

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, 2018

or

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

Commission File Number 001-35443

## ARGOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

56-2110007  
(I.R.S. Employer  
Identification No.)

4233 Technology Drive  
Durham, North Carolina  
(Address of principal executive offices)

27704  
(Zip Code)

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

No changes

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

Large accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company)

Accelerated filer   
Smaller reporting company   
Emerging growth company

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

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

As of August 17, 2018, there were 10,586,661 shares outstanding of the registrant's common stock, par value \$0.001 per share.

**ARGOS THERAPEUTICS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**For the Quarterly Period Ended June 30, 2018**

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

<u>Item 1.</u>	<u>Financial Statements</u>	<u>3</u>
	<u>Condensed Consolidated Balance Sheets (unaudited)</u>	<u>3</u>
	<u>Condensed Consolidated Statements of Operations (unaudited)</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Comprehensive Loss (unaudited)</u>	<u>5</u>
	<u>Condensed Consolidated Statements of Cash Flows (unaudited)</u>	<u>6</u>
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>7</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>33</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>55</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>	<u>55</u>

**PART II. OTHER INFORMATION**

<u>Item 1.</u>	<u>Legal Proceedings</u>	<u>56</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>56</u>
<u>Item 2.</u>	<u>Unregistered Sales of Securities and Use of Proceeds</u>	<u>56</u>
<u>Item 6.</u>	<u>Exhibits</u>	<u>57</u>
<u>Signatures</u>		<u>58</u>

Argos Therapeutics®, Argos® and Arcelis™, the Argos Therapeutics logo and other trademarks or service marks of Argos appearing in this Quarterly Report on Form 10-Q are the property of Argos Therapeutics, Inc. The other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

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

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ARGOS THERAPEUTICS, INC.  
 CONDENSED CONSOLIDATED BALANCE SHEETS  
 (unaudited)

	December 31, 2017	June 30, 2018
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 15,188,838	\$ 12,125,661
Assets held for sale	600,000	—
Prepaid expenses	1,252,134	1,960,954
Other receivables	143,449	79,341
Total current assets	17,184,421	14,165,956
Property and equipment, net	3,582,323	2,611,148
Other assets	11,020	11,020
Total assets	<u>\$ 20,777,764</u>	<u>\$ 16,788,124</u>
<b>Liabilities and Stockholders' Deficit</b>		
Current liabilities		
Accounts payable	\$ 970,650	\$ 113,622
Accrued expenses	1,263,867	2,569,000
Notes payable	4,972,649	4,979,885
Current portion of other convertible notes	2,350,000	1,835,000
Total current liabilities	9,557,166	9,497,507
Convertible note payable to related party	6,302,959	6,587,098
Long-term portion of other convertible notes	5,830,583	5,540,585
Deferred liabilities	8,153,500	3,298,500
Warrants	167,636	—
Commitments	—	—
Stockholders' deficit		
Preferred stock \$0.001 par value; 5,000,000 shares authorized as of December 31, 2017 and June 30, 2018; 0 shares issued and outstanding as of December 31, 2017 and June 30, 2018	—	—
Common stock \$0.001 par value; 200,000,000 shares authorized as of December 31, 2017 and June 30, 2018; 5,906,620 and 10,586,661 shares issued and outstanding as of December 31, 2017 and June 30, 2018	5,907	10,587
Accumulated other comprehensive loss	(125,864)	(131,390)
Additional paid-in capital	363,450,204	373,139,547
Accumulated deficit	(372,564,327)	(381,154,310)
Total stockholders' deficit	(9,234,080)	(8,135,566)
Total liabilities and stockholders' deficit	<u>\$ 20,777,764</u>	<u>\$ 16,788,124</u>

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

**ARGOS THERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(unaudited)

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2018</b>	<b>2017</b>	<b>2018</b>
Revenue	\$ 69,693	\$ 54,247	\$ 174,952	\$ 5,987,180
Operating expenses				
Research and development	5,120,952	3,924,380	13,034,781	9,469,445
General and administrative	2,679,867	2,495,646	6,642,758	4,994,648
Impairment of property and equipment	—	—	27,204,349	—
Restructuring costs	344,474	—	5,352,766	—
Total operating expenses	8,145,293	6,420,026	52,234,654	14,464,093
Operating loss	(8,075,600)	(6,365,779)	(52,059,702)	(8,476,913)
Other income (expense)				
Interest income	8,881	19,925	39,458	37,970
Interest expense	(294,329)	(151,978)	(1,022,760)	(300,915)
Gain on early extinguishment of debt	—	—	249,458	—
Change in fair value of warrant liability	(177,563)	18,534	20,179,761	167,636
Other expense, net	—	583	(4,905)	(17,762)
Other income (expense), net	(463,011)	(112,936)	19,441,012	(113,071)
Net loss	\$ (8,538,611)	\$ (6,478,715)	\$ (32,618,690)	\$ (8,589,984)
Net loss per share, basic and diluted	\$ (4.13)	\$ (0.61)	\$ (15.78)	\$ (0.94)
Weighted average common shares outstanding, basic and diluted	2,068,743	10,584,644	2,067,218	9,109,917

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,	
	2017	2018	2017	2018
Net loss	\$ (8,538,611)	\$ (6,478,715)	\$ (32,618,690)	\$ (8,589,984)
Other comprehensive gain (loss):				
Foreign currency translation gain (loss)	2,628	(2,564)	3,953	(5,526)
Total comprehensive loss	<u>\$ (8,535,983)</u>	<u>\$ (6,481,279)</u>	<u>\$ (32,614,737)</u>	<u>\$ (8,595,510)</u>

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

ARGOS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(unaudited)

