ARGOS THERAPEUTICS INC

FORM 10-Q
(Quarterly Report)

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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 June 30, 2017

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, 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. (Check one):

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 August 2, 2017, there were 54,974,739 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 June 30, 2017

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ARGOS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	December 31, 2016	June 30, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 52,973,376	$ 9,337,084
Restricted cash	—	740,000
Assets held for sale	1,452,172	10,341,529
Prepaid expenses	940,106	1,431,473
Other receivables	136,140	42,193
Total current assets	55,501,794	21,892,279
Property and equipment, net	40,951,577	4,054,990
Restricted cash	740,000	—
Other assets	11,020	11,020
Total assets	$ 97,204,391	$ 25,958,289
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 5,377,377	$ 794,278
Accrued expenses	9,980,891	7,385,997
Current portion of restructuring obligation	—	292,951
Current portion of notes payable	11,475,480	17,871
Current portion of manufacturing research and development obligation	3,653,203	5,273,458
Current portion of facility lease obligation	—	588,620
Current portion of capital lease obligations	122,887	130,447
Total current liabilities	30,609,838	14,483,622
Convertible note payable to related party	—	6,015,616
Long-term portion of notes payable	18,673,298	6,579,596
Long-term portion of manufacturing research and development obligation	4,509,033	3,070,463
Long-term portion of facility lease obligation	7,390,000	6,801,380
Long-term portion of capital lease obligations	2,202,966	2,166,046
Deferred liabilities	6,723,500	6,668,500
Warrants	20,926,061	746,300
Commitments		
Stockholders' equity (deficit)		
Preferred stock $0.001 par value; 5,000,000 shares authorized as of December 31, 2016 and June 30, 2017; 0 shares issued and outstanding as of December 31, 2016 and June 30, 2017	—	—
Common stock $0.001 par value; 200,000,000 shares authorized as of December 31, 2016 and June 30, 2017; 41,263,179 and 42,229,330 shares issued and outstanding as of December 31, 2016 and June 30, 2017, respectively	41,263	42,229
Accumulated other comprehensive loss	(134,208)	(130,255)
Additional paid-in capital	338,249,457	344,120,299
Accumulated deficit	(331,986,817)	(364,605,507)
Total stockholders' equity (deficit)	6,169,695	(20,573,234)
Total liabilities and stockholders' equity (deficit)	$ 97,204,391	$ 25,958,289

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 June 30,		Six Months Ended June 30,	
	2016	**2017**	**2016**	**2017**
Revenue	$ 488,643	$ 69,693	$ 635,072	$ 174,952
Operating expenses				
Research and development	9,164,184	5,120,952	18,666,160	13,034,781
General and administrative	3,389,479	2,679,867	6,364,503	6,642,758
Impairment of property and equipment	—	—	—	27,204,349
Restructuring costs	—	344,474	—	5,352,766
Total operating expenses	12,553,663	8,145,293	25,030,663	52,234,654
Operating loss	(12,065,020)	(8,075,600)	(24,395,591)	(52,059,702)
Other income (expense)				
Interest income	2,237	8,881	3,813	39,458
Interest expense	(543,462)	(294,329)	(1,034,655)	(1,022,760)
Gain on early extinguishment of debt	—	—	—	249,458
Change in fair value of warrant liability	—	(177,563)	—	20,179,761
Other expense	—	—	—	(4,905)
Other income (expense), net	(541,225)	(463,011)	(1,030,842)	19,441,012
Net loss	$ (12,606,245)	$ (8,538,611)	$ (25,426,433)	$ (32,618,690)
Net loss per share, basic and diluted	$ (0.48)	$ (0.21)	$ (1.04)	$ (0.79)
Weighted average common shares outstanding, basic and diluted	26,066,160	41,374,852	24,336,393	41,344,356

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 June 30,		Six Months Ended June 30,	
	2016	2017	2016	2017
Net loss	$ (12,606,245)	$ (8,538,611)	$ (25,426,433)	$ (32,618,690)
Other comprehensive gain				
Foreign currency translation gain	181	2,628	8,137	3,953
Unrealized gain on short-term investments	—	—	271	—
Total comprehensive loss	$ (12,606,064)	$ (8,535,983)	$ (25,418,025)	$ (32,614,737)

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

ARGOS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Six Months Ended June 30,	
	2016	**2017**
Cash flows from operating activities		
Net loss	$ (25,426,433)	$ (32,618,690)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	439,738	490,701
Compensation expense related to stock options	2,497,254	5,065,654
Common stock issued as payment for services	149,815	—
Amortization of debt discount	70,408	—
Amortization of debt issuance costs	17,002	—
Gain on early extinguishment of debt	—	(249,458)
Impairment loss on property and equipment	—	27,204,349
Decrease in fair value of warrant liability	—	(20,179,761)
Loss on disposal of equipment	—	13,347
Interest accrued on long-term debt	—	453,045
Changes in operating assets and liabilities:		
Prepaid expenses and other receivables	(894,849)	(471,760)
Accounts payable	378,776	(2,417,702)
Accrued expenses	1,134,276	(1,854,106)
Current portion of restructuring obligation	—	292,951
Deferred liabilities	(82,500)	(55,000)
Manufacturing research and development obligation	200,104	181,684
Net cash used in operating activities	(21,516,409)	(24,144,746)
Cash flows from investing activities		
Purchase of property and equipment	(6,039,352)	(3,599,040)
Proceeds from sale of property and equipment	—	1,460,615
Proceeds from maturity of short-term investments	1,003,431	—
Net cash used in investing activities	(5,035,921)	(2,138,425)
Cash flows from financing activities		
Proceeds from sale of common stock and warrants	54,826,380	316,152
Proceeds from exercise of common stock warrants	299,932	—
Proceeds from issuance of convertible note payable	—	6,000,000
Stock issuance costs	(75,188)	—
Payments on notes payable	(9,538)	(23,643,786)
Payment on facility lease obligation	(100,000)	—
Payments on capital lease obligations	—	(37,756)
Proceeds from exercise of common stock options	132,772	—
Proceeds from exercise of employee stock purchase plan shares	136,958	8,369
Net cash provided by (used in) financing activities	55,211,316	(17,357,021)
Effect of exchange rate changes on cash	8,034	3,900
Net increase (decrease) in cash and cash equivalents	28,667,020	(43,636,292)
Cash and cash equivalents		
Beginning of period	6,163,144	52,973,376
End of period	$ 34,830,164	$ 9,337,084
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 974,526	$ 568,240
Supplemental disclosure of noncash investing and financing activities		
Issuance of warrants in exchange for early extinguishment of debt	—	87,100
Stock issuance costs included in accounts payable and accrued expenses	$ 803,352	$ —
Interest capitalized on Construction-in-progress	$ 850,551	$ —
Purchase of property and equipment included in accounts payable and accrued expenses	$ 782,548	$ 2,441,585
Recognition of asset and facility lease obligation related to construction of new property	$ 10,000	$ —

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.

The Company's most advanced product candidate is rocapuldencel-T, which it is developing for the treatment of metastatic renal cell carcinoma, ("mRCC"), and other cancers. The Company is currently conducting a pivotal Phase 3 clinical trial of rocapuldencel-T plus sunitinib or another therapy for the treatment of newly diagnosed mRCC (the "ADAPT trial") under a special protocol assessment (the "SPA"), with the Food and Drug Administration (the "FDA"). The Company dosed the first patient in the ADAPT trial in May 2013 and completed enrollment of the trial in July 2015. In February 2017, the independent data monitoring committee (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. 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 FDA, the Company now plans to continue the ADAPT trial until at least the pre-specified number of 290 events occurs, which it expects will occur in the first half of 2018. The Company also plans to continue to analyze interim data from the trial 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. The Company believes that extending the evaluation of rocapuldencel-T beyond 290 events in the trial could enhance its ability to observe rocapuldencel-T's expected delayed treatment effect. The FDA has agreed to review the planned protocol amendment, and the Company expects to continue discussions with the FDA regarding its development program for rocapuldencel-T. If the Company agrees with the FDA on an amended protocol that increases the pre-specified number of events for the primary analysis, the SPA for the ADAPT trial would no longer be in effect. In addition to the ADAPT trial, the Company is also currently supporting an investigator-initiated Phase 2 trial of rocapuldencel-T in patients with early stage RCC. Subject to obtaining sufficient financing, the Company plans to support an investigator-initiated Phase 2 trial of rocapuldencel-T in bladder cancer and a Phase 2 trial of rocapuldencel-T in combination with a checkpoint inhibitor in mRCC.

The Company is also developing a separate Arcelis-based product candidate, AGS-004, 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 the Company's 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 and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the year ended December 31, 2017 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 our Annual Report on Form 10-K for the year ended December 31, 2016.

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 incurred losses in each year since inception and as of June 30, 2017, had an accumulated deficit of $364.6 million. Also, as of June 30, 2017, the Company's current assets totaled $21.9 million compared with current liabilities of $14.5 million, and the Company had cash and cash equivalents of $9.3 million. These factors raise substantial doubt about the Company's ability to continue as a going concern. Based upon its current and projected cash flow, the Company notes there is substantial doubt about its ability to continue as a going concern within one year after the date that these financial statements are issued. The financial statements for the three months ended June 30, 2017 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 100,000 shares of common stock at an exercise price of $1.30 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.

As of June 30, 2017, the Company had cash and cash equivalents of $9.3 million and working capital of $7.4 million. The Company does not currently have sufficient cash resources to pay its obligations as they become due. 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 $1.1 million in severance costs and $2.6 million in stock-based compensation expense from the acceleration of stock options for the employees associated with the workforce reduction. The Company has also initiated discussions with Saint-Gobain Performance Plastics Corporation ("Saint-Gobain"), Invetech Pty Ltd ("Invetech"), and Medpace, Inc. ("Medpace"), regarding the fees that the Company owes them, including potentially the conversion by them of some or all of the outstanding fees into a convertible note or equity of the Company. Additionally, in June 2017, the Company issued a secured convertible note to Pharmstandard International S.A. ("Pharmstandard"), a collaborator and the Company's largest shareholder, in the aggregate principal amount of $6.0 million. In an at-the-market offering under its sales agreement with Cowen & Company, LLC ("Cowen") in June 2017, the Company has raised proceeds of $4.9 million through the issuance of common stock as of August 3, 2017, of which $4.6 million was raised subsequent to June 30, 2017. However, even taking these measures into account, the Company does not have sufficient cash resources to pay all of its accrued obligations in full or to continue its business operations beyond September 2017. Therefore, the Company will need to raise additional capital by the end of September 2017 in order to continue to operate its business beyond that time. Alternatively, the Company may seek to engage in one or more potential transactions, such as the 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, but there can be no assurance that the Company will be able to enter into such a transaction or transactions on a timely basis or on terms that are favorable to the Company. Under these circumstances, the Company may instead 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 stockholders.

Until such time, if ever, as the Company can generate substantial product revenues, it expects to seek to raise additional funds 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. There can be no assurance that the Company will be able to generate funds in these manners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition and the Company could be forced to delay, reduce, terminate or eliminate its product development programs, wind up its operations, liquidate or seek bankruptcy protection.

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. Significant intercompany transactions and accounts have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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 and six months ended June 30, 2017, as compared with the significant accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2016.

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, 2016 and June 30, 2017, $52.7 million and $9.1 million, respectively, in cash and cash equivalents was uninsured.

Recently Issued Accounting Pronouncements Not Yet Adopted

In May 2014, the Financial Accounting Standards Board ("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. The original effective date of this new standard was for periods beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers: Deferral of the Effective Date,* which deferred the effective date of ASU 2014-09 by one year to periods beginning after December 15, 2017, with early adoption permitted but not earlier than the original effective date. Accordingly, this new standard will be effective for the Company in first quarter of 2018. Additionally, the FASB issued ASU 2016-10, *Identifying Performance Obligations and Licensing,* which provided additional guidance and clarity on this topic. 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 is currently performing an assessment of the impact of the new standard on its collaboration arrangements with third parties and is in the process of mapping those activities to deliverables and tracing those deliverables to the new standard. The Company will assess what impact the new standard will have on those deliverables.

The Company is currently evaluating the impact that the implementation of this standard will have on the Company's consolidated financial statements.

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).* T his ASU requires changes in the pres entation 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 will be effective for annual periods and interim periods within those annual periods beginning after December 15, 2017, will require adoption on a retrospective basis and will be effective for the Company on January 1, 2018. The Company is currently evaluating the impact that adoption of this standard will have on the Company's consolidated financial statements.

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.

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. ASU 2016-18 is effective for the Company beginning in the first quarter of 2019, with early adoption permitted, and must be adopted using a retrospective approach. Other than this change in presentation within the statement of cash flows, ASU 2016-18 will not have an impact on the Company's consolidated financial statements.

Recently Adopted Accounting Standards

In August 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 simplifies several aspects related to the accounting for and financial statement presentation of share-based payments, including the accounting for income taxes at award settlement and forfeitures, and the classification of excess tax benefits and shares surrendered for tax withholdings in the statement of cash flows. The Company adopted this standard during the six months ended June 30, 2017 with no effect on the Company's consolidated financial statements.

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, 2016 and June 30, 2017.

As of December 31, 2016 and June 30, 2017, 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, 2016 and June 30, 2017, 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 and restricted cash in a deposit account at a bank. 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. As of June 30, 2017, the Company had no Level 2 assets.

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 11).

During the six months ended June 30, 2017, there were no transfers between Levels 1, 2, and 3 assets or liabilities.

As of December 31, 2016 and June 30, 2017, these financial instruments and respective fair values have been 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, 2016
Assets				
Money-market funds	$ 45,389,314	$ —	$ —	$ 45,389,314
Restricted cash	740,000	—	—	740,000
Total assets at fair value	$ 46,129,314	$ —	$ —	$ 46,129,314
Liabilities				
Warrants	$ —	$ —	$ 20,926,061	$ 20,926,061
Total liabilities at fair value	$ —	$ —	$ 20,926,061	$ 20,926,061

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of June 30, 2017
Assets				
Money-market funds	$ 4,079,487	$ —	$ —	$ 4,079,487
Restricted cash	740,000	—	—	740,000
Total assets at fair value	$ 4,819,487	$ —	$ —	$ 4,819,487
Liabilities				
Warrants	$ —	$ —	$ 746,300	$ 746,300
Total liabilities at fair value	$ —	$ —	$ 746,300	$ 746,300

Changes in the fair value of the Company's Level 3 liability for warrants during the six months ended June 30, 2017 were as follows:

Balance as of December 31, 2016	$ 20,926,061
Change in fair value during the period	(20,179,761)
Balance as of June 30, 2017	$ 746,300

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 and restricted cash as of December 31, 2016 and June 30, 2017 were as follows:

	As of December 31, 2016			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Money-market funds	$ 45,389,314	$ —	$ —	$ 45,389,314
Restricted cash	740,000	—	—	740,000
	$ 46,129,314	$ —	$ —	$ 46,129,314

	As of June 30, 2017			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Money-market funds	$ 4,079,487	$ —	$ —	$ 4,079,487
Restricted cash	740,000	—	—	740,000
	$ 4,819,487	$ —	$ —	$ 4,819,487

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, 2016 was approximately $29.8 million compared with its carrying value of $30.1 million. The fair value of the Company's debt as of June 30, 2017 was approximately $6.2 million compared with its carrying value of $6.6 million (see Note 6).

