product that we produce using our manual processes and such product produced using the automated processes.

We will need regulatory approval to use the automated manufacturing processes for commercial purposes. If the FDA requires us to conduct a bridging study to demonstrate comparability between an Arcelis-based product that we produce manually and such product produced using the automated processes, the implementation of the automated manufacturing processes and the filing for such approval will likely be delayed.

If we are unable to successfully implement the automated processes required and demonstrate comparability between the Arcelis-based product that we produce manually and such product produced using the automated processes, our filing for regulatory approval of the commercial use of our automated manufacturing processes may be delayed or denied and we may not be able to initiate commercial manufacturing using our automated manufacturing processes. In such event, our commercial manufacturing costs will be higher than anticipated and we may not be able to manufacture sufficient product to meet our expected commercial requirements.

Lack of coordination internally among our employees and externally with physicians, hospitals and third- party suppliers and carriers, could cause manufacturing difficulties, disruptions or delays and cause us to not have sufficient product to meet our clinical trial requirements or potential commercial requirements.

Manufacturing our Arcelis-based product candidates requires coordination internally among our employees and externally with physicians, hospitals and third party suppliers and carriers. For example, a patient's physician or clinical site will need to coordinate with us for the shipping of a patient's disease sample and leukapheresis product to our manufacturing facility in a timely manner, and we will need to coordinate with them for the shipping of the manufactured product to them. Such coordination involves a number of risks that may lead to failures or delays in manufacturing our Arcelis-based product candidates, including:

- failure to obtain a sufficient supply of key raw materials of suitable quality;
- difficulties in manufacturing our product candidates for multiple patients simultaneously;
- difficulties in obtaining adequate patient-specific material, such as tumor samples, virus samples or leukapheresis product, from physicians;
- difficulties in completing the development and validation of the specialized assays required to ensure the consistency of our product candidates;
- failure to ensure adequate quality control and assurances in the manufacturing process as we increase production quantities;
- difficulties in the timely shipping of patient-specific materials to us or in the shipping of our product candidates to the treating physicians due to errors by third party carriers, transportation restrictions or other reasons;
- destruction of, or damage to, patient-specific materials or our product candidates during the shipping process due to improper handling by third party carriers, hospitals, physicians or us;
- destruction of, or damage to, patient-specific materials or our product candidates during storage at our facilities; and
- destruction of, or damage to, patient-specific materials or our product candidates stored at clinical and future commercial sites due to improper handling or holding by clinicians, hospitals or physicians.

If we are unable to coordinate appropriately, we may encounter delays or additional costs in achieving our clinical and commercialization objectives, including in obtaining regulatory approvals of our product candidates and supplying product, which could materially damage our business and financial position.

If our existing manufacturing facilities or any commercial manufacturing facility that we use are damaged or destroyed, or production at one of these facilities is otherwise interrupted, our business and prospects would be negatively affected.

We currently lease two manufacturing facilities. If we establish a commercial manufacturing facility, it will be our only commercial manufacturing facility in North America. If our existing manufacturing facilities or a commercial manufacturing facility that we decide to build out and equip, or the equipment in either of these facilities, is damaged or destroyed, we likely would not be able to quickly or inexpensively replace our manufacturing capacity and possibly would not be able to replace it at all. Any new facility needed to replace either of our existing manufacturing facilities or a new commercial manufacturing facility would need to comply with the necessary regulatory requirements, need to be tailored to our specialized automated manufacturing requirements and require specialized equipment. We would need FDA approval before selling any products manufactured at a new facility. Such an event could delay our clinical trials or, if any of our product candidates are approved by the FDA, reduce or eliminate our product sales.

We maintain insurance coverage to cover damage to our property and equipment and to cover business interruption and research and development restoration expenses. If we have underestimated our insurance needs with respect to an interruption in our clinical manufacturing of our product candidates, we may not be able to adequately cover our losses.

Risks Related to Our Intellectual Property

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 a party to a number of intellectual property license agreements with third parties, including with respect to each of rocapuldencel-T and AGS-004, and we may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors may have the right to terminate these license agreements, in which event we might not be able to market any product that is covered by these agreements, or to convert the license to a non-exclusive license, which could materially adversely affect the value of the product candidate being developed under the license agreement. Termination of these 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.

If we are unable to obtain and maintain patent protection for our technology and products, or if our licensors are unable to obtain and maintain patent protection for the technology or products that we license from them, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We and our licensors have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development efforts before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties and are reliant on our licensors. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. If such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Third parties could practice our inventions in territories where we do not have patent protection. Furthermore, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, we own or exclusively license patents relating to our process of manufacturing an individualized drug product. A U.S. patent may be infringed by anyone who, without authorization, practices the patented process in the United States or imports a product made by a process covered by the U.S. patent. In foreign countries, however, importation of a product made by a process patented in that country may not constitute an infringing activity, which would limit our ability to enforce our process patents against importers in that country. Furthermore, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. If competitors are able to use our technologies, our ability to compete effectively could be harmed.

Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Assuming the other requirements for patentability are met, in the United States, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is generally entitled to the patent. Under the America Invents Act, or AIA, enacted in September 2011, the United States moved to a first inventor to file system in March 2013. The United States Patent and Trademark Office only recently finalized the rules relating to these changes and courts have yet to address the new provisions. These changes could increase the costs and uncertainties surrounding the prosecution of our patent applications and the enforcement or defense of our patent rights. Furthermore, we may become involved in interference proceedings, opposition proceedings, or other post-grant proceedings, such as reissue, reexamination or inter partes review proceedings, which may challenge our patent rights or the patent rights of others. An adverse determination in any such proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to or stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, certain of the U.S. patents we exclusively licensed from Duke University expired in 2016 and the European and Japanese patents exclusively licensed from Duke University expired in April 2017. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents. To counter such infringement or unauthorized use, we may be required to file infringement claims against third parties, which can be expensive and time consuming. In addition, during an infringement proceeding, a court may decide that the patent rights we are asserting are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, our licensors may have rights to file and prosecute such claims and we are reliant on them.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot ensure that third parties do not have, or will not in the future obtain, intellectual property rights such as granted patents that could block our ability to operate as we would like. There may be patents in the United States or abroad owned by third parties that, if valid, may block our ability to make, use or sell our products in the United States or certain countries outside the United States, or block our ability to import our products into the United States or into certain countries outside the United States.

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. For example, third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may be unable to obtain any required license on commercially reasonable terms or even obtain a license at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We have research licenses to certain reagents and their use in the development of our product candidates. We would need commercial licenses to these reagents for any of our product candidates that receive approval for sale in the United States. We believe that commercial licenses to these reagents will be available. However, if we are unable to obtain any such commercial licenses, we may be unable to commercialize our product candidates without infringing the patent rights of third parties. If we did seek to commercialize our product candidates without a license, these third parties could initiate legal proceedings against us.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial 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.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. The types of protections available for trade secrets are particularly important with respect to our Arcelis precision immunotherapy technology platform's manufacturing capabilities, which involve significant unpatented know-how. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Legal Compliance Matters

Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, cGTP requirements, requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved label. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the marketing of a product;
- restrictions on product distribution;

- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Our relationships with customers and third party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, the PPACA, or the Health Care Reform Law will require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with 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 fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Numerous statements made by President Trump and members of the U.S. Congress indicate that it is likely that legislation will be passed by Congress and signed into law by President Trump that repeals the PPACA, in whole or in part, and/or introduces a new form of health care reform. It is unclear at this point what the scope of such legislation will be and when it will become effective. Because of the uncertainty surrounding this replacement health care reform legislation, we cannot predict with any certainty the likely impact of the PPACA's repeal or the adoption of any other health care reform legislation on our financial condition or operating results. Whether or not there is alternative health care legislation enacted in the United States, there is likely to be significant disruption to the health care market in the coming months and years.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class in certain cases. Cost reduction initiatives and other provisions of this and other more recent legislation could decrease the coverage and reimbursement that is provided for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act or other more recent legislation may result in a similar reduction in payments from private payors.

In March 2010, former President Obama signed into law the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. In addition, with the new Administration and Congress, there will likely be additional administrative or legislative changes, including modification, repeal, or replacement of all, or certain provisions of, the ACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices.

At the same time, Congress has focused on additional legislative changes, including in particular repeal and replacement of certain provisions of the ACA. For example, with enactment of the Tax Cuts and Jobs Act of 2017, in December 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Further, each chamber of the Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. The Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost-sharing reduction (CSR) payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years, or approved by the FDA until 12 years, after the original brand product identified as the reference product was approved under a BLA. The new law is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if any of our product candidates were to be approved as biological products under a BLA, such approved products should qualify for the four-year and 12-year periods of exclusivity. However, there is a risk that the U.S. Congress could amend the BPCIA to significantly shorten these exclusivity periods as proposed by President Obama, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Organizational Employee Matters

Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Jeffrey Abbey, our president and chief executive officer, Charles Nicolette, our vice president of research and development and chief scientific officer, and Richard Katz, our vice president and chief financial officer, as well as the other principal members of our management and scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified personnel is critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel, our decision to terminate development of rocapuldencel-T, the workforce reduction plans that we have conducted, the delisting of our common stock by the Nasdaq Capital Market and our limited cash resources. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Risks Related to Our Common Stock

Our executive officers, directors, affiliates of all officers and directors and other of our affiliates who own our outstanding common stock have the ability to significantly influence matters submitted to stockholders for approval.