	<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2018</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (32,618,690)	\$ (8,589,984)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	490,701	943,444
Compensation expense related to stock options	5,065,654	1,409,490
Issuance of common shares for research and development license agreement	—	360,000
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)	(167,636)
Loss on disposal of equipment	13,347	17,762
Interest accrued on long-term debt	453,045	300,497
Changes in operating assets and liabilities:		
Prepaid expenses and other receivables	(471,760)	(644,712)
Accounts payable	(2,417,702)	(857,027)
Accrued expenses	(1,854,106)	1,305,132
Current portion of restructuring obligation	292,951	—
Deferred liabilities	(55,000)	(4,855,000)
Manufacturing research and development obligation	181,684	—
Net cash used in operating activities	(24,144,746)	(10,778,034)
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(3,599,040)	—
Proceeds from sale of property and equipment	1,460,615	609,884
Net cash (used in) provided by investing activities	(2,138,425)	609,884
<b>Cash flows from financing activities</b>		
Net proceeds from sale of common stock	316,152	7,924,533
Proceeds from issuance of convertible note payable	6,000,000	—
Payments on notes payable	(23,643,786)	(814,121)
Payments on capital lease obligations	(37,756)	—
Proceeds from exercise of employee stock purchase plan shares	8,369	—
Net cash (used in) provided by financing activities	(17,357,021)	7,110,412
Effect of exchange rate changes on cash	3,900	(5,439)
Net decrease in cash and cash equivalents	(43,636,292)	(3,063,177)
<b>Cash, cash equivalents and restricted cash</b>		
Beginning of period	52,973,376	15,188,838
End of period	<u>\$ 9,337,084</u>	<u>\$ 12,125,661</u>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 568,240	\$ 481
<b>Supplemental disclosure of noncash investing and financing activities</b>		
Issuance of warrants in exchange for early extinguishment of debt	87,100	—
Purchase of property and equipment included in accounts payable and accrued expenses	\$ 2,441,585	\$ —

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

## ARGOS THERAPEUTICS, INC.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

#### 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 that has been focused on the development and commercialization of individualized immunotherapies for the treatment of cancer and infectious diseases based on its proprietary precision immunotherapy technology platform called Arcelis.

In the three month period ended June 30, 2018, the Company recorded expense of \$0.4 million for an out of period adjustment to research and development expenses, to correct a prior period error related to an unrecorded obligation incurred during the three months ended March 31, 2018. The Company has concluded that this adjustment was not material to previously reported financial statements nor to current or estimated full year fiscal 2018 results.

In April 2018 the Company terminated its development program for rocapuldencel-T, its lead product candidate, which the Company had been developing for the treatment of metastatic renal cell carcinoma, or mRCC, and other cancers. Additionally, in August 2018, the Company ceased its support for the development of its other clinical product candidate, AGS-004, which it was developing for the eradication of HIV. The Company has ceased its research and development activities, reduced its workforce and expects to reduce its workforce further. Based on a review of the status of its internal programs, resources and capabilities, the Company is exploring a wide range of strategic alternatives that may include a potential merger or sale of the Company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some or all of the Company’s assets or proprietary technologies, among other potential alternatives. There can be no assurance that the Company will be able to enter into a strategic transaction or transactions on a timely basis, on terms that are favorable to the Company, or at all. If the Company is unable to successfully conclude a strategic transaction in the near future, the Company expects that it will seek protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of the Company. If the Company decides to seek protection under the bankruptcy laws, and if the Company decides to wind down under the bankruptcy laws or otherwise, it is unclear to what extent the Company will be able to pay its obligations to creditors, and, whether and to what extent any resources will be available for distributions to the Company’s stockholders. However, based on the Company’s current resources, the Company believes that it is unlikely that any resources will be available for distributions to its stockholders and that a likely outcome of the Company’s wind-down and potential bankruptcy proceeding will be the cancellation or extinguishment of all outstanding shares in the Company without any payment or other distribution on account of those shares.

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

The Company had also been developing AGS-004, also an Arcelis-based product candidate, for the treatment of HIV. The Company has completed Phase 1 and Phase 2 trials funded by government grants and a Phase 2b trial that was funded in full by the National Institutes of Health (“NIH”) and the National Institute of Allergy and Infectious Diseases (“NIAID”). More recently, the Company was supporting an 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. In connection with the cessation of its research and development activities, the Company recently ceased its support for the trial, and enrollment was suspended.

#### *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 presentation of financial position, results of operations and cash flows for such periods. The results for the three and six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the year ended December 31, 2018 or future operating periods. The information included in these interim financial statements should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Quarterly Report on Form 10-Q and the consolidated financial statements and footnotes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017.

The Company's consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has evaluated principal conditions and events that may raise substantial doubt about its ability to continue as a going concern within one year from the date that these financial statements are issued. The Company has incurred losses in each year since inception and as of June 30, 2018, had an accumulated deficit of \$381.2 million. Also, as of June 30, 2018, the Company's current assets totaled \$14.2 million compared with current liabilities of \$9.5 million, and the Company had cash and cash equivalents of \$12.1 million. Based upon its current and projected cash flow, the Company concluded there is substantial doubt about its ability to continue as a going concern within one year from the date that these financial statements are issued. The financial statements for the three and six months ended June 30, 2018 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

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

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

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

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

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

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

From June 2017 through December 31, 2017, the Company raised proceeds of \$15.5 million through the issuance of common stock in an at-the-market offering under its sales agreement with Cowen & Company, LLC (“Cowen”). From December 31, 2017 through June 30, 2018, an additional \$7.5 million of proceeds was raised. However, upon the delisting of its common stock from The Nasdaq Capital Market in April 2018, the Company ceased to sell any additional shares under the sales agreement.

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

As of June 30, 2018, the Company had cash and cash equivalents of \$12.1 million. The Company does not currently have sufficient cash resources to pay all of its accrued obligations in full or to continue its business operations beyond the end of 2018. As a result, in order to continue to operate its business beyond that time, the Company will need to raise additional funds. However, there can be no assurance that the Company will be able to generate funds on terms acceptable to the Company, on a timely basis, or at all.

In light of the termination of the development of rocapudencel-T, cessation of the Company’s research and development activities and the Company’s cash resources, and based on a review of the status of its internal programs, resources and capabilities, the Company is exploring a wide range of strategic alternatives that may include a potential merger or sale of our company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some or all of the Company’s assets or proprietary technologies, among other potential alternatives. There can be no assurance that the Company will be able to enter into a strategic transaction or transactions on a timely basis, on terms that are favorable to the Company, or at all. If the Company is unable to successfully conclude a strategic transaction in the near future, the Company expects that it will seek protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of the Company. If the Company decides to seek protection under the bankruptcy laws, and if the Company decides to wind down under the bankruptcy laws or otherwise, it is unclear to what extent the Company will be able to pay its obligations to creditors, and, whether and to what extent any resources will be available for distributions to the Company’s stockholders. However, based on the Company’s current resources, the Company believes that it is unlikely that any resources will be available for distributions to its stockholders and that a likely outcome of the Company’s wind-down and potential bankruptcy proceeding will be the cancellation or extinguishment of all outstanding shares in the Company without any payment or other distribution on account of those shares.