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

As discussed in Note 1, the Company's most advanced product candidate is rocapuldencel-T, which the Company is developing for the treatment of mRCC and other cancers. The Company is currently conducting a pivotal Phase 3 clinical trial of rocapuldencel-T plus sunitinib or another therapy for the treatment of newly diagnosed mRCC under an SPA with the FDA. 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 recent development triggered a restructuring of the Company's operations and impairments of property and equipment and leases. As set forth below and in Notes 4 and 7, the Company recognized restructuring costs of $5.4 million and impairment loss of property and equipment of $27.2 million during the six months ended June 30, 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. Through additional targeted reductions and attrition, the workforce was further reduced to 44 employees as of July 31, 2017. The principal objective of the reduction was to enable the Company to conserve its financial resources as the Company conducted its ongoing review of the preliminary ADAPT trial data set and discussed the data with the FDA. The Company recognized $1.1 million in severance costs during the six months ended June 30, 2017, of which $0.3 million was unpaid as of June 30, 2017. The Company also recognized $2.6 million in stock-based compensation costs from the acceleration of vesting of stock options held by the terminated employees during the six months ended June 30, 2017.

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 the Center for Technology Innovation, or 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. The Company had intended to utilize this facility to prepare for a biologics license application, or BLA, to the FDA and to support initial commercialization of rocapuldencel-T. The Company had expected to complete the initial build-out and equipping of the facility, including capacity qualification necessary for BLA filing, by the end of the first quarter of 2018. However, due to the IDMC recommendation in February 2017 to discontinue the ADAPT trial, the Company is currently reassessing its manufacturing plans. As a result, the Company initiated discussions with the landlord of its CTI facility regarding the termination of this lease.

On March 17, 2017 the landlord notified the Company that it was terminating the lease (the "Termination Notice"), effective immediately. The Company never occupied the leased space. In the Termination Notice, the landlord asserted that the Company was in default under the Lease due to nonpayment of invoices for up-fit costs. The Company did not disputed the occurrence of the event of default or the termination of the Lease and did not plan to seek to cure the default. In the Termination Notice, the landlord stated that the Company was liable for any and all costs incurred by the landlord in re-letting the premises, any deficiency between the Company's scheduled rent for the remainder of the term of the Lease and the rent charged to the new tenant, the unamortized portion of the funded up-fit costs, rent abatement, interest at the rate of 12% per annum on the sums noted and all attorneys' fees incurred by the landlord in enforcing the Lease. The Company instructed the landlord to begin the process of re-letting the premises in order to mitigate damages. On March 31, 2017, the Company entered into a Lease Termination Agreement (the "Termination Agreement") with the landlord whereby the lease was deemed terminated 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 drew down another $1.7 million in April 2017 for lease termination damages and agreed to return $0.1 million to the Company in consideration for being able to salvage some of the construction costs. During the six months ended June 30, 2017, the Company recorded a lease termination fee of $1.6 million which is included in Restructuring costs on the statement of operations. The Company also recorded an impairment loss on Construction-in-progress on the property of $0.9 million.

Impairment of Centerpoint Facility and Construction-in-Progress

The Company also determined during the three months ended March 31, 2017 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 and is currently working with the landlord to actively find another tenant for the property. The Company estimates it will take up to nine months to exit the arrangement and terminate the operating lease with TKC. In the statement of operations for the six months ended June 30, 2017, the Company recorded an impairment loss of $18.3 million for the Construction-in-progress on the property. As of June 30, 2017, the Centerpoint property is classified as Assets held for sale in the amount of $7.4 million. The related facility lease obligation is $7.4 million as of June 30, 2017.

The Company believes that its current Technology Drive and Patriot Center facilities are sufficient for the manufacture of rocapuldencel-T and AGS-004 to support its ongoing clinical trials and any potential clinical trials that may be initiated in the near-term.

The restructuring liability during the six months ended June 30, 2017 consisted of the following:

	Severance and Other Employee Costs	Lease and Other Facility Costs	Total
Balance as of December 31, 2016	$ —	$ —	$ —
Restructuring costs	3,737,176	1,615,590	5,352,766
Acceleration of stock options	(2,608,008)	—	(2,608,008)
Cash payments	(836,217)	(1,615,590)	(2,451,807)
Balance as of June 30, 2017	$ 292,951	$ —	$ 292,951

4. Property and Equipment

Property and equipment consist of the following:

	December 31, 2016	June 30, 2017
Office furniture and equipment	$ 657,875	$ 657,875
Computer equipment	1,018,173	1,029,555
Computer software	3,146,978	3,146,978
Laboratory equipment	5,709,215	6,108,348
Leasehold improvements	2,435,530	2,435,530
Assets related to facility lease obligation	8,070,033	—
Construction-in-progress	28,807,957	—
Total property and equipment, gross	49,845,761	13,378,286
Less: Accumulated depreciation and amortization	(8,894,184)	(9,323,296)
Property and equipment, net	$ 40,951,577	$ 4,054,990

The Company reviews its property and equipment for impairment whenever events or changes indicate its carrying value may not be recoverable. As discussed in Note 3, the Company determined during the three months ended March 31, 2017 that it would no longer need to develop various equipment included in Construction-in-progress under its current manufacturing plans. The Company has agreements and understandings with various vendors to attempt to sell or dispose this equipment at prices less than the Company's carrying value. Accordingly, the Company determined that the fair value of this equipment held for sale was $0.7 million as of June 30, 2017 and recorded an impairment loss of $1.1 million during the six months ended June 30, 2017. Additionally, the Company recorded a $6.1 million impairment loss on other equipment included in Construction-in-progress during the six months ended June 30, 2017 that had to be abandoned or had no net realizable value.

Centerpoint Facility and Construction-in-Progress

As of December 31, 2016, assets related to the Centerpoint facility lease obligation and Construction-in-progress were recognized primarily due to the Company being deemed to be the accounting owner of the Centerpoint facility being built to be the Company's corporate headquarters and primary manufacturing facility during its construction period under build-to-suit lease accounting (see Note 8). As discussed in Note 3, the Company determined during the three months ended March 31, 2017 that it would no longer need to develop the Centerpoint facility and is currently working with the landlord to actively find another tenant or buyer for the property. The Company estimates it will take up to nine months from June 30, 2017 to exit the arrangement and terminate the operating lease. The Company recorded an impairment loss of $18.3 million for the Construction-in-progress on the property during the six months ended June 30, 2017. As of June 30, 2017, the Centerpoint property is classified as Assets held for sale in the amount of $7.4 million. The related facility lease obligation is $7.4 million as of June 30, 2017.

Construction-in-progress under capital leases included $2,372,880 and $0 as of December 31, 2016 and June 30, 2017, respectively. As of December 31, 2016 and June 30, 2017, Construction-in-progress included $2,652,261 and $0, respectively, of capitalized interest.

Depreciation and amortization expense was as follows:

Three months ended June 30, 2016	$	237,996
Three months ended June 30, 2017	$	246,206
Six months ended June 30, 2016	$	439,738
Six months ended June 30, 2017	$	490,701

5. Income Taxes

The Company has incurred net operating losses since inception and is forecasting additional losses through December 31, 2017. Therefore, no U.S. Federal, state or foreign income taxes are expected for 2017 and no provision for such taxes has been recorded as of June 30, 2017.

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, 2016 and June 30, 2017, 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.

6. Notes Payable

Notes payable consist of the following as of December 31, 2016 and June 30, 2017:

		December 31, 2016		June 30, 2017
Notes payable under the venture loan and security agreement, including accrued interest	$	24,035,029	$	—
Less debt discount and debt issuance costs		(320,409)		—
Notes payable under the venture loan and security agreement, net		23,714,620		—
Convertible note payable to Pharmstandard, including accrued interest		—		6,015,616
Promissory note payable to Medinet, including accrued interest		6,403,186		6,574,891
Other notes payable		30,972		22,575
Total notes payable including convertible note payable to Pharmstandard		30,148,778		12,613,082
Less convertible note payable to Pharmstandard, including accrued interest		—		(6,015,616)
Less current portion		(11,475,480)		(17,870)
Long-term portion of notes payable	$	18,673,298	$	6,579,596

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 convertible secured promissory note in the original principal amount of $6,000,000 (the "Note") in a private placement (the "Financing").

The Company 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 the Company's intellectual property. The Company 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 the Company 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 on the Note into shares of the Company's common stock at a price per share equal to $0.50. 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 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 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 the Company's largest stockholder, and beneficially owned, in the aggregate, shares representing approximately 39.9% of the Company's outstanding common stock as of July 31, 2017. In addition, two members of the Company's board of directors are closely associated with Pharmstandard.

Venture Loan Facility. In September 2014, the Company entered into a venture loan and security agreement (the "Loan Agreement") with Horizon Technology Finance Corporation and Fortress Credit Co LLC (together, 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 $449,796 in debt issuance costs in connection with the closing of the Loan Facility. Debt issuance costs are presented in the 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 June 30, 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 making 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 $625,000 was due on September 30, 2018, or such earlier date specified in the Loan Agreement. The Company was recognizing the final payment of $625,000 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 $625,000 was due on February 7, 2019, or such earlier date specified in the Loan Agreement. The Company was recognizing the final payment of $625,000 as accrued interest over the expected life of the second tranche loan. In addition, the Company agreed that if the Company repays 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 100,000 shares of the Company's common stock at an exercise price of $1.30 per share in consideration of the Lenders accepting the $23.1 million. The Company recognized a gain on this early extinguishment of debt of $249,458 during the six months ended June 30, 2017 which is included in Other income (expense) on the statement of operations.

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.

The Company's obligations under the Loan Agreement were secured by a first priority security interest in substantially all of its assets other than its intellectual property. The Company also agreed not to pledge or otherwise encumber its intellectual property assets, subject to certain exceptions.

In connection with the Loan Agreement, the Company issued to the Lenders and their affiliates warrants to purchase a total of 82,780 shares of the Company's common stock at a per share exercise price of $9.06 (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 $338,673 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 June 30, 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 Co., Ltd and its wholly-owned subsidiary, MEDcell Co., Ltd. (together "Medinet"), as described in Note 13, 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 recognized 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 recognized 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 and June 30, 2017, the amount of the note payable was $6.4 million and $6.6 million, respectively, including $1.8 million and $2.0 million, respectively, of accrued interest. As of December 31, 2016 and June 30, 2017, the total deferred liability associated with the Medinet note was $5.3 million (see Note 13).

Other Notes. During November 2013, the Company borrowed $77,832 from a lending institution to finance the purchase of computer equipment, of which $30,972 and $22,575 in principal was outstanding as of December 31, 2016 and June 30, 2017, 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. Manufacturing Research and Development Obligation

In October 2014, the Company entered into a development agreement (the "Invetech Development Agreement") with Invetech. The Invetech Development Agreement supersedes and replaces the development agreement entered into by the parties in July 2005. Under the Invetech Development Agreement, Invetech has agreed to develop and provide prototypes of the automated production system to be used for the manufacture of the Company's Arcelis-based products (the "Production Systems"). Development services will be performed on a proposal by proposal basis.

Invetech has agreed to defer 30% of its fees, up to $5.0 million. Under the Invetech Development Agreement, deferred fees (plus interest of 7% per annum) would become payable, at the Company's option, either in a lump sum within 90 days of the "Sunset Date Trigger Event" or pursuant to an installment plan (either in four installments payable within the first year or eight installments payable within the first two years after the "Sunset Date Trigger Event"). The "Sunset Date Trigger Event" was December 31, 2016. Invetech is entitled to a 10% bonus payment if the ADAPT trial is closed early indicating positive efficacy or if the ADAPT trial meets the primary endpoint of overall survival and the 100% of events analysis indicates positive efficacy, and if Invetech has timely completed all activities up to the time the ADAPT trial is stopped.

As of December 31, 2016, the Company recorded this manufacturing research and development obligation on its consolidated balance sheet at $8.2 million, representing $5.2 million in deferred fees, $2.3 million in estimated bonus payments and $0.6 million in accrued interest, of which $3.7 million is included in the current liabilities as the current portion of the obligation. As of June 30, 2017, the Company recorded this manufacturing research and development obligation on its consolidated balance sheet at $8.3 million, representing $5.2 million in deferred fees, $2.3 million in estimated bonus payments and $0.7 million in accrued interest, of which $5.3 million is included in current liabilities as the current portion of the obligation.

The Invetech Development Agreement requires the parties to discuss in good faith Invetech's supply of Production Systems for use in manufacturing commercial product. The Company has an obligation to purchase $25.0 million worth of Production Systems, components, subsystems and spare parts for commercial use. Once that obligation has been satisfied, the Company has the right to have a third party supply Production Systems for use in manufacturing commercial product provided that Invetech has a right of first refusal with respect to any offer by a third party and the Company may not accept an offer from a third party unless that offer is at a price that is less than that offered by Invetech and otherwise under substantially the same or better terms. The Company will own all intellectual property arising from the development services (with the exception of existing Invetech intellectual property incorporated therein under which the Company will have a license). 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 the Company without cause.

The Company is currently in discussions with Invetech regarding the Invetech Development Agreement related to the deferred fees, and the repayment of the fees, including potentially through the conversion of some or all of the outstanding fees into equity of the Company.

8. Facility Lease Obligation, Capital Lease Obligations and Assets Held for Sale

Facility Lease Obligation

In August 2014, the Company entered into a Lease Agreement (the "Lease Agreement") with TKC LXXII, LLC, a North Carolina limited liability company ("TKC"). Under the Lease Agreement, the Company agreed to lease certain land and an approximately 125,000 square-foot building to be constructed in Durham County, North Carolina, which the Company refers to as Centerpoint. The Company intended this facility to be built to house the Company's corporate headquarters and primary manufacturing facility. The shell of the new facility was constructed on a build-to-suit basis by TKC in accordance with agreed upon specifications and plans as set forth in the Lease Agreement and at the expense of TKC, other than those costs resulting from changes requested by the Company, for which the Company has paid $1.7 million as of June 30, 2017.

The term of the Lease Agreement is 10 years from the commencement date of July 1, 2015. The Company has an option to extend the Lease Agreement by six five-year renewal terms. Current rent payments in the second year are $47,972 per month, subject to certain fixed increases over the course of the term as set forth in the Lease Agreement.

The Lease Agreement required the Company to provide TKC with a letter of credit. The Company provided the bank that issued the letter of credit on its behalf a security deposit of $1,325,000 to guarantee the letter of credit. In accordance with the Lease Agreement, this deposit was reduced to $740,000 as of December 31, 2015 under a purchase and sale agreement with TKC. The deposit was recorded as restricted cash as of December 31, 2016 and June 30, 2017 on the Company's consolidated balance sheets.

Under the Lease Agreement, the Company is involved in the construction of the building. To the extent the Company is involved with the structural improvements of the construction project or takes construction risk prior to the commencement of a lease, ASC 840-40-05-5 requires for accounting purposes that the Company be considered the owner of this project during the construction period. Therefore, the Company recorded an asset in property and equipment, net on the Company's consolidated balance sheets for the cost of the Company's portion of the building plus the amount of estimated structural construction costs incurred by TKC and the Company as of the applicable balance sheet date. The Company recorded a corresponding facility lease obligation on its consolidated balance sheets representing the amounts paid by TKC.