Our executive officers, directors, affiliates of our executive officers and directors and other of our affiliates beneficially own, in the aggregate, shares representing approximately 20.03% of our outstanding common stock as of May 8, 2018. As a result, if these stockholders were to choose to act together, they would be able to significantly influence matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, could significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Our largest stockholder, Pharmstandard, could exert significant influence over us and could limit your ability to influence the outcome of key transactions, including any change of control.

Our largest stockholder, Pharmstandard, beneficially owns, in the aggregate, shares representing approximately 14.23% of our outstanding common stock as of May 8, 2018. Pharmstandard is also the holder of the $6.0 million principal amount of a secured convertible note that we issued in June 2017, although the ability of Pharmstandard to exercise its conversion option is limited to the extent such exercise would cause Pharmstandard's ownership in our Company to exceed 39.9%. In addition, two members of our board of directors are closely associated with Pharmstandard. As a result, we expect that Pharmstandard will be able to exert significant influence over our business. Pharmstandard may have interests that differ from your interests, and it may vote in a way with which you disagree and that may be adverse to your interests. The concentration of ownership of our capital stock may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and may adversely affect the market price of our common stock.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

An active trading market for our common stock may not be sustained, and investors may not be able to resell their shares at or above the price they paid. In addition, our common stock has been delisted from The Nasdaq Capital Market and now trades on the OTCQB® Venture Market, which could decrease the liquidity of our common stock and our ability to raise additional capital.

On April 23, 2018, we received a notification from The Nasdaq Stock Market LLC indicating that, because we indicated that we would be unable to meet the stockholders' equity requirement for continued listing as of the April 24, 2018 deadline that had been set by the Nasdaq Hearing Panel, the Nasdaq Hearing Panel had determined to delist our common stock from The Nasdaq Capital Market and to suspend trading in our common stock effective at the open of business on April 25, 2018. Following such delisting, we transferred our common stock to the OTCQB® Venture Market (the "OTC Market"). Trading on the OTC Market is likely to make it more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, the common stock and could result in a decrease in the trading price of our common stock. We may also face other material adverse consequences as a result of our common stock being listed on the OTC Market, such as negative publicity, a decreased ability to obtain additional financing, delays in the timing of transactions, reduction in security analysts' and the new media's coverage of us, diminished investor and/or employee confidence, and the loss of business development opportunities, some or all of which may contribute to a further decline in our stock price. In addition, there can be no assurance that our common stock will remain eligible for trading on the OTC Market.

If our stock price continues to be volatile, purchasers of our common stock could incur substantial losses.

Our stock price has been volatile. For example, our stock has traded in a range from a low price per share of $0.17 and a high price per share of $113.66 during the period of from January 1, 2017 through May 8, 2018 on a post-split adjusted basis. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. In addition, the market prices for securities listed on the OTC Market have been volatile and such securities have experienced sharp share price and trading volume changes. The market price for our common stock may be influenced by many factors, including:

- our cash resources;
- results of clinical trials of AGS-004 or any product candidate we may develop, or those of our competitors;
- the success of competitive products or technologies;
- potential approvals of any product candidate we may develop for marketing by the FDA or equivalent foreign regulatory authorities or our failure to obtain such approvals;
- regulatory or legal developments in the United States and other countries;
- the results of our efforts to commercialize any product candidate we may develop;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;

- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, pharmaceutical companies have experienced significant share price volatility in recent years, and securities class action litigation, shareholder derivative litigation, or other proceedings often follow a decline in the market price of a company's securities. For instance, in March 2017, a purported stockholder of our company filed a putative class action lawsuit against us, our chief executive officer, our chief financial officer, and our vice president of finance generally alleging that the defendants violated the federal securities laws by, among other things, making material misstatements or omissions concerning the progress of the ADAPT Phase 3 clinical trial of rocapuldencel-T, the planned biologics licensing application for rocapuldencel-T and the prospects for approval. This matter was dismissed in September 2017. If we face such litigation or proceedings, it could result in substantial costs and a diversion of management's attention and resources.

We will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and make some activities more time-consuming and costly.