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

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

#### ***Use of Estimates***

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

#### ***Significant Accounting Policies***

There have been no material changes in our significant accounting policies as of and for the three and six months ended June 30, 2018, as compared with the significant accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2017, except as described below under Revenue Recognition and Recently Adopted Accounting Standards.

#### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less as of the date of purchase to be cash equivalents. Cash deposits are all in financial institutions in the United States of America, Canada and the European Union. The Company maintains cash in accounts which are in excess of federally insured limits. As of December 31, 2017 and June 30, 2018, \$14.7 million and \$11.9 million, respectively, in cash and cash equivalents was uninsured.

#### ***Revenue Recognition***

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

Effective January 1, 2018, the Company adopted ASC 606, using the modified retrospective transition method. Under this method, results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with Topic 605. The Company applied the modified retrospective transition method to contracts that were not completed as of January 1, 2018, the effective date of adoption for ASC 606. The contracts to which the Company is a party that were not completed as of January 1, 2018 are the multi-year research contract with the NIH and NIAID (see Note 10) and the collaboration agreements included in Note 11. The Company assessed the potential effects to the consolidated financial statements and retained earnings of adoption of the modified retrospective transition method and has concluded that, upon adoption of the new standard, there was no impact on the Company's consolidated financial statements and there was no difference in what would have been recognized under Topic 605 or Topic 606 for the three and six months ended June 30, 2018.

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

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

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

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

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

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

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

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

*Summary.* During the three and six months ended June 30, 2017, the Company recognized \$78,000 and \$120,000, respectively, of contract revenue under the Company's contract with the NIH and NIAID and \$27,500 and \$55,000, respectively, of deferred revenue as revenue under the Company's license agreement with Lummy (Hong Kong) Co. Ltd. ("Lummy HK"). During the three months ended June 30, 2018, the Company recognized \$27,000 of contract revenue under the contract with the NIH and NIAID and \$27,500 of deferred revenue as revenue and a \$1.1 million milestone as deferred revenue under the Lummy license agreement. During the six months ended June 30, 2018, the Company recognized \$5.8 million of deferred milestone revenue as revenue under the Company's license agreement with Medinet Co., Ltd and its wholly-owned subsidiary, MEDcell Co., Ltd. (together "Medinet"), \$57,000 of contract revenue under its contract with the NIH and NIAID, \$55,000 of deferred revenue as revenue and \$14,000 in reimbursement of costs under the Lummy license agreement and \$11,000 of grant revenue.

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

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

#### ***Recently Issued Accounting Pronouncements Not Yet Adopted***

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

#### ***Recently Adopted Accounting Standards***

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

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

In November 2016, the FASB issued ASU 2016-18, *Restricted Cash* ("ASU 2016-18"). ASU 2016-18 requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and restricted cash. Accordingly, restricted cash will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted ASU 2016-18 during the first quarter of 2018, and the standard has been retrospectively applied to all periods presented. The following provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Condensed Consolidated Balance Sheet to the total of the same such amounts shown in the Condensed Consolidated Statement of Cash Flows as of June 30, 2017:

Cash and cash equivalents	\$ 9,337,084
Restricted cash included in current assets	740,000
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statement of Cash Flows	<u>\$ 10,077,084</u>

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

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

There was no restricted cash as of December 31, 2017 and June 30, 2018.

## 2. Fair Value of Financial Instruments

The estimated fair values of all of the Company's financial instruments, excluding long-term debt, approximate their carrying amounts in the consolidated balance sheets as of December 31, 2017 and June 30, 2018.

As of December 31, 2017 and June 30, 2018, the Company held certain assets and liabilities that are required to be measured at fair value on a recurring basis. These assets include money market funds included in cash equivalents. Additionally, as of December 31, 2017 and June 30, 2018, the Company had outstanding warrants recorded as a liability and measured at fair value on a recurring basis. The valuation of these financial instruments uses a three-tiered approach, which requires that fair value measurements be classified and disclosed in one of three tiers. These tiers are: Level 1, defined as quoted prices in active markets for identical assets or liabilities; Level 2, defined as valuations based on observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets, or other inputs that are observable or can be corroborated by observable input data; and Level 3, defined as valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants.

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

The Company's warrant liability is classified as a Level 3 financial liability. The fair value of the warrant liability is measured using the Black-Scholes valuation model. Inherent in the Black-Scholes valuation model are assumptions related to expected stock price volatility, expected life, risk-free interest rate and dividend yield (see Note 9). Due to the market value of the Company's common stock and the \$110.00 exercise price of its warrants, the Company determined that its outstanding warrants had no value as of June 30, 2018.

During the six months ended June 30, 2018 and 2017, there were no transfers between Levels 1, 2, and 3 assets or liabilities.

As of December 31, 2017 and June 30, 2018, 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, 2017
<b>Assets</b>				
Money-market funds	\$ 4,098,037	\$ —	\$ —	\$ 4,098,037
Total assets at fair value	<u>\$ 4,098,037</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,098,037</u>
<b>Liabilities</b>				
Warrants	\$ —	\$ —	\$ 167,636	\$ 167,636
Total liabilities at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 167,636</u>	<u>\$ 167,636</u>

	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, 2018
<b>Assets</b>				
Money-market funds	\$ 4,126,424	\$ —	\$ —	\$ 4,126,424
Total assets at fair value	<u>\$ 4,126,424</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,126,424</u>
<b>Liabilities</b>				
Warrants	\$ —	\$ —	\$ —	\$ —
Total liabilities at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Changes in the fair value of the Company's Level 3 liability for warrants during the six months ended June 30, 2018 were as follows:

Balance as of December 31, 2017	\$ 167,636
Change in fair value during the period	(167,636)
Balance as of June 30, 2018	<u>\$ —</u>

The amortized cost, gross unrealized holding gains, gross unrealized holding losses, and estimated fair value of money-market funds included in cash and cash equivalents as of December 31, 2017 and June 30, 2018 were as follows:

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

	As of June 30, 2018			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Money-market funds	\$ 4,126,424	\$ —	\$ —	\$ 4,126,424
	\$ 4,126,424	\$ —	\$ —	\$ 4,126,424

The fair value of the Company's debt was derived by evaluating the nature and terms of each note, considering the prevailing economic and market conditions as of each balance sheet date and based on the Level 2 valuation hierarchy of the fair value measurements standard using a present value methodology. The fair value of the Company's debt as of December 31, 2017 was approximately \$19.1 million compared with its carrying value of \$19.5 million (see Note 6). The fair value of the Company's debt as of June 30, 2018 was approximately \$18.6 million compared with its carrying value of \$18.9 million (see Note 6).