The initial recording of these assets and liabilities is classified as non-cash investing and financing items, respectively, for purposes of the Company's consolidated statements of cash flows.

Under the Lease Agreement, the Company had an option to purchase the property. In February 2015, the Company exercised this purchase option and entered into a Purchase and Sale Agreement (the "Purchase Agreement") with TKC. The purchase price to be paid by the Company at closing was $7.4 million plus the amount of any additional costs incurred by TKC as a result of changes requested by the Company, for which the Company had paid $1.7 million as of December 31, 2016, and the amount of any improvement allowances advanced to the Company by TKC prior to the closing. Under the terms of the Purchase Agreement, the Company had until October 31, 2016 to consummate the purchase of the property. The Company did not purchase the property by such date. As a result, the Company has no further right to purchase the property and remains subject to the lease under the Lease Agreement.

As of December 31, 2016, assets related to the Company's facility lease obligation were recognized primarily due to the Company being deemed to be the accounting owner of the Centerpoint facility which was being built to be the Company's corporate headquarters and primary manufacturing facility during its construction period under build-to-suit lease accounting. As discussed in Note 3, the Company determined during the three months ended March 31, 2017 that it would no longer need to develop the Centerpoint facility and is currently working with the landlord to actively find another tenant or buyer for the property. The Company estimates it will take up to nine months from June 30, 2017 to exit the arrangement and terminate the facility lease. The Company recorded an impairment loss for the net carrying value of the facility asset of $0.7 million during the six months ended June 30, 2017. The Company recorded an asset related to the facility lease obligation included in property and equipment of $7.9 million as of December 31, 2016 and $7.4 million in assets held for sale as of June 30, 2017. The facility lease obligation on the Company's consolidated balance sheet is $7.4 million as of December 31, 2016 and June 30, 2017. The Company also recorded an impairment loss of $18.3 million for the Construction-in-progress on the property during the six months ended June 30, 2017 (see Note 3).

Capital Lease Obligations

In August 2016, the Company entered into two agreements (the "Power Generation Agreements") with an electric utility company. The Power Generation Agreements are being 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. The Power Generation Agreements require monthly minimum payments of $32,948 for a period of 128 months, or a total of $4.2 million ending in March 2027. 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 June 30, 2017, $2.3 million of these assets were classified as Assets held for sale on the Company's Balance Sheet. Since the capital leases are for electrical equipment held for sale on the Centerpoint property, the Company recorded an impairment loss of $0.1 million during the six months ended June 30, 2017 (see Note 3).

9. Stockholders' Equity (Deficit)

Common Stock Issued in 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 80,105 restricted shares of common stock with an aggregate value of $394,534 were issued. Each of the restricted stock awards was 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. During the three months ended June 30, 2017, one of the restricted stock awards of 7,378 shares of common stock was forfeited back to the Company. Also during the three months ended June 30, 2017, one grant of 46,664 restricted shares of common stock was awarded to an employee resulting in stock-based compensation expense of $20,999 included in General and administrative expenses.

At-the-market Offering in 2017

In May 2015, the Company entered into a sales agreement, the ("Sales Agreement"), with Cowen, pursuant to which the Company may 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. 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, including sales made directly on or through the Nasdaq Global Market, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices, and/or any other method permitted by law. Cowen is not required to sell any specific amount, but acts as the Company's sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. Shares sold pursuant to the Sales Agreement are sold pursuant to a shelf registration statement, which became effective on May 14, 2015. 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 six months ended June 30, 2017, the Company sold 829,096 shares of common stock pursuant to the Sales Agreement, resulting in proceeds of $0.3 million, net of commissions and issuance costs. The Company sold an additional 13,945,932 shares resulting in $4.6 million in net proceeds between July 1, 2017 and August 3, 2017. During the year ended December 31, 2016, the Company sold 872,682 shares of common stock pursuant to the Sales Agreement, resulting in proceeds of $5.5 million, net of commissions and issuance costs.

10. Stock Incentive 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 as approved in January 2014, the Company may grant incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards for the purchase of that number of shares of common stock equal to the sum of 1,951,182 shares, plus such number of shares, up to 357,841 shares, as is equal to the sum of the number of shares reserved for issuance under the Company's 2008 Stock Incentive Plan (the "2008 Plan") that remained available for grant under the 2008 Plan immediately prior to the closing of the Company's initial public offering on February 12, 2014 (381,250 shares) and the number of shares subject to outstanding awards under the 2008 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right, plus an annual increase, to be added on the first day of each fiscal year from January 1, 2015 through January 1, 2024, equal to the lowest of 2,309,023 shares of common stock, 4% of the number of the Company's outstanding shares on the first day of each such fiscal year and an amount determined by the Company's 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 6,000,000 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 2,690,977 shares, such that the total number of shares of common stock authorized for issuance under the 2014 Plan is equal to the sum of 11,611,506 shares, plus an annual increase to be added on the first day of each of the 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) 5,000,000 shares of Common Stock, (ii) four percent (4%) of the outstanding shares of Common Stock on such date or (iii) an amount determined by our 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, 13,054 shares were purchased with employee withholdings at an option exercise price based upon 85% of the lower of the closing price at the beginning of the first Purchase Plan Period of $9.83 and the closing price on February 27, 2015 of $9.02, 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, 20,301 shares were purchased with employee withholdings at an option exercise price based upon 85% of the lower of the closing price at the beginning of the second Purchase Plan Period of $9.02 and the closing price on August 31, 2015 of $6.21, 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, 36,290 shares were purchased with employee withholdings at an option exercise price based upon 85% of the lower of the closing price at the beginning of the third Purchase Plan Period of $6.24 and the closing price of $4.44 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, 30,157 shares were purchased with employee withholdings at an option exercise price based upon 85% of the lower of the closing price at the beginning of the fourth Purchase Plan Period of $4.91 and the closing price of $4.95 on August 31, 2016, 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, 8,562 shares were purchased with employee withholdings at an option exercise price based upon 85% of the lower of the closing price at the beginning of the fifth Purchase Plan Period of $4.95 and the closing price of $1.15 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 will end on August 31, 2017. Based upon 85% of the lower of the closing price at the beginning of the sixth Purchase Plan Period of $1.20 and the closing price of $0.36 on June 30, 2017, stock-based compensation expense of $12,492 was recognized.

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 June 30, 2017, there were 1,365,052 shares of common stock remaining available for future issuance under the 2014 Plan and 237,989 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 June 30,		Six Months Ended June 30,	
	2016	2017	2016	2017
Research and development	$ 1,019,199	$ 653,624	$ 1,447,800	$ 2,261,911
General and administrative	726,038	764,359	1,250,639	2,803,743
Total stock-based compensation expense	$ 1,745,237	$ 1,417,983	$ 2,698,439	$ 5,065,654

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 nonemployees 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. During the three months ended June 30, 2016, modifications were made to stock option grants to 18 employees that accelerated the vesting of such grants, resulting in an increase in stock-based compensation expense of $0.6 million. As part of the restructuring costs discussed in Note 3, the Company recognized $0.2 million and $2.6 million in stock-based compensation expense from the acceleration of stock options vesting during the three and six months ended June 30, 2017, respectively, for 58 employees that were terminated in March and April 2017.

During the three months ended June 30, 2016, the Company granted options to employees to purchase a total of 899,456 shares of the Company's common stock at exercise prices ranging from $5.71 to $10.97 per share, which in each instance was the closing price of the Company's common stock on the grant date, except for options to purchase 565,000 shares of common stock granted to the Company's executive committee employees which have an exercise price of $7.41 compared with the $5.95 closing price of the Company's common stock on the grant date. During the three months ended June 30, 2017, the Company did not grant options.

During the six months ended June 30, 2016, the Company granted options to employees to purchase a total of 1,210,106 shares of the Company's common stock at exercise prices ranging from $2.16 to $10.97 per share, which in each instance was the closing price of the Company's common stock on the grant date, except for 565,000 options granted to the Company's executive committee employees which have an exercise price of $7.41 compared with the $5.95 closing price of the Company's common stock on the grant date. During the six months ended June 30, 2017, the Company granted options to employees to purchase a total of 1,382,084 shares of the Company's common stock at exercise prices ranging from $1.35 to $5.05 per share, which, in each instance was the closing price of the Company's common stock on the grant date.

The following table summarizes the Company's stock option activity during the six months ended June 30, 2017:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)
Outstanding as of December 31, 2016	4,902,828	$ 6.07	
Granted	1,382,084	$ 4.87	
Exercised	-	$ -	
Cancelled	(675,062)	$ 4.85	
Outstanding as of June 30, 2017	5,609,850	$ 5.92	6.17
Exercisable as of June 30, 2017	3,299,044	$ 5.93	4.31
Vested and expected to vest as of June 30, 2017	5,431,918	$ 5.92	6.08

Valuation Assumptions for Stock Option Plans and Employee Stock Purchase Plan

The employee stock-based compensation expense recognized 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 Plan		Employee Stock Purchase Plan	
	Six Months Ended June 30,		Six Months Ended June 30,	
	2016	2017	2016	2017
Risk-free interest rate	1.53%	2.27%	0.50%	0.79%
Dividend yield	0%	0%	0%	0%
Expected option term (in years)	7	7	0.5	0.5
Volatility	82%	86%	141%	210%

11. Warrants

In March 2016, the Company sold and certain investors purchased for a total purchase price of $19,882,915 a total of 3,652,430 shares of common stock and warrants to purchase a total of 2,739,323 shares of common stock at a per share exercise price of $5.35. These warrants will terminate on March 14, 2021 or such earlier date as specified in the warrants. Additionally, on June 29, 2016, the Company sold and such investors purchased for a total purchase price of $29,824,520 a total of 5,478,672 shares of common stock and warrants to purchase a total of 4,109,005 shares of common stock at a per share exercise price of $5.35. These warrants will terminate on June 29, 2021 or such earlier date as specified in the warrants. In June 2016, warrants to purchase 56,062 shares of common stock were exercised for proceeds of $299,932 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 9,090,909 shares of common stock and warrants to purchase a total of 6,818,181 shares of common stock at a per share exercise price of $5.50 (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, on March 6, 2017, the Company issued to the Lenders five year warrants to purchase an aggregate of 100,000 shares of the Company's common stock at an exercise price of $1.30 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 June 30, 2017.

As of June 30, 2017, outstanding warrants to purchase a total of 13,793,227 shares of the Company's common stock are set forth in the table below. All outstanding warrants were issued with an original life of five years.

Type of Warrant and Classification	Number of Shares	Exercise Price	Expiration Date(s)
Common stock - Equity	82,780	$ 9.06	9/29/21
Common stock - Equity	2,683,261	$ 5.35	3/14/21
Common stock - Equity	4,109,005	$ 5.35	6/29/21
Common stock - Liability	6,818,181	$ 5.50	8/02/21
Common stock - Equity	100,000	$ 1.30	3/06/22

The August 2016 Warrants, which remained outstanding as of June 30 2017, include provisions that could require cash settlement of the August 2016 Warrants. The August 2016 Warrants are 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 statement of operations in each subsequent period:

	August 2016 Warrants
Exercise price	$ 5.50
Expiration date	August 2, 2021
Total shares issuable on exercise	6,818,181

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 a weighted average of several peer public companies and the Company's historical volatility. The expected life of the August 2016 Warrants is assumed to be equivalent to their remaining contractual term. The decrease in the fair value of the warrants during the six months ended June 30, 2017 was primarily due to the decline in the Company's stock price and an increase in the expected stock price volatility.

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, 2016 and June 30, 2017:

	December 31, 2016	June 30, 2017
Exercise price of warrants	$ 5.50	$ 5.50
Closing underlying stock price on date of valuation	$ 4.90	$ 0.36
Expected stock price volatility	84%	108%
Expected life (in years)	4.58	4.08
Risk-free interest rate	1.93%	1.72%
Expected dividend yield	0.0%	0.0%
Valuation per common share underlying each warrant	$ 3.07	$ 0.11
Total liability for warrants on the balance sheet	$ 20,926,061	$ 746,300
Decrease in fair value	$ 1,007,352	$ 20,179,761

In November 2013, the Company entered into an agreement with Pharmstandard under which Pharmstandard purchased shares of the Company's Series E preferred stock. Upon the closing of the Company's initial public offering, all of the outstanding shares of redeemable convertible preferred stock automatically converted into 13,188,251 shares of the Company's common 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 499,788 shares of the Company's common stock at an exercise price of $5.82 per share. As of August 2, 2017, the Company had not entered into this manufacturing rights agreement or issued such warrants.

12. Revenue and Concentration of Credit Risk

In September 2006, the Company entered into a multi-year research contract with NIH and the 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 June 30, 2016 and 2017, the Company recorded revenue under the NIH and NIAID agreement of $461,143 and $42,193, respectively. For the six months ended June 30, 2016 and 2017, the Company recorded revenue under the NIH and NIAID agreement of $552,572 and $119,952, respectively. The Company has recorded total revenue of $38.0 million through June 30, 2017 under the NIH and NIAID agreement. As of June 30, 2017, there was up to $1.8 million of potential revenue remaining to be earned under the NIH and NIAID agreement. As of December 31, 2016 and June 30, 2017, the Company recorded a receivable from the NIH and NIAID of $136,140 and $42,193, 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.

13. Collaboration Agreements

Pharmstandard License Agreement

In August 2013, Pharmstandard purchased shares of the Company's series E preferred stock. Concurrently 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 ours. 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 499,788 shares of the Company's common stock at an exercise price of $5.82 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.

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 $500,000 upon the initial submission of an application for regulatory approval of a licensed product in South Korea, $500,000 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 with a $1.0 million payment was achieved in July 2015 and the second milestone with a $2.0 million payment was achieved in June 2016, reducing the outstanding principal of the loan as of September 30, 2016 to $6.0 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 recognized 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 recognized 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. As of June 30, 2017, the amount of the note payable was $6.6 million, including $2.0 million accrued interest. As of December 31, 2016 and June 30, 2017, the total deferred liability associated with the Medinet note was $5.3 million.

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 (Hong Kong) Co. Ltd. ("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.

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 $20.5 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.

14. 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 June 30,		Six Months Ended June 30,	
	2016	2017	2016	2017
Net loss	$ (12,606,245)	$ (8,538,611)	$ (25,426,433)	$ (32,618,690)
Weighted average common shares outstanding, basic and diluted	26,066,160	41,374,852	24,336,393	41,344,356
Net loss per share, basic and diluted	$ (0.48)	$ (0.21)	$ (1.04)	$ (0.79)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2017	2016	2017
Stock options outstanding	3,716,923	5,879,915	3,635,868	5,869,056
Warrants outstanding	2,854,320	13,793,227	1,724,422	13,757,315

15. Legal Proceedings

On March 14, 2017, a securities class action lawsuit was commenced in the United States District Court, Middle District of North Carolina, Durham Division, naming the Company and certain of the Company's officers as defendants, and alleging violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by the defendants between February 7, 2014 and February 21, 2017 (the "Class Period"). The plaintiff seeks to represent a class comprised of purchasers of the Company's common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court. The Court appointed co-lead plaintiffs by order dated June 23, 2017. The Court has set a deadline of September 18, 2017 for lead plaintiffs to file an amended complaint, and the defendants' response to the amended complaint will be due 60 days thereafter. The Company believes it has meritorious defenses and intends to defend the lawsuit vigorously. It is possible that similar lawsuits may yet be filed in the same or other courts that name the same or additional defendants.