We cannot predict or estimate the amount of additional costs we may incur to continue to operate as a public company, nor can we predict the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of the Sarbanes-Oxley Act of 2002 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company for up to five years following our initial public offering in February 2014. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In our Annual Report on Form 10-K for the year ended December 31, 2017, we did not include all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us, particularly given that our common stock is listed in the OTC Market. Even if we obtain coverage, there can be no assurance the coverage will be favorable. If one or more analysts downgrade our stock or change their opinion of our stock to be less favorable, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Item 6. Exhibits

Exhibit Number	Description of Exhibit
3.1	Restated Certificate of Incorporation of the Registrant, as amended (filed as Exhibit 3.1 to the Registrant's Annual Report on Form 10-K on April 2, 2018 and incorporated herein by reference)
10.1	Amended and Restated Sales Agreement, dated February 2, 2018, by and between the Registrant and Cowen and Company, LLC (filed as Exhibit 1.1 to the Registrant's Current Report on Form 8-K on February 5, 2018 and incorporated herein by reference)
10.2+	Evaluation and Option Agreement for a Patent License, dated February 1, 2018, by and between the Registrant, Pharmstandard International S.A. and Actigen Limited (filed as Exhibit 10.49 to the Registrant's Annual Report on Form 10-K on April 2, 2018 and incorporated herein by reference)
10.3+	Third Amendment to License Agreement, dated March 23, 2018, between the Registrant and Lummy (Hong Kong) Co., Ltd. (filed as Exhibit 10.51 to the Registrant's Annual Report on Form 10-K on April 2, 2018 and incorporated herein by reference)
10.4*	Letter from the Registrant to Medinet Co., Ltd., dated February 14, 2018, regarding revocation of certain rights under the novated, amended and restated license agreement
21.1*	Subsidiaries of the Registrant
31.1*	Certification of principal executive officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of principal financial officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, by the Registrant's principal executive officer and principal financial officer
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

\# This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

\+ Confidential treatment granted as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities Exchange Commission.

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.

ARGOS THERAPEUTICS, INC.

By: /s/ Jeffrey D. Abbey
Name: Jeffrey D. Abbey
Title: President and Chief Executive Officer

Date: May 15, 2018

Exhibit 10.4

February 14, 2018

BY EMAIL

Medinet Co., Ltd.
Shin-Yokohama Square Bldg.
14F, 2-3-12 Shin-Yokohama,
Kohoku-ku, Yokohama, Kanagawa, 222-0033 JAPAN

MEDcell Co., Ltd.
2-8 Tamagawa-dai Setagaya-ku
Tokyo, 158-0096 JAPAN

Re: Novated, Amended and Restated License Agreement

Gentlemen:

I am writing on behalf of Argos Therapeutics, Inc. ("Argos") with respect to the Novated, Amended and Restated License Agreement dated as of October 1, 2014, as amended (the "License Agreement"), by and among Argos, Medinet Co., Ltd. ("Medinet"), and MEDcell Co., Ltd. ("MEDcell" and together with Medinet, the "Medinet Parties").

As you know, Argos has the right under Section 5.1 of the License Agreement to terminate the CMO License (as defined in the License Agreement) granted to the Medinet Parties. However, the parties are currently in discussions regarding potential amendments to the License Agreement., including with respect to the licenses granted and potential licenses to be granted to the Medinet Parties under the License Agreement. It is in consideration of these discussions, and for other good and valuable consideration, that Argos, intending to be legally bound, hereby irrevocably agrees that from and after the date of this letter, Argos shall have no further right to exercise its Revocation Right under Section 5.1 of the License Agreement, and the Revocation Right shall be of no further force and effect. In all other respects, the License Agreement shall remain in full force and effect.

We look forward to our continued discussions.

Very truly yours,

/s/ Jeff Abbey
Jeff Abbey
President and CEO

Exhibit 21.1

Subsidiaries of the Registrant

Name	Jurisdiction
DC Bio Corp.	Nova Scotia, Canada
Argos Therapeutics (Europe) S.à.r.l	Bertrange, Luxembourg

Exhibit 31.1

CERTIFICATIONS

I, Jeffrey D. Abbey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Argos Therapeutics, 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 Rule 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 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 functions):

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.

By: /s/ JEFFREY D. ABBEY
Jeffrey D. Abbey
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2018

Exhibit 31.2

CERTIFICATIONS

I, Richard D. Katz, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Argos Therapeutics, 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 Rule 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 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 functions):

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.

By: /s/ RICHARD D. KATZ, M.D.
Richard D. Katz, M.D.
Vice President and Chief Financial Officer
(Principal Financial Officer)

Date: May 15, 2018

Exhibit 32.1

CERTIFICATIONS PURSUANT TO 18 U.S.C. 1350

The undersigned, the Chief Executive Officer and the Vice President and Chief Financial Officer of Argos Therapeutics, Inc. (the "Company"), each hereby certifies that, to his knowledge on the date hereof:

(a) the Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2018 filed on the date hereof with the Securities and Exchange Commission (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 15, 2018

By: /s/ JEFFREY D. ABBEY
Jeffrey D. Abbey
President and Chief Executive Officer

May 15, 2018

By: /s/ RICHARD D. KATZ, M.D.
Richard D. Katz, M.D.
Vice President and Chief Financial Officer