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

During the six months ended June 30, 2017, the Company had restructuring activities and impairments of property and equipment and leases. These activities were completed during the year ended December 31, 2017 and there were no such activities during the six months ended June 30, 2018. Following is a discussion of these activities during the six months ended June 30, 2017.

As discussed in Note 1, the Company's most advanced product candidate was rocapuldencel-T, which the Company was developing for the treatment of mRCC and other cancers. The Company was conducting a pivotal Phase 3 clinical trial of rocapuldencel-T in combination with sunitinib / standard of care for the treatment of newly diagnosed mRCC. In February 2017, the IDMC for the ADAPT trial recommended that the trial be discontinued for futility based on its planned interim data analysis. The IDMC concluded that the trial was unlikely to demonstrate a statistically significant improvement in overall survival in the combination treatment arm utilizing the intent-to-treat population at the pre-specified number of 290 events (deaths), the primary endpoint of the study. This development triggered a restructuring of the Company's operations and impairments of property and equipment and leases during the three months ended March 31, 2017. As set forth below, the Company recognized restructuring costs of \$5.4 million and an impairment loss of property and equipment of \$27.2 million during the six months ended June 30, 2017 and restructuring costs of \$0.3 million during the three 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 58 employees (or 48%) during the six months ended June 30, 2017. The Company recognized \$1.1 million in severance costs and \$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 CTI on the Centennial Campus of North Carolina State University in Raleigh, North Carolina. The Company provided a security deposit in the amount of \$2.4 million as security for obligations under the lease agreement, which was provided in the form of a letter of credit. In March 2017, the Company initiated discussions with the landlord of the CTI facility regarding the termination of this lease.

In March 2017 the landlord of the CTI facility notified the Company that it was terminating the lease due to nonpayment of invoices for up-fit costs, effective immediately. On March 31, 2017, the Company entered into a termination agreement with the landlord terminating the lease as of March 17, 2017. From the \$2.4 million letter of credit, the landlord drew down \$0.7 million to cover unpaid construction costs in March 2017 and \$1.7 million in April 2017 for lease termination damages and agreed to return \$0.1 million in consideration for being able to salvage some of the construction costs. Pursuant to the termination agreement, the Company had no further obligations under the lease. 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 during the six months ended June 30, 2017.

#### ***Impairment of Centerpoint Facility and Construction-in-Progress***

During the three months ended March 31, 2017, the Company also determined that it would no longer need to develop its facility in Durham County, North Carolina ("Centerpoint"), which the Company intended to be built to house the Company's corporate headquarters and primary manufacturing facility. In November 2017, the Company and TKC Properties, the landlord of the Centerpoint facility, entered into a lease termination agreement in connection with the sale by TKC of the facility to a third party. In the statement of operations for the six months ended June 30, 2017, the Company recorded an impairment loss of \$18.3 million for the Construction-in-progress on the property.

#### **4. Property and Equipment and Assets Held for Sale**

Property and equipment consist of the following:

	<b>December 31, 2017</b>	<b>June 30, 2018</b>
Office furniture and equipment	\$ 639,603	\$ 639,603
Computer equipment	989,137	905,323
Computer software	3,146,978	3,143,633
Laboratory equipment	6,050,640	5,914,448
Leasehold improvements	2,435,530	2,435,530
Total property and equipment, gross	13,261,888	13,038,537
Less: Accumulated depreciation and amortization	(9,679,565)	(10,427,389)
Property and equipment, net	<u>\$ 3,582,323</u>	<u>\$ 2,611,148</u>

The Company sold two isolators included in assets held for sale at December 31, 2018 during the three month period ended March 31, 2018 and received proceeds of \$0.6 million. The Company reviews its property and equipment for impairment whenever events or changes indicate its carrying value may not be recoverable.

#### **5. Income Taxes**

The Company has incurred net operating losses since inception and is forecasting additional losses through December 31, 2018. Therefore, no U.S. Federal, state or foreign income taxes are expected for 2018 and no provision for such taxes has been recorded as of June 30, 2018.

Due to the Company's history of losses since inception, there is not enough evidence at this time to support the conclusion that the Company will generate future income of a sufficient amount and nature to utilize the benefits of the Company's net deferred tax assets. Accordingly, as of December 31, 2017 and June 30, 2018, the Company provided a full valuation allowance against its net deferred tax assets since as of that time, the Company could not assert that it was more likely than not that these deferred tax assets would be realized.

On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). ASC 740 "Income Taxes" generally requires the effects of the tax law change under the Tax Act to be recorded in the period of enactment. However, the SEC staff issued Staff Accounting Bulletin No. 118 to address situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. The Company has recognized the tax impacts in its consolidated financial statements for the year ended December 31, 2017, on a provisional basis. The ultimate impact may differ from these provisional amounts, possibly materially, due to among other things, additional analysis, changes in interpretations and assumptions the Company has made, and additional interpretive regulatory guidance that may be issued. The accounting is expected to be complete when the 2017 U.S. corporate income tax return is filed in 2018. The Company is continuing to evaluate the impact of the recently enacted tax law on its business and consolidated financial statements. For the three and six months ended June 30, 2018, the Company has not made any measurement-period adjustments related to the provisional amounts recorded as of December 31, 2017.