Other than as described above, the Company is not a party to any legal proceedings and is not aware of any claims or actions pending or threatened against the Company. In the future, the Company might from time to time become involved in litigation relating to claims arising from its ordinary course of business.

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.

Overview

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.

Our most advanced product candidate is rocapuldencel-T, which we are developing for the treatment of metastatic renal cell carcinoma, or mRCC, and other cancers. We are currently conducting a pivotal Phase 3 clinical trial of rocapuldencel-T plus sunitinib or another therapy for the treatment of newly diagnosed mRCC under a special protocol assessment, or SPA, with the Food and Drug Administration, or FDA. We refer to this trial as the ADAPT trial. We dosed the first patient in the ADAPT trial in May 2013 and completed enrollment of the ADAPT trial in July 2015. 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 study 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. 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 FDA, we now plan to continue the ADAPT trial until at least the pre-specified number of 290 events occurs, which we expect will occur in the first half of 2018. We also plan to continue to analyze interim data from the trial 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. We believe that extending our evaluation of rocapuldencel-T beyond 290 events in the trial could enhance our ability to observe rocapuldencel-T's expected delayed treatment effect. The FDA has agreed to review our planned protocol amendment, and we expect to continue our discussions with the FDA regarding our development program for rocapuldencel-T. If we agree with the FDA on an amended protocol that increases the pre-specified number of events for the primary analysis, the SPA for the ADAPT trial would no longer be in effect. In addition to the ADAPT trial, we are also currently supporting an investigator-initiated Phase 2 trial of rocapuldencel-T in patients with early stage RCC. Subject to our obtaining sufficient financing, we plan to support an investigator-initiated Phase 2 trial of rocapuldencel-T in bladder cancer and a Phase 2 trial of rocapuldencel-T in combination with a checkpoint inhibitor in mRCC.

We are developing AGS-004, our second 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 our ongoing 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 100,000 shares of common stock at an exercise price of $1.30 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.

As of June 30, 2017, we had cash and cash equivalents of $9.3 million and working capital of $7.4 million. We do not currently have sufficient cash resources to pay our obligations as they become due. In March 2017, we announced that our board of directors approved a workforce action plan designed to streamline operations and reduce operating expenses. We recognized $1.1 million in severance costs and $2.6 million in stock-based compensation expense from the acceleration of stock options for the employees associated with the workforce reduction. As of June 30, 2017, we had paid approximately $0.8 million in severance costs associated with the workforce reduction contemplated by the plan and anticipate paying an additional $0.3 million, primarily during the third and fourth quarters of 2017, related to the plan. We expect that the workforce reduction will decrease our annual operating costs by $5.7 million once the plan is fully implemented. We have also initiated discussions with Saint-Gobain Performance Plastics Corporation, or Saint-Gobain, Invetech Pty Ltd, or Invetech, and Medpace, Inc., or Medpace, regarding the fees that we owe them, including potentially the conversion by them of some or all of the outstanding fees into a convertible note or equity of our company. Additionally, in June 2017, we issued a secured convertible note to Pharmstandard International S.A., or Pharmstandard, a collaborator and our largest shareholder, in the aggregate principal amount of $6.0 million. In an at-the-market offering under its sales agreement with Cowen in June 2017, the Company has raised proceeds of $4.9 million through the issuance of common stock as of August 3, 2017, of which $4.6 million was raised subsequent to June 30, 2017. However, even taking these measures into account, we do not have sufficient cash resources to pay all of our accrued obligations in full or to continue our business operations beyond September 2017. Therefore, we will need to raise additional capital by the end of September 2017 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. 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.

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 June 30, 2017, we have raised a total of $501.1 million in cash, including:

- $337.7 million from the sale of our common stock, convertible debt, warrants and preferred stock;
- $32.9 million from the licensing of our technology;
- $105.5 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 $74.8 million for the year ended December 31, 2015, $53.0 million for the year ended December 31, 2016 and $32.6 million for the six months ended June 30, 2017. As of June 30, 2017, we had an accumulated deficit of $364.6 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.

If we are able to raise the capital necessary to continue the development of our product candidates, including rocapuldencel-T and AGS-004, we anticipate that our expenses will increase substantially if and as we:

- continue our ongoing ADAPT trial of rocapuldencel-T for the treatment of mRCC or initiate other clinical trials of rocapuldencel-T for the treatment of mRCC;
- continue to support ongoing investigator-initiated clinical trials of rocapuldencel-T and AGS-004;
- support planned investigator-initiated clinical trials of rocapuldencel-T and AGS-004;
- initiate and conduct additional clinical trials of rocapuldencel-T and AGS-004 for the treatment of cancers and HIV;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- lease, build out and equip a facility for the commercial manufacture of our 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 commercialization efforts.

We have no external 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 rocapuldencel-T, AGS-004 or any of our other product candidates if we determine to continue our business operation. 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 $500,000 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 $38.0 million through June 30, 2017 under the NIH and NIAID contract. This contract is the only arrangement under which we have generated substantial revenue. As of June 30, 2017, there was up to $1.8 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 is to enter into arrangements with third parties for the development and commercialization of our product candidates.

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 499,788 shares of our common stock at an exercise price of $5.82 per share. As of August 9, 2017, we had not entered into this manufacturing rights agreement or issued the warrants.

Green Cross . In July 2013, in connection with the purchase of our series E preferred stock by 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 $500,000 upon the initial submission of an application for regulatory approval of a licensed product in South Korea, $500,000 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 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. The first milestone with a $1.0 million payment was achieved in July 2015 and the second milestone with a $2.0 million payment was achieved in June 2016, reducing the outstanding principal of the loan as of December 31, 2016 to $6.0 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. 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 have the right to revoke both the manufacturing license and the sale license to be granted to Medinet or the sale license only. If we exercise this right, we will be obligated to make a one-time payment to Medinet calculated based on the nonroyalty payments made to us by Medinet under the agreement, repay the outstanding amount due under the loan and assume certain obligations of Medinet, and Medinet will be obligated to assist us in transitioning the relevant rights in Japan to us or a party that we designate. If we exercise our revocation right with respect to the sale license only, the one-time payment will equal the total amount of nonroyalty payments. If we exercise our revocation right with respect to the manufacturing license and the sale license, the one-time payment will equal 150% or 200% of the nonroyalty payments depending on the timing of the exercise of the revocation right.

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 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.

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 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 $20.5 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. 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 . On October 29, 2014, we entered into a development agreement with Invetech Pty Ltd, or Invetech. The development agreement supersedes and replaces a prior agreement entered into by the parties as of July 20, 2005. Under the development agreement, Invetech has agreed to develop and provide prototypes of the automated production system to be used for the manufacture of our Arcelis-based products, or the Production Systems. Development services will be performed on a proposal by proposal basis. Invetech has agreed to defer 30% of its fees, up to $5,000,000. Under the development agreement, we are obligated to pay these deferred fees (plus interest of 7% per annum) pursuant to an installment plan (eight installments payable within the first two years after December 31, 2016). We are currently in discussions with Invetech regarding the development agreement related to the deferred fees, and the repayment of the fees, including potentially through conversion of a portion of the outstanding fees into equity or a convertible note providing for the further deferral of the fees.

The development agreement requires the parties to discuss in good faith Invetech's supply of Production Systems for use in manufacturing commercial product. We have an obligation to purchase $25.0 million worth of Production Systems, components, subsystems and spare parts for commercial use. Once that obligation has been satisfied, we have the right to have a third party supply Production Systems for use in manufacturing commercial product, provided that Invetech has a right of first refusal with respect to any offer by a third party and we may not accept an offer from a third party unless that offer is at a price that is less than that offered by Invetech and otherwise under substantially the same or better terms. We will own all intellectual property arising from the development services (with the exception of existing Invetech intellectual property incorporated therein-under which we will have a license). The term of the development agreement will continue until the completion of the development of the Production Systems. The development agreement can be terminated early by either party because of a technical failure or by us without cause.

Saint-Gobain . In January 2015, we entered into a development agreement with Saint-Gobain Performance Plastics Corporation, or Saint-Gobain, that was subsequently amended in December 2015 and 2016. Under the 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, which we refer to as the Disposables. We expect total development fees and expenses incurred under the Saint-Gobain Agreement to be approximately $7.1 million, of which $3.1 million has been paid to date and $4.0 million has been accrued as of June 30, 2017. We have also agreed separately to purchase $3.5 million in Disposables under the agreement during 2017 of which $0.8 million has been accrued as of June 30, 2017. 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. By its terms the agreement was set to expire on March 1, 2017, but the parties have agreed to extend the term while discussions referenced below are ongoing. The agreement 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. We are currently in discussions with Saint-Gobain regarding modification of the terms of the commercial supply agreement and payment of the development fees, including potentially through conversion of a portion of the outstanding fees into equity or a convertible note providing for the further deferral of the fees.

Cellscript . In December 2015, we entered into a development and supply agreement with Cellscript, LLC. 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 $4,600,000. Upon the execution of the agreement, we made an initial payment to Cellscript of $2,000,000 through the issuance to Cellscript of 906,194 shares of our common stock. The balance of these fees are 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 amounts for each kit that is purchased under the agreement.

The agreement will continue until the earlier of (i) December 31, 2017 or (ii) 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.

Manufacturing

We currently have manufacturing suites located at our Technology Drive and Patriot Center facilities in Durham, North Carolina. We manufacture our 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 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 IDMC recommendation to discontinue the ADAPT study, we are currently reassessing our manufacturing plans. We have therefore initiated discussions with the landlord of our Centerpoint facility regarding that lease and we are currently working with the landlord to actively find another tenant for the property. We estimate that it will take up to nine months from June 30, 2017 to exit the arrangement and terminate the operating 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. We never occupied the leased space. We did not dispute the occurrence of the event of default or the termination of the lease and did not plan to seek to cure the default. In the termination notice, the landlord stated that we were liable for any and all costs incurred by the landlord in re-letting the premises, any deficiency between our scheduled rent for the remainder of the term of the lease and the rent charged to the new tenant, the unamortized portion of the funded up-fit costs, rent abatement, interest at the rate of 12% per annum on the sums noted and all attorneys' fees incurred by the landlord in enforcing the lease. We had instructed the landlord to begin the process of re-letting the premises in order to mitigate damages. On March 31, 2017, we entered into a Lease Termination Agreement, or the Termination Agreement, with the landlord whereby the lease was deemed terminated 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 drew down another $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 six months ended June 30, 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.

We expect that we would establish both manual and automated manufacturing processes in our commercial manufacturing facilities if we determine to build out such facilities. We had decided to delay the implementation of our automated manufacturing process until after initial commercialization of rocapuldencel-T, and thus planned to seek marketing approval of rocapuldencel-T and, if approved, to initially commercially supply rocapuldencel-T using our manual manufacturing process. Prior to implementing commercial manufacturing of rocapuldencel-T, 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 rocapuldencel-T that we produce using the manual processes in our current facility and rocapuldencel-T produced using the manual process in our new facility.

Our Development Programs

The following table summarizes our development programs for rocapuldencel-T and AGS-004.

Product Candidate	Primary Indication	Status
Rocapuldencel-T	mRCC	• Ongoing ADAPT trial; enrollment completed in July 2015; IDMC recommended study discontinuation; plan to continue until at least the pre-specified number of 290 events occurs, anticipated in the first half of 2018; plan to submit to the FDA a protocol amendment to increase the pre-specified number of events beyond 290 events; data analysis and discussions with the FDA ongoing
		• Planned Phase 2 clinical trial, in combination with a checkpoint inhibitor, expected to open for enrollment in the second half of 2017 provided that financing is obtained
	Early stage RCC (neoadjuvant)	• Ongoing investigator-initiated Phase 2 clinical trial; initial data expected in 2017
	Advanced solid tumors	• Planned investigator-initiated Phase 2 clinical trial in muscle invasive bladder cancer, expected to open for enrollment in the second half of 2017 provided that financing is obtained
AGS-004	HIV	• Ongoing second stage of investigator-initiated clinical trial in combination with vorinostat for HIV eradication
		• Decision to open planned investigator-initiated Phase 2 clinical trial for long-term viral control in pediatric patients expected in 2017

We hold all commercial rights to rocapuldencel-T and AGS-004 in all geographies other than rights to rocapuldencel-T in Russia and the other states comprising the Commonwealth of Independent States, which we exclusively licensed to Pharmstandard International S.A., or Pharmstandard, rights to rocapuldencel-T for the treatment of mRCC in South Korea, which we exclusively licensed to Green Cross Corp., or Green Cross, and rights to rocapuldencel-T in China, Hong Kong, Taiwan and Macau, which we exclusively licensed to Lummy (Hong Kong) Co. Ltd., or Lummy HK. We have granted to MEDcell Co., Ltd., a wholly-owned subsidiary of Medinet Co. Ltd., hereinafter referred to together as "Medinet," an exclusive license to manufacture rocapuldencel-T for the treatment of mRCC in Japan.

Rocapuldencel-T

We are developing rocapuldencel-T for the treatment of mRCC and other cancers. We are conducting the ADAPT trial of rocapuldencel-T plus sunitinib / targeted therapy for the treatment of newly diagnosed mRCC under an SPA with the FDA. We dosed the first patient in the ADAPT trial in May 2013. In July 2015 we completed enrollment in the ADAPT trial, enrolling 462 patients with the goal of generating 290 events for the primary endpoint of overall survival. We enrolled these patients at 107 clinical sites in North America, Europe and Israel. Under the ADAPT trial protocol, these patients were randomized between the rocapuldencel-T plus sunitinib / targeted therapy combination arm and sunitinib / targeted therapy alone control arm on a two-to-one basis. 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 study 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. 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 FDA, we now plan to continue the ADAPT trial until at least the pre-specified number of 290 events occurs, which we expect will be in the first half of 2018. We also plan to continue to analyze interim data from the trial 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. We believe that extending our evaluation of rocapuldencel-T beyond 290 events in the trial could enhance our ability to observe rocapuldencel-T's expected delayed treatment effect. The FDA has agreed to review our planned protocol amendment, and we expect to continue our discussions with the FDA regarding our development program for rocapuldencel-T. If we agree with the FDA on an amended protocol that increases the pre-specified number of events for the primary analysis, the SPA for the ADAPT trial would no longer be in effect.

In addition to the ADAPT trial, we are currently supporting an ongoing investigator-initiated Phase 2 clinical trial designed to evaluate treatment with rocapuldencel-T in patients with early stage RCC prior to nephrectomy. This trial was opened for enrollment in late 2014 and five patients were enrolled as of May 1, 2017. We expect that a total of 10 patients will be enrolled in this trial. This trial provides the opportunity to observe the impact of rocapuldencel-T on the immune response in both the peripheral blood and in the primary tumor that is removed after rocapuldencel-T treatment, the latter as evidenced by the presence of tumor infiltrating lymphocytes in the tumor. Additionally, we have developed a protocol for a Phase 2 clinical trial of rocapuldencel-T in combination with a checkpoint inhibitor for the treatment of patients with mRCC, but initiation of this trial is subject to our obtaining financing for the trial.