## 6. Notes Payable and Gain on Early Extinguishment of Debt

Notes payable consist of the following as of December 31, 2017 and June 30, 2018:

	December 31, 2017	June 30, 2018
Convertible note payable to Pharmstandard, including accrued interest	\$ 6,302,959	\$ 6,587,098
Convertible note payable to Invetech, including accrued interest	5,845,655	5,495,657
Convertible note payable to Saint-Gobain, including accrued interest	2,334,929	1,879,928
Note payable to Medinet, including accrued interest	4,958,824	4,975,181
Other notes payable	13,825	4,704
Total notes payable	19,456,192	18,942,568
Less current portion of convertible note payable to Invetech, including accrued interest	(1,300,000)	(1,050,000)
Less current portion of convertible note payable to Saint-Gobain, including accrued interest	(1,050,000)	(785,000)
Less current portion of note payable to Medinet, including accrued interest	(4,958,824)	(4,975,181)
Less current portion of other notes payable	(13,825)	(4,704)
Long-term portion of notes payable and convertible notes payable	<u>\$ 12,133,543</u>	<u>\$ 12,127,683</u>

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

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

The Company was required to make quarterly installment payments under the Invetech Note for the fiscal quarters ending December 31, 2017 and March 31, 2018, each in an aggregate amount of up to \$0.4 million, consisting of (i) cash in the amount of \$0.2 million and (ii) if certain specified conditions are met as of the corresponding payment date, up to \$0.2 million of shares of the Company's common stock. For the fiscal quarters ending June 30, 2018 through March 31, 2019, the Company is required to make quarterly installment payments, each in an aggregate amount of up to \$0.3 million, consisting of (i) cash in the amount of \$150,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to \$150,000 of shares of the Company's common stock. For the fiscal quarters ending June 30, 2019 through June 30, 2020, the Company is required to make quarterly installment payments, each in an amount of \$150,000, payable in cash. The Company made an installment payment of \$0.2 million in cash to Invetech in each of the year ended December 31, 2017 and the three months ended March 31, 2018 and made an installment payment of \$150,000 in the three months ended June 30, 2018. The payments in common stock were not made in each of the year ended December 31, 2017, the three months ended March 31, 2018 and the three months ended June 30, 2018 because the specified conditions were not met.

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

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

- *Maturity of the Invetech Note.* Upon maturity of the Invetech Note or at any time within 75 days of such maturity, Invetech may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.
- *Change of Control.* Upon a change of control pursuant to which Invetech has a redemption right, Invetech may, at its option, elect to convert any amount of the outstanding principal and accrued interest, less any remaining installment payments required to be made in cash, into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.
- *Default.* Upon the occurrence of certain events of default, Invetech may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.

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

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

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

The Company was required to make quarterly installment payments for the fiscal quarters ending December 31, 2017 and March 31, 2018, each in an aggregate amount of up to \$340,000, consisting of (i) cash in the amount of \$200,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to \$140,000 of shares of the Company's common stock. For the fiscal quarters ending June 30, 2018 and September 30, 2018, the Company is required to make quarterly installment payments, each in an aggregate amount of up to \$245,000, consisting of (i) cash in the amount of \$125,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to \$120,000 of shares of the Company's common stock. For the fiscal quarters ending December 31, 2018 and March 31, 2019, the Company is required to make quarterly installment payments, each in an aggregate amount of up to \$220,000, consisting of (i) cash in the amount of \$100,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to \$120,000 of shares of the Company's common stock. For the fiscal quarter ending December 31, 2017, March 31, 2018, June 30, 2018, September 30, 2018, December 31, 2018 and March 31, 2019, if the conditions required for the issuance of common stock are not met solely because the price of the common stock at the time is less than \$4.06 per share (as adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction), then the Company will be required to pay in each such quarter cash equal to 50% of the value of the common stock that would otherwise have been issued. For the fiscal quarters ending June 30, 2019 through June 30, 2020, the Company is required to make quarterly installment payments, each in an amount of \$100,000, payable in cash. The Company made an installment payment of \$0.3 million in cash to Saint-Gobain in each of the year ended December 31, 2017 and the three months ended March 31, 2018 and made an installment payment of \$0.2 million in the three months ended June 30, 2018. The payments in common stock were not made in each of the year ended December 31, 2017, the three months ended March 31, 2018 and the three months ended June 30, 2018 because the specified conditions were not met.

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

- *Maturity of the Note.* Upon maturity of the Saint-Gobain Note or at any time during the 75 day period prior to the maturity date of the note, Saint-Gobain may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.
- *Change of Control.* Upon a change of control pursuant to which Saint-Gobain has a redemption right, Saint-Gobain may, at its option, elect to convert any amount of the outstanding principal and accrued interest, less any remaining installment payments required to be made in cash, into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.
- *Default.* Upon the occurrence of certain events of default, Saint-Gobain may, at its option, elect to convert any amount of the outstanding principal and accrued interest into shares of the Company's common stock. The Company will be required to pay any amount not so converted in cash.

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

*Convertible Note Payable to Pharmstandard.*

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

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

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

Pharmstandard is the Company's largest stockholder, and beneficially owned, in the aggregate, shares representing approximately 14.49% of the Company's outstanding common stock as of August 17, 2018. In addition, two members of the Company's board of directors are closely associated with Pharmstandard.

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

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

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

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

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

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

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

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

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

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

As of December 31, 2017 and June 30, 2018, the amount of the note payable was \$5.0 million, including \$1.9 million of accrued interest. As of December 31, 2017 and June 30, 2018, the total deferred liability associated with the Medinet note was \$6.9 million and \$1.1 million, respectively (see Note 11).

*Other Notes.* During November 2013, the Company borrowed \$77,832 from a lending institution to finance the purchase of computer equipment, of which \$13,825 and \$4,704 in principal was outstanding as of December 31, 2017 and June 30, 2018, respectively. Borrowings are collateralized by substantially all of the computer equipment financed under the agreement, bear interest at a rate of 8.31% per annum and are to be repaid in 60 equal monthly installments commencing on the date of borrowing.