Beyond renal cell carcinoma, we plan to support an additional investigator-initiated Phase 2 clinical trial of rocapuldencel-T in muscle invasive bladder cancer subject to our obtaining financing for such support. The trial would have two phases: a pre-treatment phase and a treatment phase. In the pre-treatment phase, tumor tissue will be obtained via a transurethral resection of the bladder tumor, which will then be used to extract RNA for the manufacture of rocapuldencel-T. In the treatment phase, rocapuldencel-T will be given before tumor resection and combined with standard-of-care cytotoxic chemotherapy. Booster doses of rocapuldencel-T will continue after tumor resection. As with the neoadjuvant renal cancer trial, we have the unique opportunity to observe any meaningful impact of rocapuldencel-T on the immune response in the peripheral blood and immune responses infiltrating the primary tumor.

AGS-004

We are developing AGS-004 for the treatment of HIV and are focusing this program on the use of AGS-004 in combination with other therapies for the eradication of HIV. We believe that by combining AGS-004 with therapies that are being developed to expose the virus in latently infected cells to the immune system, we can potentially eradicate the virus. The current standard of care, antiretroviral drug therapy, or ART, can reduce levels of HIV in a patient's blood, increase the patient's life expectancy and improve the patient's quality of life. However, ART cannot eliminate the virus, which persists in latently infected cells, remains undetectable by the immune system and can recur. In addition, ART requires daily, life-long treatment and can have significant side effects.

We are supporting an investigator-initiated clinical trial of AGS-004 in up to 12 adult HIV patients to evaluate the use of AGS-004 in combination with one of these latency reversing therapies for the eradication of HIV at the University of North Carolina. This trial is being conducted in two stages. Stage 1 of this trial has been completed and was designed to study immune response kinetics to AGS-004 in patients on continuous ART. These data were used to better define the optimal dosing strategy in combination with a latency reversing therapy in the ongoing Stage 2. We expect that some patients in Stage 1 will rollover into Stage 2, which is studying AGS-004 in combination with one of the latency reversing drugs. The patient clinical costs for the first stage of this trial were funded by Collaboratory of AIDS Researchers for Eradication, or CARE. The NIH Division of AIDS has approved $6.6 million in funding for the second stage of this trial.

We also plan to determine whether to conduct a trial to explore the use of AGS-004 monotherapy to provide long-term control of HIV viral load in otherwise immunologically healthy patients and eliminate their need for ART. Accordingly, if initial data from Stage 2 of the ongoing adult eradication study are favorable, government funding is available and necessary approvals are obtained, we expect to support an investigator-initiated Phase 2 clinical trial of AGS-004 monotherapy in pediatric patients infected with HIV who have otherwise healthy immune systems and have been treated with ART since birth or shortly thereafter and, as a result, are lacking the antiviral memory T-cells to combat the virus. The commencement of this trial is subject to supportive data obtained from the adult eradication trial and approval of the protocol by the principal investigator(s), institutional review boards, the IMPAACT Network leadership and the FDA and to the agreement by the NIH to fund the trial costs not related to AGS-004 manufacturing.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2016 with the Three and Six Months Ended June 30, 2017

The following table summarizes the results of our operations for each of the three and six month periods ended June 30, 2016 and 2017, together with the changes in those items in dollars and as a percentage:

	Three Months Ended June 30,		$	%	Six Months Ended June 30,		$	%
	2016	2017	Change	Change	2016	2017	Change	Change
	(in thousands)							
Revenue	$ 489	$ 70	$ (419)	(85.7)%	$ 635	$ 175	$ (460)	(72.5)%
Operating expenses								
Research and development	9,164	5,121	(4,043)	(44.1)%	18,666	13,035	(5,631)	(30.2)%
General and administrative	3,390	2,680	(710)	(20.9)%	6,365	6,643	278	4.4%
Impairment of property and equipment	—	—	—	*	—	27,204	27,204	*
Restructuring costs	—	344	344	*	—	5,353	5,353	*
Total operating expenses	12,554	8,145	(4,408)	(35.1)%	25,031	52,235	27,204	108.7%
Loss from operations	(12,065)	(8,076)	3,989	33.1%	(24,396)	(52,060)	(27,664)	(113.4)%
Interest income	2	9	7	*	4	39	36	*
Interest expense	(543)	(294)	249	45.8%	(1,034)	(1,023)	12	1.1%
Gain on early extinguishment of debt	—	—	—	*	—	249	249	*
Change in fair value of warrant liability	—	(178)	(178)	*	—	20,180	20,180	*
Other expense	—	—	—	*	—	(5)	(5)	*
Net loss	$ (12,606)	$ (8,539)	$ 4,068	32.3%	$ (25,426)	$ (32,619)	$ (7,192)	(28.3)%

* 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. 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 $70,000 for the three months ended June 30, 2017, compared with $489,000 for the three months ended June 30, 2016, a decrease of $419,000, or 85.7%. The decrease for the three months ended June 30, 2017 compared with the three months ended June 30, 2016 resulted from lower reimbursement under our NIH and NIAID contract primarily reflecting the achievement of certain specified development milestones during 2016.

Revenue was $175,000 for the six months ended June 30, 2017, compared with $635,000 for the six months ended June 30, 2016, a decrease of $460,000, or 72.5%. The decrease for the six months ended June 30, 2017 compared with the six months ended June 30, 2016 resulted from lower reimbursement under our NIH and NIAID contract primarily reflecting the achievement of certain specified development milestones during 2016.

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 development agreement with Invetech to develop and provide prototypes of the automated production system to be used for the manufacture of our Arcelis-based products and our development agreement with Saint-Gobain 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 June 30,		Six Months Ended June 30,	
	2016	2017	2016	2017
	(in thousands)			
Direct research and development expense by program:				
Rocapuldencel-T	$ 2,224	$ 2,151	$ 5,657	$ 4,554
AGS-004	55	21	109	77
Total direct research and development program expense	2,279	2,172	5,766	4,631
Commercial manufacturing development expense	253	—	519	(373)
Indirect research and development expense	6,632	2,949	12,381	8,777
Total research and development expense	$ 9,164	$ 5,121	$ 18,666	$ 13,035

Three months ended June 30, 2016 and 2017.
Research and development expenses were $5.1 million for the three months ended June 30, 2017, compared with $9.2 million for the three months ended June 30, 2016, a decrease of $4.0 million, or 44.1%. The decrease in research and development expense reflects a $0.1 million decrease in direct research and development expense, a $0.3 million decrease in commercial manufacturing development expense and a $3.7 million decrease in indirect research and development expense.

Direct research and development expense for rocapuldencel-T and AGS-004 was not significantly different in the three months ended June 30, 2017 compared with the three months ended June 30, 2016.

The decrease in commercial manufacturing development expense reflects our determination not to proceed with the development of commercial manufacturing capabilities following the recommendation of the IDMC to discontinue the ADAPT trial.

The decrease in indirect research and development expense was primarily due to our decision following the IDMC recommendation to significantly reduce the size of our workforce engaged in research and development activities. As of June 30, 2017, we had 36 employees engaged in such activities, compared with 99 employees engaged in such activities as of June 30, 2016.

Six Months ended June 30, 2016 and 2017 .
Research and development expenses were $13.0 million for the six months ended June 30, 2017, compared with $18.7 million for the six months ended June 30, 2016, a decrease of $5.6 million, or 30.2%. The decrease in research and development expense reflects a $1.1 million decrease in direct research and development expense, a $0.9 million decrease in commercial manufacturing development expense, and a $3.6 million decrease in indirect research and development expense.

The decrease in direct research and development expenses resulted primarily from the following:

- Direct research and development expense for rocapuldencel-T decreased from $5.7 million for the six months ended June 30, 2016 to $4.6 million for the six months ended June 30, 2017. This decrease primarily reflects a reduction of costs related to the ongoing ADAPT trial of rocapuldencel-T.

- Direct research and development expense with respect to AGS-004 was not significantly different in the six months ended June 30, 2016 compared with the six months ended June 30, 2017.

The decrease in commercial manufacturing development expense reflects our determination not to proceed with the development of commercial manufacturing capabilities following the recommendation of the IDMC to discontinue the ADAPT trial. During the six months ended June 30, 2017, we recorded a credit of $0.4 million related to amounts owed to Saint-Gobain under our agreement with Saint-Gobain which we recorded as a reduction of research and development expense.

The decrease in indirect research and development expense was primarily due to our decision following the IDMC recommendation to significantly reduce the size of our workforce engaged in research and development activities. As of June 30, 2017, we had 36 employees engaged in such activities, compared with 99 employees engaged in such activities as of June 30, 2016.

The successful development of our clinical and preclinical product candidates 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 remainder of the development of any of our clinical or preclinical product candidates or the period, if any, in which material net cash inflows from these 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 $2.7 million for the three months ended June 30, 2017, compared with $3.4 million for the three months ended June 30, 2016, a decrease of $0.7 million or 20.9%. This decrease was primarily due to a $0.5 million reduction in consulting costs and a $0.2 million reduction in personnel costs.

General and administrative expenses were $6.4 million for the six months ended June 30, 2016, compared with $6.6 million for the six months ended June 30, 2017, an increase of $0.2 million or 4.4%. This increase was primarily due to an additional $0.4 million in personnel costs, partially offset by a reduction of $0.1 million in consulting costs and a reduction of $0.1 million in marketing costs.

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 $0 and $27.2 million for the three and six months ended June 30, 2017, respectively, compared with $0 for both the three and six months ended June 30, 2016. 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. We are currently working with the landlord to actively identify another tenant for the property. We estimated it will take up to nine months from June 30, 2017 to exit the arrangement and terminate the operating lease. In our statement of operations for the six months ended June 30, 2017, we recorded an impairment loss of $18.3 million related to 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 have 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 June 30, 2017 and recorded an impairment loss of $1.1 million during the six months ended June 30, 2017. Additionally, during the six months ended June 30, 2017 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 at our 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 are being 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 June 30, 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 six months ended June 30, 2017.

Restructuring Costs

We recognized restructuring costs of $0.3 million and $5.4 million during the three and six months ended June 30, 2017, respectively, compared with $0 during both the three and six months ended June 30, 2016. As discussed elsewhere in this Quarterly Report on Form 10-Q, our most advanced product candidate is rocapuldencel-T, which we are developing for the treatment of mRCC and other cancers. We are currently conducting a pivotal Phase 3 clinical trial of rocapuldencel-T plus sunitinib or another therapy for the treatment of newly diagnosed mRCC under an SPA with the FDA. 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 our operations and impairments of property and equipment and leases, as discussed above.

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. Through additional targeted reductions and attrition, the workforce was further reduced to 44 employees as of July 31, 2017. The principal objective of the reduction was to enable us to conserve our financial resources while we conducted a review of the preliminary ADAPT trial data set and discuss the data with the FDA. We recognized $1.1 million in severance costs and $2.6 million in stock-based compensation expense from the acceleration of stock options for the employees associated with the workforce reduction. As of June 30, 2017, we had paid approximately $0.8 million in severance costs associated with the workforce reduction contemplated by the plan and anticipate paying an additional $0.3 million, primarily during the third and fourth quarters of 2017, related to the plan.

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 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 prepare for a biologics license application, or BLA, to the U.S. Food & Drug Administration and to support initial commercialization of rocapuldencel-T. We had expected to complete the initial build-out and equipping of the facility, including capacity qualification necessary for BLA filing, by the end of the first quarter of 2018. As a result, we initiated discussions with the landlord of the CTI facility regarding the termination of this lease. We believe that our current Technology Drive and Patriot Center facilities are sufficient for the manufacture of rocapuldencel-T and AGS-004 to support our ongoing clinical trials and any potential clinical trials that may be initiated in the near-term.

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. We never occupied the leased space. In the termination notice, the landlord asserted that we were in default under the lease due to nonpayment of invoices for up-fit costs. We did not dispute the occurrence of the event of default or the termination of the lease and did not plan to seek to cure the default. In the termination notice, the landlord stated that we were liable for any and all costs incurred by the landlord in re-letting the premises, any deficiency between our scheduled rent for the remainder of the term of the lease and the rent charged to the new tenant, the unamortized portion of the funded up-fit costs, rent abatement, interest at the rate of 12% per annum on the sums noted and all attorneys' fees incurred by the landlord in enforcing the lease. We had instructed the landlord to begin the process of re-letting the premises in order to mitigate damages. On March 31, 2017, we entered into the Termination Agreement with the landlord whereby the lease was deemed terminated 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 drew down another $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 three and six months ended June 30, 2017, we recorded a lease termination fee of $0 and $1.6 million, respectively, which is included in Restructuring costs on the statement of operations. We also recorded an impairment loss on Construction-in-progress on the property of $0 and $0.9 million during the three and six months ended June 30, 2017, respectively.

Interest Expense

Interest expense was $294,000 for the three months ended June 30, 2017, compared with $543,000 for the three months ended June 30, 2016, a decrease of $249,000 or 45.8%. The decrease primarily resulted from our repayment of the Loan Agreement on March 6, 2017.

Interest expense was $1,023,000 for the six months ended June 30, 2017, compared with $1,034,000 for the six months ended June 30, 2016, a decrease of $12,000 or 1.1%. The decrease resulted from our repayment of the Loan Agreement on March 6, 2017, which was largely offset by our decision to no longer capitalize the interest related to construction of our Centerpoint facility as we decided not to proceed with our plans to develop this facility.

Gain on Early Extinguishment of Debt

We recognized a gain on early extinguishment of debt of $0 and $249,458 for the three and six months ended June 30, 2017, respectively, compared with $0 for both the three and six months ended June 30, 2016. 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 100,000 shares of our common stock at an exercise price of $1.30 per share in consideration of the Lenders accepting the $23.1 million. We recognized a gain on this early extinguishment of debt of $249,458 during the six months ended June 30, 2017 which is included in Other income (expense) on the statement of operations.

Change in Fair Value of Warrant Liability

The (loss) gain from the change in fair value of the warrant liability was $(0.2) million and $20.2 million for the three and six months ended June 30, 2017, respectively, compared with $0 for both the three and six months ended June 30, 2016, during which periods there were no warrants classified as a liability. The 2017 amounts represent the change in the fair value of our liability for the warrants issued in August 2016, which contain provisions that could require cash settlement and are therefore recorded as a liability at fair value on the date of issuance and as of the end of each reporting period. The significant gain from the warrant liability during the six months ended June 30, 2017 was due to a significant decline in the price of our common stock and a shorter expected life of the August 2016 Warrants. As of June 30, 2017, the fair value of the August 2016 Warrants was $0.7 million.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2017, we had cash and cash equivalents of $9.3 million and working capital of $7.4 million.

Since our inception in May 1997 through June 30, 2017, we have funded our operations principally with $337.7 million from the sale of common stock, convertible debt, warrants and preferred stock, $32.9 million from the licensing of our technology, $105.5 million from government contracts, grants and license and collaboration agreements, and $25.0 million from the Loan Agreement.

Venture Loan and Security Agreement . In September 2014, we entered into the Loan Agreement with the Lenders, under which we could borrow up to $25.0 million in two tranches of $12.5 million each.

We 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 following completion of enrollment of the ADAPT trial. The per annum interest rate for each tranche is 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 shall not exceed 10.75%.