## **7. Stockholders' Deficit**

### ***Issuance of Restricted Stock in Six Months Ended June 30, 2017***

In lieu of paying certain annual cash bonuses for 2016, in January 2017 the Company granted restricted stock awards to certain of its executive officers and employees. The number of shares granted to each executive officer and employee was calculated by dividing 25% of the amount of the 2016 annual cash bonus that would otherwise have been paid by the closing price of the Company's common stock on January 13, 2017. A total of 4,005 restricted shares of common stock with an aggregate value of \$394,534 were issued. Each of the restricted stock awards is subject to a lapsing right of repurchase in the Company's favor, which right lapsed with respect to 100% of the underlying shares of each award on April 17, 2017, for those executive officers and employees still providing services to the Company on such date. In April 2017 prior to vesting, 368 restricted shares of common stock were forfeited back to the Company. The Company granted an additional award of 2,333 restricted shares of common stock to an employee resulting in stock-based compensation expense of \$20,999 included in General and administrative expenses.

### ***Issuance of Common Stock in Six Months Ended June 30, 2017***

#### **At-the-market Offering**

In May 2015, the Company entered into a sales agreement with Cowen pursuant to which the Company could issue and sell shares of the Company's common stock from time to time having an aggregate offering price of up to \$30 million through Cowen, acting as the Company's agent. Sales of the Company's common stock through Cowen could be made by any method permitted that was 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 was not required to sell any specific amount, but acted 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 were sold pursuant to a shelf registration statement, which became effective on May 14, 2015. Under the sales agreement, the Company paid 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 41,454 shares of common stock pursuant to the sales agreement, resulting in proceeds of \$0.3 million, net of commissions and issuance costs.

### ***Issuance of Restricted Stock in Six Months Ended June 30, 2018***

During March 2018, the Company issued 210,000 restricted shares of common stock to employees, including certain executives. In connection with the delisting of the Company's common stock from The Nasdaq Capital Market, in April 2018 such restricted shares of common stock were forfeited back to the Company.

### ***Issuance of Common Stock in Six Months Ended June 30, 2018***

#### **At-the-Market Offering**

In February 2018, the Company amended and restated the sales agreement with Cowen to increase the maximum aggregate offering price from \$30 million to up to \$45 million. During the six months ended June 30, 2018, the Company sold 4,135,993 shares of common stock pursuant to the sales agreement, resulting in proceeds of \$7.5 million, net of commissions and issuance costs. However, upon the delisting of the Company's common stock from The Nasdaq Capital Market in April 2018, the Company ceased to sell any additional shares under the sales agreement.

#### **Issuance of Common Stock under Collaboration Agreements**

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

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

## 8. Stock Incentive Plans

### *2014 Stock Incentive Plan and 2014 Employee Stock Purchase Plan*

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

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

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

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

Upon the exercise of stock options, vesting of other awards and purchase of shares through the 2014 ESPP or under the 2014 Plan, the Company issues new shares of common stock. All awards granted under the 2014 Plan that are canceled prior to vesting or expire unexercised are returned to the approved pool of reserved shares under the 2014 Plan and made available for future grants. As of June 30, 2018, there were 309,505 shares of common stock remaining available for future issuance under the 2014 Plan and 10,899 shares of common stock remaining available for future issuance under the 2014 ESPP.

The Company recorded the following share-based compensation expense:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2018	2017	2018
Research and development	\$ 437,598	\$ 248,636	\$ 925,505	\$ 508,429
General and administrative	739,886	445,120	1,488,046	901,061
Restructuring costs	240,499	—	2,652,103	—
<b>Total stock-based compensation expense</b>	<b>\$ 1,417,983</b>	<b>\$ 693,756</b>	<b>\$ 5,065,654</b>	<b>\$ 1,409,490</b>

Allocations to research and development and general and administrative expenses are based upon the department to which the associated employee reported. No related tax benefits of the stock-based compensation expense have been recognized. Stock-based payments issued to non-employees are recorded at their fair values and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period. As part of the restructuring costs discussed in Note 3, the Company recognized \$2.7 million in stock-based compensation expense from the acceleration of stock option vesting for 58 employees who were terminated during the six months ended June 30, 2017.

No options were granted during the three months ended June 30, 2017 or June 30, 2018. During the six months ended June 30, 2017, the Company granted options to employees to purchase a total of 69,104 shares of the Company's common stock at exercise prices ranging from \$27.00 to \$101.00 per share, which, in each instance was the closing price of the Company's common stock on the grant date. No options were granted during the six months ended June 30, 2018.

The following table summarizes the Company's stock option activity during the six months ended June 30, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)
<b>Outstanding as of December 31, 2017</b>	269,514	\$ 111.91	
Granted	—	\$ —	
Exercised	—	\$ —	
Cancelled	(72,165)	\$ 116.49	
<b>Outstanding as of June 30, 2018</b>	<b>197,349</b>	<b>\$ 118.05</b>	<b>6.72</b>
Exercisable as of June 30, 2018	140,076	\$ 119.16	6.16
Vested and expected to vest as of June 30, 2018	192,939	\$ 118.11	6.96

### 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,	
	2017	2018	2017	2018
Risk-free interest rate	2.27%	—	0.79%	—
Dividend yield	0%	—	0%	—
Expected option term (in years)	7	—	0.5	—
Volatility	86%	—	210%	—

### 9. Warrants

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

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

As discussed in Note 6 regarding the Company's notes payable, in connection with the Loan Agreement in September 2014, the Company issued to the Lenders and their affiliates the Venture Loan Warrants. Upon the Company's satisfaction of the conditions precedent to the making of the second tranche loan, the Venture Loan Warrants became exercisable in full. The Venture Loan Warrants will terminate on September 29, 2021 or such earlier date as specified in the Venture Loan Warrants. In addition, in March 2017, the Company issued to the Lenders five year warrants to purchase an aggregate of 5,000 shares of the Company's common stock at an exercise price of \$26.00 per share in consideration of the Lenders accepting the early pay-off of the indebtedness under the Loan Agreement. These warrants were recorded at a fair value of \$87,100 and included in additional paid-in capital as of December 31, 2017 and June 30, 2018.

All outstanding warrants were issued with an original life of five years. As of December 31, 2017 and June 30, 2018, outstanding warrants to purchase a total of 689,661 shares of the Company's common stock were as follows:

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

The following warrants were issued in August 2016 and remained outstanding as of December 31, 2017 and June 30, 2018, and include provisions that could require cash settlement. The August 2016 Warrants were therefore recorded as liabilities of the Company at the estimated fair value as of the date of issuance. The August 2016 Warrants are required to be recorded at fair value as of the end of each subsequent reporting period, with changes in fair value recorded as other income or expense in the Company's condensed consolidated statement of operations in each subsequent period:

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

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

The assumptions used by the Company to determine the fair value of the August 2016 Warrants are summarized in the following table as of December 31, 2017. Due to the market value of the Company's common stock and the \$110.00 exercise price of its warrants, the Company determined that its outstanding warrants had no value as of June 30, 2018.