We made payments with respect to the first tranche of $12.5 million on an interest-only basis monthly through October 31, 2016, and, prior to the payoff letter, had been making 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 $625,000 would have been due on September 30, 2018, or such earlier date specified in the Loan Agreement. Prior to the payoff letter, we had agreed to repay the second tranche 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 $625,000 would have been due on February 7, 2019, or such earlier date specified in the Loan Agreement. In addition, prior to the payoff letter, we had agreed that if we repaid all or a portion of the loan prior to the applicable maturity date, we 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 thereof, 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.

Our obligations under the Loan Agreement were secured by a first priority security interest in substantially all of our assets other than our intellectual property. We also had agreed not to pledge or otherwise encumber our intellectual property assets, subject to certain exceptions.

In connection with the Loan Agreement, we issued to the Lenders and their affiliates warrants to purchase a total of 82,780 shares of our common stock at a per share exercise price of $9.06. Upon our satisfaction of the conditions precedent to the making of the second tranche loan, the warrants became exercisable in full. The warrants will terminate on September 29, 2021 or such earlier date as specified in the warrants.

On March 3, 2017, we entered into a payoff agreement 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 100,000 shares of common stock at an exercise price of $1.30 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 agreement, 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.

Lummy License Agreement . On April 7, 2015, we and Lummy HK entered into a license agreement, or the License Agreement, whereby we granted to Lummy HK an exclusive license to our 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. This agreement was subsequently amended in December 2016.

In connection with the License Agreement, we entered into stock purchase agreements with Tianyi Lummy and China BioPharma of which Lummy HK's parent company is an affiliate and limited partner, respectively. Pursuant to the purchase agreements, the purchasers purchased an aggregate of 1,000,000 shares of our common stock at a per share price of $10.11, or approximately $10.1 million. The purchasers also agreed to purchase approximately $10.0 million in additional shares of our common stock, for a total aggregate investment of approximately $20.0 million, within 31 days of and subject to reaching full enrollment of our ADAPT trial of rocapuldencel-T for the treatment of mRCC receiving a recommendation of the review board for the continuation of our ADAPT trial following 50% of events and receiving positive feedback from the FDA on a qualified protocol to demonstrate comparability of our automated manufacturing process for rocapuldencel-T to the manufacturing process used by us in our ADAPT trial. However, in March 2016, in connection with the agreement by Tianyi Lummy and China BioPharma to purchase approximately $10.0 million of shares of our common stock and warrants in our PIPE financing described below, we agreed they would have no further obligation to purchase shares pursuant to the purchase agreements.

PIPE Financing . On March 4, 2016, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to issue and sell an aggregate of up to $60 million of our common stock and warrants to purchase shares of common stock in a PIPE financing. The financing was to take place in up to three tranches. At the closing of the initial tranche in March 2016, we sold and the investors purchased, for a total purchase price of approximately $19.9 million, a total of 3,652,430 shares of common stock and warrants to purchase a total of 2,739,323 shares of common stock (0.75 shares of common stock for each share of common stock purchased), based on a purchase price per share of common stock and accompanying warrant equal to $5.44375. At the closing of the second tranche in June 2016, we sold and the investors purchased, for a total purchase price of approximately $29.8 million, a total of 5,478,672 shares of common stock and warrants to purchase a total of 4,109,005 shares of common stock at the same price and on the same terms as the first tranche. The warrants issued in each closing have an exercise price of $5.35 per share and expire five years from the date of issuance. Our stockholder, Pharmstandard International S.A., or Pharmstandard, had also agreed pursuant to the securities purchase agreement that, at our option following the satisfaction of certain conditions, Pharmstandard could be required to purchase at a third closing up to approximately $10.3 million of shares of common stock (without warrants). The dollar amount committed to be purchased by Pharmstandard at the third closing was subject to reduction on a dollar-for-dollar basis for certain cash amounts raised by us after the initial closing through equity or debt financings or collaborations. The net proceeds received from the follow-on public offering that closed on August 2, 2016 reduced in full the dollar amount committed to be purchased in the third tranche, and as a result we have no further ability to effect the closing of, and Pharmstandard has no further obligation to purchase shares in, a third tranche of the PIPE financing.

In connection with entering into the securities purchase agreement, we entered into a registration rights agreement with the investors pursuant to which we agreed to register for resale the shares issued in the financing and the shares issuable upon exercise of the warrants issued in the financing.

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 $125,000,000 of our common stock, preferred stock, debt securities, depositary shares, purchase contracts, purchase units and warrants. We simultaneously entered into a Sales Agreement with Cowen and Company LLC, or Cowen, to provide for the offering, issuance and sale of up to $30,000,000 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. Sales of our 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, including sales made directly on or through the Nasdaq Global Market, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices, and/or any other method permitted by law. Cowen is not required to sell any specific amount, but acts as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. Shares sold pursuant to the Sales Agreement have been sold pursuant to the 2015 Shelf. Under the Sales Agreement, we pay Cowen a commission of up to 3% of the gross proceeds. During the year ended December 31, 2016, we sold 872,682 shares of common stock pursuant to the Sales Agreement, resulting in proceeds of $5.5 million, net of commissions and issuance costs. During the six months ended June 30, 2017, we sold 829,096 shares of common stock pursuant to the Sales Agreement, resulting in proceeds of $0.3 million, net of commissions and issuance costs. We sold an additional 13,945,932 shares resulting in $4.6 million in net proceeds between July 1, 2017 and August 3, 2017.

Follow-On Public Offering . On August 2, 2016, we issued and sold 9,090,909 shares of common stock and warrants to purchase an aggregate of 6,818,181 shares of common stock, or the August 2016 Warrants, in an underwritten public offering at a price to the public of $5.50 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 August 2016 Warrants have an exercise price of $5.50 per share, became immediately exercisable upon issuance and will expire on August 2, 2021. The aggregate net proceeds to us of the offering was approximately $48.2 million after deducting underwriting discounts and commissions and offering expenses.

Convertible Note . 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 $0.50. 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 39.9% of our outstanding common stock as of July 31, 2017. In addition, two members of our board of directors are closely associated with Pharmstandard.

We have agreed to pay the legal expenses of Pharmstandard, including legal expenses incurred in connection with the our resale registration obligations set forth in a registration rights agreement that we entered into with Pharmstandard; provided, however, that we shall have no obligation to pay more than a total of $100,000 with respect to such expenses. 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:

	Six Months Ended June 30,	
	2016	**2017**
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (21,516)	$ (24,145)
Investing activities	(5,036)	(2,138)
Financing activities	55,211	(17,357)
Effect of exchange rate changes on cash	8	4
Net increase (decrease) in cash and cash equivalents	$ 28,667	$ (43,636)

Operating Activities .
Net cash used in operating activities of $24.1 million during the six months ended June 30, 2017 was primarily a result of our $32.6 million net loss and an increase in net operating assets of $4.3 million, partially offset by non-cash items of $12.8 million.

The non-cash items primarily reflect an impairment loss on property and equipment of $27.2 million, compensation expense related to stock options of $5.1 million, depreciation and amortization expense of $0.5 million and interest accrued on long term debt of $0.5 million, partially offset by a decrease in the fair value of the warrant liability of $20.2 million and a gain on the early extinguishment of debt of $0.2 million.

The increase in net operating assets reflects a decrease in accounts payable of $2.4 million, a decrease in accrued expenses of $1.9 million, and an increase in prepaid expenses and other receivables of $0.5 million and a decrease in deferred liabilities of $0.1 million, partially offset by an increase in the current portion of the restructuring obligation of $0.3 million, and an increase in the manufacturing research and development obligation of $0.2 million.

Net cash used in operating activities of $21.5 million during the six months ended June 30, 2016 was primarily a result of our $25.4 million net loss, partially offset by non-cash items of $3.2 million and a decrease in net operating assets of $0.7 million.

The non-cash items primarily reflect compensation expense related to stock options of $2.5 million, depreciation and amortization expense of $0.4 million, common stock issued as payment for services of $0.1 million and amortization of debt discount of $0.1 million.

The decrease in net operating assets primarily reflects an increase in accrued expenses of $1.1 million, an increase in accounts payable of $0.4 million and an increase in the manufacturing and development obligation of $0.2 million, partially offset by an increase in prepaid expenses and other receivables of $0.9 million and a decrease in deferred liabilities of $0.1 million.

Investing Activities.
Net cash used in investing activities was $2.1 million during the six months ended June 30, 2017, consisting of $3.6 million of purchases of property and equipment, partially offset by proceeds of $1.5 million from the sale of property and equipment.

Net cash used in investing activities was $5.0 million during the six months ended June 30, 2016, consisting of $6.0 million of purchases of property and equipment, partially offset by proceeds of $1.0 million from maturities of short-term investments.

Financing Activities.
Net cash used in financing activities was $17.4 million during the six months ended June 30, 2017, consisting primarily of $23.6 million for repayment of the Loan Agreement, partially offset by $6.0 million of proceeds from the issuance of the Convertible Note and $0.3 million of proceeds from the issuance of common stock through our at-the-market offering.

Net cash provided by financing activities was $55.2 million during the six months ended June 30, 2016, consisting primarily of proceeds of $54.8 million from the issuance and sale of common stock and warrants under our private placement financing and the issuance and sale of common stock pursuant to the Sales Agreement, $0.3 million from the exercise of warrants and $0.3 million of proceeds from the exercise of stock options and from our employee stock purchase plan, partially offset by a $0.1 million payment on our facility lease obligation and $0.1 million of stock issuance costs.

Other Significant Changes in the Consolidated Balance Sheet as of June 30, 2017 Compared with December 31, 2016

Property and equipment, net, decreased by $36.9 million during the six months ended June 30, 2017 primarily due to impairment charges of $27.2 million and the reclassification of $9.0 million of property to current Assets held for sale, which increased by the same amount. We also recognized a liability for restructuring of $0.3 million and reduced our Notes payable by $23.1 million by the early pay-off of our Loan Agreement in March 2017. Finally, the fair value of our liability for warrants outstanding declined by $20.2 million to $0.7 million as of June 30, 2017 as a result of the decline in the market price of our common stock relative to the exercise price of the warrants.

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, rocapuldencel-T or AGS-004. Despite our cost containment measures, including the recent workforce reduction, we expect that our ongoing expenses will be substantial and may increase in connection with our ongoing activities, particularly as we continue our ADAPT trial of rocapuldencel-T, if we initiate additional clinical trials of rocapuldencel-T and AGS-004, and, provided that we continue the development of our programs, seek regulatory approval for our product candidates and lease, build out and equip 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. We will need substantial additional funding in connection with our continuing operations.

We do not currently have sufficient cash resources to pay our obligations as they become due. In March 2017, we entered into a payoff letter with the Lenders and paid the Lenders a total of $23.1 million, representing the principal balance and accrued interest outstanding under the Loan Agreement in repayment of our outstanding obligations under the Loan Agreement. In March 2017, we announced that our board of directors approved a workforce action plan designed to streamline operations and reduce our operating expenses. We recognized $1.1 million in severance costs and $2.6 million in stock-based compensation expense from the acceleration of stock options for the employees associated with the workforce reduction. As of June 30, 2017, we had paid approximately $0.8 million in severance costs associated with the workforce reduction contemplated by the plan and anticipate paying an additional $0.3 million, primarily during the third and fourth quarters of 2017, related to the plan. We expect that the workforce reduction will decrease our annual operating costs by $5.7 million once the plan is fully implemented. We have also initiated discussions with Saint-Gobain, Invetech and Medpace regarding the fees that we owe them, including potentially the conversion by them of some or all of the outstanding fees into a convertible note or equity of the Company. Additionally, in June 2017, we issued a secured convertible note to Pharmstandard in the aggregate principal amount of $6.0 million. In an at-the-market offering under our sales agreement with Cowen in June 2017, we have also raised proceeds of $4.9 million through the issuance of common stock through August 3, 2017, of which $4.6 million was raised subsequent to June 30, 2017. However, even taking these measures into account, we do not have sufficient cash resources to pay all of our accrued obligations in full or to continue our business operations beyond September 2017. Therefore, we will need to raise additional capital by the end of September 2017 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. 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.

We have based our estimates 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 our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our product candidates.

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

- continuation of our pivotal Phase 3 ADAPT clinical trial;
- the progress and results of our ongoing and planned investigator initiated clinical trials of rocapuldencel-T that we support;
- the progress and results of the ongoing investigator-initiated clinical trial of AGS-004 in combination with vorinostat for HIV eradication and the planned investigator-initiated clinical trial of AGS-004 that we support and our ability to obtain additional funding under our NIH and NIAID contract for our AGS-004 program;
- the development, initiation and support of additional clinical trials of rocapuldencel-T in mRCC or other indications and AGS-004 in HIV;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs and timing of our leasing, build-out and equipping of 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 approximately $5.9 million in fees remaining outstanding under our commercial arrangement with Invetech, $4.0 million under our development agreement with Saint-Gobain and $1.5 million in fees payable to Medpace;
- our ability to renegotiate our purchase obligation of $3.5 million with Saint-Gobain;
- the potential need to repay the $6.0 million in principal 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;
- 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 rocapuldencel-T outside North America and arrangements for the development and commercialization of our non-oncology product candidates, including AGS-004.

Until such time, if ever, as we can generate substantial product revenue, 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, 2016. There have been no significant changes to our critical accounting policies discussed in our Annual Report on Form 10-K for the year ended December 31, 2016.

Contractual Obligations

During the six months ended June 30, 2017, 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, 2016, except for the early pay-off of the full balance of our Loan Agreement in the amount of $23.1 million.

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 unsecured promissory note payable to Medinet (3% per annum), the manufacturing research and development obligations payable to Invetech (7% per annum), the convertible note payable to Pharmstandard (9.5%) and other notes payable (8.31% per annum).

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of the Company's principal executive officer and principal financial officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of June 30, 2017. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e)) under the Exchange Act, means controls and other procedures of a company that are 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 recorded, processed, summarized and reported, within the time period specified in the SEC's rules and forms. 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 the Company's disclosure controls and procedures as of June 30, 2017, the Company's principal executive officer and principal financial officer concluded that, as of such date, the Company's disclosure controls and procedures were effective at the reasonable assurance levels.

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

On March 14, 2017, a securities class action lawsuit was commenced in the United States District Court, Middle District of North Carolina, Durham Division, naming the Company and certain of the Company's officers as defendants, and alleging violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by the defendants between February 7, 2014 and February 21, 2017 (the "Class Period"). The plaintiff seeks to represent a class comprised of purchasers of the Company's common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court. The Court appointed co-lead plaintiffs by order dated June 23, 2017. The Court has set a deadline of September 18, 2017 for lead plaintiffs to file an amended complaint, and the defendants' response to the amended complaint will be due 60 days thereafter. The Company believes it has meritorious defenses and intends to defend the lawsuit vigorously. It is possible that similar lawsuits may yet be filed in the same or other courts that name the same or additional defendants.

Other than as described above, the Company is not a party to any legal proceedings and is not aware of any claims or actions pending or threatened against the Company. In the future, the Company might from time to time become involved in litigation relating to claims arising from its 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 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 rocapuldencel-T for the treatment of metastatic renal cell carcinoma, or mRCC, and other cancers and AGS-004 for the treatment of HIV. 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 study be discontinued for futility based on its planned interim data analysis. The IDMC concluded that the study 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. 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 FDA, we now plan to continue the ADAPT trial until at least the pre-specified number of 290 events occurs, which we expect will occur in the first half of 2018. We also plan to continue to analyze interim data from the trial 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. We believe that extending our evaluation of rocapuldencel-T beyond 290 events in the trial could enhance our ability to observe rocapuldencel-T's expected delayed treatment effect. The FDA has agreed to review our planned protocol amendment, and we expect to continue our discussions with the FDA regarding our development program for rocapuldencel-T. If we agree with the FDA on an amended protocol that increases the pre-specified number of events for the primary analysis, the special protocol assessment, or SPA, for the ADAPT trial would no longer be in effect.

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 our product candidates, including rocapuldencel-T, if we determine to proceed with its 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 commercial manufacturing capabilities through the lease, build-out and equipping of 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.

If clinical trials of our product candidates, such as our ADAPT trial of rocapuldencel-T, 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 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.

To date, we have not completed a randomized clinical trial of rocapuldencel-T against a placebo or a comparator therapy. Our phase 2 trial of rocapuldencel-T was a single arm trial in which only 21 patients received the combination of rocapuldencel-T and sunitinib. Our ADAPT trial of rocapuldencel-T is a randomized trial designed to compare directly the combination of rocapuldencel-T and sunitinib or another therapy to treatment with sunitinib or another therapy monotherapy. Under the protocol for the trial, the data from the trial needed to demonstrate an increase in median overall survival of approximately six months for the rocapuldencel-T plus sunitinib / targeted therapy arm as compared to the sunitinib / targeted therapy monotherapy control arm in order to show statistical significance and achieve the primary endpoint of the trial. The IDMC concluded that the study was unlikely to demonstrate a statistically significant improvement in overall survival in the combination treatment arm, utilizing the intent-to-treat population, the primary endpoint of the study. However, even demonstration of statistical significance and achievement of the primary endpoint of the trial would not assure approval by the FDA or similar regulatory authorities outside the United States.

In designing the ADAPT trial we considered other reported clinical trials and data from the International Metastatic Renal Cell Carcinoma Database Consortium, or the Consortium. However, results from two different trials or between a trial and an analysis of a treatment database often cannot be reliably compared. Accordingly, patients in our ADAPT trial who received treatment with sunitinib / targeted therapy monotherapy may not have results similar to patients studied in other clinical trials of sunitinib or to patients in the Consortium database who were treated with sunitinib or other therapies. If the patients in our ADAPT trial who received sunitinib / targeted therapy alone have results which are better than the results that occurred in other clinical trials of sunitinib or the results described in the Consortium database, we may not demonstrate a sufficient clinical benefit from rocapuldencel-T in combination with sunitinib and other therapies to allow the FDA to approve rocapuldencel-T for marketing. Moreover, if the patients in our ADAPT trial who received the combination of rocapuldencel-T and sunitinib / targeted therapy have results which are worse than the results that occurred in our Phase 2 clinical trial, we may not demonstrate a sufficient benefit from the combination therapy to allow the FDA to approve rocapuldencel-T for marketing.

For drug and biological products, the FDA typically requires the successful completion of two adequate and well-controlled clinical trials to support marketing approval because a conclusion based on two such trials will be more reliable than a conclusion based on a single trial. In the case of rocapuldencel-T, we intended to seek approval based upon the results of a single pivotal Phase 3 clinical trial, our ADAPT trial, because rocapuldencel-T is intended for life threatening disease. The FDA reviewed our plans to conduct our ADAPT trial under its SPA process. In February 2013, the FDA advised us in a letter that it had completed its review of our plans under the SPA process. The FDA also informed us that in order for a single trial to support approval of an indication, the trial must be well conducted, and the results of the trial must be internally consistent, clinically meaningful and statistically persuasive.

In February 2017, we announced that the 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 study be discontinued for futility based on its planned interim data analysis. 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 FDA, we now plan to continue the ADAPT trial until at least the pre-specified number of 290 events occurs, which we expect will occur in the first half of 2018. We also plan to continue to analyze interim data from the trial 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. The FDA has agreed to review our planned protocol amendment, and we expect to continue our discussions with the FDA regarding our development program for rocapuldencel-T. If we agree with the FDA on an amended protocol that increases the pre-specified number of events for the primary analysis, the SPA for the ADAPT trial would no longer be in effect. In addition, and given the IDMC's recommendation, one or more additional clinical trials or other testing is highly likely to be necessary. Such additional clinical trials and other testing and development efforts may be complicated and expensive and may significantly delay our program. Moreover, we may not have sufficient resources to complete such further development of rocapuldencel-T.

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, in February 2017, we announced that the 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 study be discontinued for futility based on its planned interim data analysis. 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. This is a population for which published research has shown that sunitinib alone, as well as other of the therapies for mRCC, rarely if ever produce complete responses in mRCC, and in our Phase 2 clinical trial in this population, the combination therapy of rocapuldencel-T and sunitinib did not show a complete response rate that met the endpoint of the trial.

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, the 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 study be discontinued for futility based on its planned interim data analysis. 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 FDA, we now plan to continue the ADAPT trial until at least the pre-specified number of 290 events occurs, which we expect will occur in the first half of 2018. We also plan to continue to analyze interim data from the trial 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. If we decide to further pursue the development of rocapuldencel-T, one or more additional clinical trials or other testing is highly likely to be necessary, which may be complicated and expensive.

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.

The FDA has reviewed the protocol for our ADAPT trial of rocapuldencel-T in combination with sunitinib / targeted therapy under the SPA process. However, agreement by the FDA with the protocol under the SPA process would not guarantee the FDA will grant marketing approval , even if rocapuldencel-T had achieved the primary endpoint in the ADAPT trial.

The FDA has reviewed, under the SPA process, the protocol for our ADAPT trial of rocapuldencel-T in combination with sunitinib / targeted therapy. The SPA process is designed to facilitate the FDA's review and approval of drug and biological products by allowing the FDA to evaluate the proposed design and size of Phase 3 clinical trials that are intended to form the primary basis for determining a drug candidate's efficacy.

In February 2012, we received a letter from the FDA advising us that the FDA had completed its review of our protocol for the ADAPT trial under the SPA process. In the letter, the FDA stated that it had determined that the protocol sufficiently addressed the trial's objectives and that the trial was adequately designed to provide the necessary data to support a submission for marketing approval. However, in February 2017, we announced that the IDMC for our ADAPT clinical trial of rocapuldencel-T in combination with sunitinib / standard-of-care recommended that the study be discontinued for futility based on its planned interim data analysis. The IDMC concluded that the study was unlikely to demonstrate a statistically significant improvement in overall survival in the combination treatment arm, utilizing the intent-to-treat population, the 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 FDA, we now plan to continue the ADAPT trial until at least the pre-specified number of 290 events occurs, which we expect will occur in the first half of 2018. We also plan to continue to analyze interim data from the trial 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. We believe that extending our evaluation of rocapuldencel-T beyond 290 events in the trial could enhance our ability to observe rocapuldencel-T's expected delayed treatment effect. The FDA has agreed to review our planned protocol amendment, and we expect to continue our discussions with the FDA regarding our development program for rocapuldencel-T.

Even if rocapuldencel-T had achieved the primary endpoint in the ADAPT trial, an SPA does not guarantee that rocapuldencel-T would have received marketing approval. The FDA may raise issues related to safety, trial conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision. Many companies which have been granted SPAs have ultimately failed to obtain final approval to market their products.

In its February 2012 letter, the FDA informed us that in order for a single trial to support approval of an indication, the trial must be well conducted, and the results of the trial must be internally consistent, clinically meaningful and statistically very persuasive. If the results for the primary endpoint are not robust, are subject to confounding factors, or are not adequately supported by other trial endpoints, the FDA may refuse to approve our BLA based upon a single clinical trial. Particularly in light of the recommendation by the IDMC that the ADAPT trial be terminated for futility with regard to the primary endpoint, it is highly unlikely, even if the continuation of the ADAPT trial results in subsequent data that are more favorable, that the FDA would not require one or more additional clinical trials before, or as a condition for, approving rocapuldencel-T. Moreover, if we agree with the FDA on an amended protocol that increases the pre-specified number of events for the primary analysis, the SPA for the ADAPT trial would no longer be in effect.

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. In particular, the recommendation by the IDMC that the ADAPT study be terminated for futility may negatively impact our ability to enroll patients in ongoing and future clinical trials of rocapuldencel-T.

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.

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.

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.

All of our product candidates are still in preclinical or clinical development and their 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, in February 2017, the IDMC for our ADAPT clinical trial of rocapuldencel-T in combination with sunitinib / standard-of-care recommended that the study be discontinued for futility based on its planned interim data analysis. 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 one individualized immunotherapy product 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 either 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 one individualized immunotherapy product. 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.

A fast track designation by the FDA may not actually lead to a faster development, regulatory review or approval process.

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address an unmet need for this condition, the treatment sponsor may apply for FDA fast track designation. In April 2012, the FDA notified us that we obtained fast track designation for rocapuldencel-T for the treatment of mRCC. Fast track designation does not ensure that we will experience a faster development, regulatory review or approval process compared to conventional FDA procedures. Additionally, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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 $74.8 million for the year ended December 31, 2015, $53.0 million for the year ended December 31, 2016 and $32.6 million for the six months ended June 30, 2017. As of June 30, 2017, we had an accumulated deficit of $364.6 million. 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. We have not completed development of any product candidates.

We have devoted a significant portion of our financial resources to the development of rocapuldencel-T and expect this to continue as we continue the ADAPT trial. The continued development of rocapuldencel-T will necessarily impact the amount of expenses we incur and the size of our operating losses for the foreseeable future.

In March 2017, our board of directors approved 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. Through additional targeted reductions and attrition, the workforce was further reduced to 44 employees as of July 31, 2017. The principal objective of the workforce reduction is to enable us to conserve our financial resources while we conduct our ongoing review of the preliminary ADAPT trial data set, discuss the data with the FDA, and continue the ADAPT study. We recognized $1.1 million in severance costs during the six months ended June 30, 2017, of which $0.3 million was unpaid as of June 30, 2017. We expect that the workforce reduction will decrease our annual operating costs by $5.7 million once the plan is fully implemented.

As we proceed with the development of our product candidates, including rocapuldencel-T, 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 our ADAPT trial of rocapuldencel-T for the treatment of mRCC or initiate other clinical trials of rocapuldencel-T for the treatment of mRCC;
- continue to support ongoing investigator-initiated clinical trials of rocapuldencel-T and AGS-004;
- support planned investigator-initiated clinical trials of rocapuldencel-T and AGS-004;
- initiate and conduct additional trials of rocapuldencel-T and AGS-004 for the treatment of cancers and HIV;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- lease, build out and equip 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 are making a determination as to the next steps for the rocapuldencel-T clinical program that could significantly impact our future operations and financial position.

We are in the process of making a determination as to the next steps for the rocapuldencel-T clinical program. 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 study 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. 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 FDA, we now plan to continue the ADAPT trial until at least the pre-specified number of 290 events occurs, which we expect will occur in the first half of 2018. We also plan to continue to analyze interim data from the trial 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.

We also may consider changes to our current business strategy and future operations. As part of this process, we are reviewing alternatives with a goal of maximizing the value of our company. We could determine 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, or to continue to operate our business in accordance with our existing business strategy. Pending any decision to change strategic direction, we are continuing to conduct our ongoing clinical trials while managing our cash position. We cannot provide any commitment as to the timing of our determination or the strategy we may adopt. If we determine to change our business strategy or to seek to engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change in our existing business strategy.

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 plans to lease, build out and equip 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 to increase in connection with our ongoing activities, particularly as we continue our ADAPT trial of rocapuldencel-T for the treatment of mRCC, and if we decided to initiate other clinical trials of rocapuldencel-T for mRCC, support ongoing investigator-initiated clinical trials of rocapuldencel-T and AGS-004, support planned investigator-initiated clinical trials of rocapuldencel-T and AGS-004, initiate and conduct additional clinical trials of rocapuldencel-T and AGS-004 for the treatment of cancers and HIV and seek regulatory approval for our product candidates. 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.

As of June 30, 2017, we had cash and cash equivalents of $9.3 million and working capital of $7.4 million. We do not currently have sufficient cash resources to pay our obligations as they become due. In March 2017, our board of directors approved a workforce action plan designed to streamline operations and reduce our operating expenses. We recognized $1.1 million in severance costs and $2.6 million in stock-based compensation expense from the acceleration of stock options for the employees associated with the workforce reduction. As of June 30, 2017, we had paid approximately $0.8 million in severance costs associated with the workforce reduction contemplated by the plan and anticipate paying an additional $0.3 million, primarily during the third and fourth quarters of 2017, related to the plan. We expect that the workforce reduction will decrease our annual operating costs by $5.7 million once the plan is fully implemented. We have also initiated discussions with Saint-Gobain Performance Plastics Corporation, or Saint-Gobain, Invetech Pty Ltd, or Invetech and Medpace, Inc., or Medpace, regarding the fees that we owe them, including potentially the conversion by them of some or all of the outstanding fees into equity of the Company. Additionally, in June 2017 we completed a $6.0 million secured convertible note financing with Pharmstandard. In an at-the-market offering under our sales agreement with Cowen in June 2017, we have also raised proceeds of $4.9 million through the issuance of common stock through August 3, 2017, of which $4.6 million was raised subsequent to June 30, 2017. However, even taking these measures into account, we do not have sufficient cash resources to pay all of our accrued obligations in full or to continue our business operations beyond September 2017. Therefore, we will need to raise additional capital by the end of September 2017 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. 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.

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

- our decision to continue development of rocapuldencel-T and our pivotal Phase 3 ADAPT clinical trial;
- the progress and results of our ongoing and planned investigator initiated clinical trials of rocapuldencel-T that we support;
- the progress and results of the ongoing investigator-initiated clinical trial of AGS-004 in combination with vorinostat for HIV eradication and the planned investigator-initiated clinical trial of AGS-004 that we support and our ability to obtain additional funding under our NIH and NIAID contract for our AGS-004 program;
- the development, initiation and support of additional clinical trials of rocapuldencel-T and AGS-004 in mRCC or other indications;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs and timing of our leasing, build-out and equipping of 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 $6.0 million 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;
- the potential need to repay approximately $5.9 million in fees remaining outstanding under our commercial arrangement with Invetech, $4.0 million under our development agreement with Saint-Gobain and $1.5 million in fees payable to Medpace;
- 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 rocapuldencel-T outside North America and arrangements for the development and commercialization of our non-oncology product candidates, 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, 2016.

Our report from our independent registered public accounting firm for the year ended December 31, 2016 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, your 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, in 2016 we issued and sold securities in a PIPE financing, under a sales agreement with Cowen and Company, LLC ("Cowen") and in a public follow-on offering each of which resulted in dilution to our existing stockholders. Similarly, during the second quarter of 2017, we issued secured convertible debt and raised equity capital under our sales agreement with Cowen, both of 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 may also seek to collaborate with third parties for the manufacturing, development or commercialization of rocapuldencel-T outside of North America. 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 been derecognized in our consolidated financial statements as of December 31, 2016. 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.

Risk 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 rocapuldencel-T or AGS-004 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 rocapuldencel-T or AGS-004 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 one individualized immunotherapy 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 candidates, 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 indications 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.