	December 31, 2017	June 30, 2018
Exercise price of warrants	\$ 110.00	\$ 110.00
Closing underlying stock price on date of valuation	\$ 3.00	\$ —
Expected stock price volatility	112%	—
Expected life (in years)	3.58	—
Risk-free interest rate	2.04%	—
Expected dividend yield	0.0%	—
Valuation per common share underlying each warrant	\$ 0.49	\$ —
Total liability for warrants on the consolidated balance sheet	\$ 167,636	\$ —
Decrease in fair value during the period	20,758,425	\$ 167,636

In 2013, the Company agreed to enter into a manufacturing rights agreement for the manufacturing of rocapuldencel-T in the European market with Pharmstandard, which also provided for the issuance of warrants to Pharmstandard to purchase 24,989 shares of the Company's common stock at an exercise price of \$116.40 per share. As of June 30, 2018, the Company had not entered into this manufacturing rights agreement or issued such warrants.

## 10. Contract with the NIH and NIAID

In September 2006, the Company entered into a multi-year research contract with the NIH and NIAID to design, develop and clinically test an autologous HIV immunotherapy capable of eliciting therapeutic immune responses. The Company used funds from this contract to develop AGS-004. Under this contract, as amended, the NIH and NIAID 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 agreed to a statement of work under the contract, and was 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. This contract expired as of July 31, 2018.

The Company recognized revenue from reimbursements earned in connection with the contract as reimbursable costs were 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, 2017 and 2018, the Company recorded revenue under the NIH and NIAID agreement of \$42,193 and \$26,747, respectively. For the six months ended June 30, 2017 and 2018, the Company recorded revenue under the NIH and NIAID agreement of \$119,952 and \$57,065, respectively. The Company has recorded total revenue of \$38.1 million through June 30, 2018 under this agreement. As of December 31, 2017 and June 30, 2018, the Company recorded a receivable from the NIH and NIAID of \$31,977 and \$79,341, respectively. The concentration of credit risk is equal to the outstanding accounts receivable and such risk is subject to the credit worthiness of the NIH and NIAID. There have been no credit losses under this arrangement.

## 11. Collaboration Agreements

### *Pharmstandard License Agreement*

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

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

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

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

#### ***Pharmstandard and Actigen Option Agreement***

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

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

#### ***Green Cross License Agreement***

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

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

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

#### ***Medinet License Agreement***

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

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

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

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

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

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

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

On February 14, 2018, the Company notified Medinet that the Company irrevocably agreed to have no further right to exercise its right under the license agreement to revoke the manufacturing and sale license, or the sale license only. In all other respects, the Medinet license agreement remains in full force and effect. As a result of the revocation right no longer being of force and effect, the Company recognized \$5.8 million of deferred milestone revenue as revenue under ASC 606 during the first quarter of 2018. As of June 30, 2018, the amount of the note payable was \$5.0 million, including \$1.9 million of accrued interest, and the total deferred liability associated with the Medinet note was \$1.1 million of which \$150,000 was deferred revenue. As of June 30, 2018, there are performance obligations related to the Medinet license agreement of \$150,000 that are unsatisfied. The remaining performance obligations are expected to be satisfied over time throughout the remainder of 2018 such that the \$150,000 of deferred revenue is expected to be recognized as revenue by December 31, 2018.

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

### *Lummy License Agreement*

On April 7, 2015, the Company and Lummy HK, a wholly owned subsidiary of Chongqing Lummy Pharmaceutical Co. Ltd., entered into a license agreement (the "License Agreement") whereby the Company granted to Lummy HK an exclusive license under the Arcelis technology, including patents, know-how and improvements to manufacture, develop and commercialize products for the treatment of cancer ("Licensed Product") in China, Hong Kong, Taiwan and Macau (the "Territory"). Under the License Agreement, Lummy HK also has a right of first negotiation with respect to a license under the Arcelis technology for the treatment of infectious diseases in the Territory. This agreement was subsequently amended in December 2016, October 2017 and March 2018.

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

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

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

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

As of June 30, 2018, there are performance obligations related to the Lummy HK License Agreement of \$2.3 million that are unsatisfied of which \$1.1 million are expected to be met in the third quarter of 2018 and recognized as revenue. The remaining \$1.2 million in performance obligations were to be satisfied and recognized as revenue on a straight-line basis over the estimated remaining license period from July 1, 2018 to December 31, 2029. As of December 31, 2017 and June 30, 2018, the Company had deferred revenue from the Lummy license agreement of \$1.2 million and \$2.2 million, respectively.

## 12. Net Loss Per Share

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

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2018</b>	<b>2017</b>	<b>2018</b>
Net loss	\$ (8,538,611)	\$ (6,478,715)	\$ (32,618,690)	\$ (8,589,984)
Weighted average common shares outstanding, basic and diluted	2,068,743	10,584,644	2,067,218	9,109,917
Net loss per share, basic and diluted	<u>\$ (4.13)</u>	<u>\$ (0.61)</u>	<u>\$ (15.78)</u>	<u>\$ (0.94)</u>

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2018</b>	<b>2017</b>	<b>2018</b>
Stock options outstanding	293,995	200,954	293,452	234,285
Warrants outstanding	689,661	689,661	687,865	689,661
Convertible notes outstanding		1,448,352		1,448,352

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

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

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

In April 2018, we terminated our development program for rocapuldencel-T, our lead product candidate, which we had been developing for the treatment of metastatic renal cell carcinoma, or mRCC, and other cancers. Additionally, in August 2018, we ceased our support for the development of our other clinical product candidate, AGS-004, which we were developing for the eradication of HIV. We have ceased our research and development activities, reduced our workforce and expect to reduce our workforce further. Based on a review of the status of our internal programs, resources and capabilities, we are exploring a wide range of strategic alternatives that may include a potential merger or sale of our company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some or all of our assets or proprietary technologies, among other potential alternatives. There can be no assurance that we will be able to enter into a strategic transaction or transactions on a timely basis, on terms that are favorable to us, or at all. If we are unable to successfully conclude a strategic transaction in the near future, we expect that we will seek protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of our company. If we decide to seek protection under the bankruptcy laws, and if we decide to wind down the company under the bankruptcy laws or otherwise, it is unclear to what extent we will be able to pay our obligations to creditors, and, whether and to what extent any resources will be available for distributions to our stockholders. However, based on our current resources, we believe that it is unlikely that any resources will be available for distributions to our stockholders and that a likely outcome of our wind-down and potential bankruptcy proceeding will be the cancellation or extinguishment of all outstanding shares in the company without any payment or other distribution on account of those shares.