The FDA has approved several targeted therapies as monotherapies for mRCC, including Nexavar (sorafenib), marketed by Bayer Healthcare Pharmaceuticals, Inc. and Onyx Pharmaceuticals, Inc.; Sutent (sunitinib) and Inlyta (axitinib), marketed by Pfizer, Inc.; Avastin (bevacizumab), marketed by Genentech, Inc., a member of the Roche Group; Votrient (pazopanib) and Afinitor (everolimus), marketed by Novartis Pharmaceuticals Corporation; Torisel (temsirolimus), marketed by Pfizer and most recently, Opdivo (nivolumab), marketed by Bristol-Myers Squibb and Cabometyx (cabozantinib), marketed by Exelixis, for second-line mRCC. In addition, we estimate that there are numerous therapies for mRCC in clinical development by many public and private biotechnology and pharmaceutical companies targeting numerous different cancer types and stages. A number of these are in late stage development including Opdivo (nivolumab) plus Yervoy (ipilimumab) in combination for first-line mRCC, which are currently being compared in a Phase 3 trial to sunitinib. If a standalone therapy for mRCC were developed that demonstrated improved efficacy over currently marketed first-line therapies with a favorable safety profile and without the need for combination therapy, such a therapy might pose a significant competitive threat to rocapuldencel-T.

We are currently conducting our ADAPT trial of rocapuldencel-T plus sunitinib / targeted therapy. We elected to study rocapuldencel-T in clinical trials in combination with sunitinib due in part to sunitinib being the current standard-of-care for first-line treatment of mRCC. Although we do not expect to seek FDA approval of rocapuldencel-T solely in combination with sunitinib and have provided that, under the protocol for the ADAPT trial, investigators may discontinue sunitinib due to disease progression or toxicity and initiate second-line treatment with other approved compatible therapies, if we obtain approval of rocapuldencel-T by the FDA, such FDA approval may be limited to the combination of rocapuldencel-T and sunitinib. In such event, the commercial success of rocapuldencel-T would be linked to the commercial success of sunitinib. As a result, if sunitinib ceases to be the standard-of-care for first-line treatment of mRCC or another event occurs that adversely affects sales of sunitinib, the commercial success of rocapuldencel-T may be adversely affected.

We estimate that there are numerous other cancer immunotherapy products in clinical development by many public and private biotechnology and pharmaceutical companies targeting numerous different cancer types. A number of these product candidates are in late-stage clinical development or have recently been approved in different cancer types including two recently approved checkpoint inhibitor-based immunotherapies, Nivolumab which is marketed by Bristol-Myers Squibb and Pembrolizumab, which is marketed by Merck. These newer immunotherapies are in addition to the targeted therapies, chemotherapeutics, radiation therapy, hormonal therapies and cytokine-based therapies used in the treatment in a wide range of oncology indications.

There are also 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. We are dependent upon further 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 intended to commercialize rocapuldencel-T independently in North America and to collaborate with other third parties to manufacture, develop or commercialize rocapuldencel-T outside North America. 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.

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. Pharmstandard, Green Cross, Medinet and Lummy HK each have this right under our license agreements with them;

- collaborators may hold rights that could preclude us from commercializing our products in certain territories. For example, we have granted Medinet an exclusive license to manufacture in Japan rocapuldencel-T for the treatment of mRCC. If we and Medinet are unable to agree to the terms of a supply agreement under these circumstances, we will not be able to sell rocapuldencel-T in Japan unless we repurchase these rights from Medinet;

- 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, 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, we may seek to collaborate with other third parties to develop and commercialize rocapuldencel-T in other parts of the world. 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 lease, build out and equip 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 facilities in Durham, North Carolina. We manufacture our Arcelis-based product candidates for research and development purposes and for clinical trials at these facilities.

In 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 had intended to utilize this facility to manufacture rocapuldencel-T to support submission of a BLA to the FDA and to support initial commercialization of rocapuldencel-T.

In addition, to provide for capacity expansion beyond the initial few years following potential launch of rocapuldencel-T, we 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 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 IDMC recommendation in February 2017 to discontinue the ADAPT trial, we are currently reassessing our manufacturing plans. We have therefore initiated discussions with the landlord of our Centerpoint facility regarding that lease. In addition on March 17, 2017 the landlord of our CTI facility notified the Company that it was terminating the lease due to nonpayment of invoices for up-fit costs, effective immediately. We believe that our Technology Drive and Patriot Center facilities are sufficient for the manufacture of rocapuldencel-T and AGS-004 to support our ongoing clinical trials and any likely near-term clinical trials that we may initiate.

We expect that we would establish both manual and automated manufacturing processes in our commercial manufacturing facilities if we determine to build out such facilities. We had decided to delay the implementation of our automated manufacturing process until after initial commercialization of rocapuldencel-T, and thus planned to seek marketing approval of rocapuldencel-T and, if approved, to initially commercially supply rocapuldencel-T using our manual manufacturing process. Prior to implementing commercial manufacturing of rocapuldencel-T, 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 rocapuldencel-T that we produce using the manual processes in our current facility and rocapuldencel-T produced using the manual process in our new 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 one company that has 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 rocapuldencel-T and any other 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 of rocapuldencel-T. If we determine to continue our plan to build out and equip a leased 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 rocapuldencel-T and secure additional funding. Thus, if we are able to successfully complete the clinical development of rocapuldencel-T and obtain marketing approval, we plan to initially commercially supply rocapuldencel-T using manual manufacturing processes. Prior to implementing commercial manufacturing of rocapuldencel-T, 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 rocapuldencel-T, we will also be required to show the comparability between rocapuldencel-T that we produce using the manual processes in our current facility and rocapuldencel-T 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. We are collaborating with Invetech and Saint-Gobain to develop the equipment and disposables necessary to implement the automated manufacturing processes for Arcelis-based products. If Invetech or Saint-Gobain 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 rocapuldencel-T in our new facility to fully validate the manufacturing and control process using the actual automated cGMP processing equipment; and
- demonstrate comparability between rocapuldencel-T that we produce using our manual processes and rocapuldencel-T 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 rocapuldencel-T that we produce manually and rocapuldencel-T 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 rocapuldencel-T that we produce manually and the rocapuldencel-T 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 have two manufacturing facilities. If we build out and equip a commercial manufacturing facility, it will be our only commercial manufacturing facility in North America. If our existing manufacturing facilities or a new 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 our existing manufacturing facility 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. For example, we have filed an application for reissue of one of our U.S. patents directed towards methods of manufacture of dendritic cells from monocytes stored for more than six hours and up to four days without freezing. 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 license from Duke University expired in 2016 and the European and Japanese patents exclusively licensed from Duke University expire in 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. To those ends, on May 4, 2017, the US House of Representatives passed the American Health Care Act, or AHCA. On the other hand, the Senate has considered but not passed the AHCA and other legislative proposals leading to new healthcare reform legislation. In addition, while the Trump Administration has threatened to allow the ACA to implode, a bipartisan group of legislators is working to address certain problems with the ACA. Accordingly, it remains to be seen whether new legislation modifying the ACA is enacted and, if so, precisely what the new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. It is possible that these legislative initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. It is also possible that some ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions. At this point, healthcare reform and its impacts on the Company are highly uncertain in many respects.

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 Employee Matters and Managing Growth

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.

In March 2017, we announced that our board of directors approved a workforce action plan designed to streamline operations and reduce our operating expenses. As part of the workforce action plan, Joan C. Winterbottom, our vice president and chief human resources officer, ceased her employment with us effective in March 2017. Additionally, Lee F. Allen, our chief medical officer resigned in April 2017. With any change in leadership and reduction in force, together with our reduced cash resources, there is a risk to retention of employees, as well as the potential for disruption to business operations, initiatives, plans and strategies.

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 setback with respect to rocapuldencel-T, the implementation of our workforce action plan 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.

We have recently reduced the size of our organization, and we may encounter difficulties in managing our business as a result of this reduction, or the attrition that may occur following this reduction, which could disrupt our operations. In addition, we may not achieve anticipated benefits and savings from the reduction .

In March 2017, we announced that our board of directors approved 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. Through additional targeted reductions and attrition, the workforce was further reduced to 44 employees as of July 31, 2017. The reduction in force, and the attrition that may occur following this reduction, will result in the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity and nature of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel. This will be made more challenging given the reduction in force described above and additional measures we may take to reduce costs. As a result, our management may need to divert a disproportionate amount of its attention away from our day-to-day strategic and operational activities, and devote a substantial amount of time to managing these organizational changes. Further, the restructuring and possible additional cost containment measures may yield unintended consequences, such as attrition beyond our intended reduction in force and reduced employee morale. In addition, the reduction in force may result in employees who were not affected by the reduction in force seeking alternate employment which would result in us seeking contract support at unplanned additional expense. In addition, we may not achieve anticipated benefits from the reduction in force. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage this transition and reduction in force and additional cost containment measures, our expenses may be more than expected, and we may not be able to implement our business strategy.

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 maintain the ability to control all 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 55.8% of our outstanding common stock as of July 31, 2017. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control 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 39.9% of our outstanding common stock as of July 31, 2017. 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, if we fail to meet the requirements for continued listing on the NASDAQ Global Market, our common stock could be delisted from trading, which would decrease the liquidity of our common stock and our ability to raise additional capital.

Although our common stock is currently listed on The NASDAQ Global Market, an active trading market for our shares may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares without depressing the market price for the shares or sell your shares at all. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

We are required to meet specified requirements to maintain our listing on The NASDAQ Global Market, including, among other things, a minimum $50,000,000 market value of listed securities, a minimum bid price of $1.00 per share and an audit committee that is comprised of at least three members, each of whom is independent.

On April 28, 2017, we received a deficiency letter from the Listing Qualifications Department, or the Staff, of The NASDAQ Stock Market notifying us that we are not in compliance with the minimum $50,000,000 market value of listed securities requirement for continued listing on The NASDAQ Global Market. We have been provided a period of 180 calendar days, or until October 25, 2017, to regain compliance with the market value of listed securities requirement. If, at any time before October 25, 2017, the market value of our common stock closes at $50,000,000 or more for a minimum of 10 consecutive business days, we may be eligible to regain compliance with the market value of listed securities requirement. If we do not regain compliance with the market value of listed securities requirement, the Staff will notify us that our common stock may be delisted.

On May 2, 2017, we received another deficiency letter from the Staff notifying us that, for the previous 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on The NASDAQ Global Market. We have been provided an initial period of 180 calendar days, or until October 30, 2017, to regain compliance with the minimum bid price requirement. If, at any time before October 30, 2017, the bid price for our common stock closes at $1.00 or more for a minimum of 10 consecutive business days, we may be eligible to regain compliance with minimum bid price requirement. If we do not regain compliance by October 30, 2017, we may be eligible for an additional 180 calendar day compliance period, provided that we transfer the listing of our common stock to The NASDAQ Capital Market. If we do not regain compliance by October 30, 2017 and we are not eligible for an additional compliance period at that time, the Staff will notify us that our common stock may be delisted.

Also, on May 2, 2017, we received another deficiency letter from the Staff notifying us that we are not in compliance with the requirement that a listed company's audit committee be comprised of at least three members, all of whom are independent. Our non-compliance with this requirement occurred upon the resignation of Ralph Snyderman, M.D. as a member of our Board of Directors and our Audit Committee, on March 31, 2017. The Staff provided us a cure period to regain compliance: (i) until the earlier of our next annual stockholders' meeting or April 2, 2018, or (ii) if the next annual stockholders' meeting is held before September 27, 2017, then we must evidence compliance no later than September 27, 2017. If we do not, the Staff will notify us that our common stock may be delisted.

In addition, on May 9, 2017, we received a deficiency letter from the Staff notifying us that we are not in compliance with the minimum $15,000,000 market value of publicly held shares requirement for continued listing on The NASDAQ Global Market. We have been provided a period of 180 calendar days, or until November 6, 2017, to regain compliance with the market value of publicly held shares requirement. If, at any time before November 6, 2017, the market value of our common stock closes at $15,000,000 or more for a minimum of 10 consecutive business days, we may be eligible to regain compliance with the market value of publicly held shares requirement. If we do not regain compliance with the market value of publicly held shares requirement, the Staff will notify us that our common stock may be delisted.

If our common stock is delisted by NASDAQ, our common stock may be eligible to trade on the OTC Bulletin Board or another over-the-counter market. Any such alternative would likely result in it being 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 in such event, such as negative publicity, a decreased ability to obtain additional financing, 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 the common stock would be eligible for trading on any such alternative exchange or markets.

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

Our stock price is likely to be volatile. For example, our stock has traded in a range from a low of $0.25 and high of $13.97 during the period of February 7, 2014 through July 31, 2017. 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. The market price for our common stock may be influenced by many factors, including:

- our determination with regard to the next steps for our rocapuldencel-T clinical program based on our ongoing review of the preliminary ADAPT trial data set and discussions with the FDA;
- our cash resources;
- results of clinical trials of our product candidates or those of our competitors;
- the success of competitive products or technologies;
- potential approvals of our product candidates 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 our product candidates;
- 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 often follows a decline in the market price of a company's securities. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources.

On March 14, 2017, a purported stockholder of our company filed a putative class action lawsuit in the United States District Court for the Middle District of North Carolina against us, our chief executive officer, our chief financial officer, and our vice president of finance, entitled Jeffrey Maurer et al. v. Argos Therapeutics, Inc., et al., Civil Action No. 1:17-cv-00216. The lawsuit purports to be brought on behalf of an alleged class of those who purchased or otherwise acquired our securities between February 7, 2014 and February 21, 2017, and purports to allege claims arising under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The lawsuit generally alleges 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. The complaint seeks, among other relief, unspecified compensatory damages, attorneys' fees, unspecified injunctive relief, and costs. The Court appointed co-lead plaintiffs by order dated June 23, 2017. The Court has set a deadline of September 18, 2017 for lead plaintiffs to file an amended complaint, and the defendants' response to the amended complaint will be due 60 days thereafter. We believe that we have valid defenses to the litigation, and intend to engage in a vigorous defense. However, an unfavorable resolution of any of this matter may have a material adverse effect on our results of operations and cash flows.

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.

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. 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, 2016, 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. 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, or provide favorable coverage. 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

The exhibits filed as part of this Quarterly Report on Form 10-Q are listed in the Exhibit Index immediately following the signatures page of this Quarterly Report on Form 10-Q and are incorporated herein by reference.

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: August 9, 2017

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1	Note Purchase Agreement, dated June 15, 2017, by and between the Company and Pharmstandard International S.A., including a form of the Convertible Secured Promissory Note to be issued by the Company and the Security Agreement to be entered into by the Company and Pharmstandard International S.A. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 16, 2017 and incorporated herein by reference)
10.2	Registration Rights Agreement, dated June 15, 2017, by and between the Company and Pharmstandard International S.A. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 16, 2017 and incorporated herein by reference)
10.3	2014 Stock Incentive Plan, as amended (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 2, 2017 and incorporated herein by reference)
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 requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities Exchange Commission.

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: August 9, 2017

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: August 9, 2017

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/her knowledge on the date hereof:

(a) the Quarterly Report on Form 10-Q of the Company for the period ended June 30, 2017 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.

August 9, 2017

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

August 9, 2017

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