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

Notwithstanding the IDMC's recommendation, we determined to continue to conduct the trial while we analyzed interim data from the trial. Following a meeting with the U.S. Food and Drug Administration, or FDA, we determined to continue the ADAPT trial until at least the pre-specified number of 290 events occurred, and to submit to the FDA a protocol amendment to increase the pre-specified number of events for the primary analysis of overall survival in the trial beyond 290 events. In April 2018, we submitted a protocol amendment to the FDA that included an amended primary endpoint analysis with four co-primary endpoints. Subsequently in April 2018, we conducted another interim analysis of the data from the ADAPT trial, at which time 51 new events (deaths) had occurred subsequent to the February 2017 interim analysis. Based upon review of the interim data from this analysis, we determined that the endpoints were unlikely to be achieved if the trial were to be continued and decided to discontinue the ADAPT clinical trial.

We have also been developing AGS-004, also an Arcelis-based product candidate, for the treatment of HIV. We have completed Phase 1 and Phase 2 trials funded by government grants and a Phase 2b trial that was funded in full by the National Institutes of Health, or NIH, and the National Institute of Allergy and Infectious Diseases, or NIAID. More recently, we were supporting an 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. In connection with the cessation of our research and development activities, we recently ceased our support for the trial, and enrollment was suspended.

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

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

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

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

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

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

From June 2017 through December 31, 2017, we raised proceeds of \$15.5 million through the issuance of common stock in an at-the-market offering under our original sales agreement with Cowen & Company, LLC, or Cowen. In February 2018, we amended and restated the original sales agreement with Cowen to increase the maximum aggregate offering price of the shares of our common stock which we may sell under the agreement from \$30 million to up to \$45 million. From December 31, 2017 through June 30, 2018, we raised an additional \$7.5 million of proceeds. However, upon the delisting of our common stock from The Nasdaq Capital Market in April 2018, we ceased to sell any additional shares under the sales agreement.

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

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

As of June 30, 2018, we had cash and cash equivalents of \$12.1 million. We do not currently have sufficient cash resources to pay all of our accrued obligations in full or to continue our business operations beyond the end of 2018. As a result, in order to continue to operate our business beyond that time, we will need to raise additional funds. However, there can be no assurance that we will be able to generate funds on terms acceptable to us, on a timely basis, or at all.

Our consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As of June 30, 2018, our current assets totaled \$14.2 million compared with current liabilities of \$9.5 million, and we had cash and cash equivalents of \$12.1 million. Based upon our current and projected cash flow, we note there is substantial doubt about our ability to continue as a going concern within one year after the date that these financial statements are issued. The financial statements for the three and six months ended June 30, 2018 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern.

We have devoted substantially all of our resources to our drug development efforts, including advancing our Arcelis precision immunotherapy technology platform, conducting clinical trials of our product candidates, protecting our intellectual property and providing general and administrative support for these operations. We have not generated any revenue from product sales and, to date, have funded our operations primarily through public offerings of our common stock and warrants, a venture loan, private placements of common stock, preferred stock and warrants, convertible debt financings, government contracts, government and other third party grants and license and collaboration agreements. From inception in May 1997 through June 30, 2018, we have raised a total of \$525.9 million in cash, including:

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

We have incurred losses in each year since our inception in May 1997. Our net loss was \$53.0 million and \$40.6 million for the years ended December 31, 2016, and 2017, respectively and \$8.6 million for the six months ended June 30, 2018. As of June 30, 2018, we had an accumulated deficit of \$381.2 million. Substantially all of our operating losses have resulted from costs incurred in connection with our development programs and from general and administrative costs associated with our operations.

In light of the termination of the development of rocapuldencel-T, cessation of our research and development activities and our cash resources, and based on a review of the status of our internal programs, resources and capabilities, we are exploring a wide range of strategic alternatives that may include a potential merger or sale of our company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some or all of our assets or proprietary technologies, among other potential alternatives. There can be no assurance that we will be able to enter into a strategic transaction or transactions on a timely basis, on terms that are favorable to us, or at all. If we are unable to successfully conclude a strategic transaction in the near future, we expect that we will seek protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of our company. If we decide to seek protection under the bankruptcy laws, and if we decided to wind down the company under the bankruptcy laws or otherwise, it is unclear to what extent we will be able to pay our obligations to creditors, and, whether and to what extent any resources will be available for distributions to our stockholders. However, based on our current resources, we believe that it is unlikely that any resources will be available for distributions to our stockholders and that a likely outcome of our wind-down and potential bankruptcy proceeding will be the cancellation or extinguishment of all outstanding shares in the company without any payment or other distribution on account of those shares.

If we determine to continue our business operations or resume our research and development activities, we would need to raise additional capital prior to the commercialization of AGS-004 or any other product candidates. If we seek to and are able to raise the capital necessary to resume the development of our product candidates, we anticipate that our expenses will increase substantially if and as we:

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

#### ***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. This contract expired as of July 31, 2018.

Under this contract, as amended, the NIH and NIAID committed to fund up to a total of \$39.8 million, including reimbursement of direct expenses and allocated overhead and general and administrative expenses of up to \$38.4 million and payment of other specified amounts totaling up to \$1.4 million upon our achievement of specified development milestones. This amount includes a September 2014 modification of the contract under which the NIH and NIAID agreed to fund up to an additional \$0.5 million to cover a portion of the manufacturing costs of the planned Phase 2 clinical trial of AGS-004 for long-term viral control in pediatric patients. 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 were subject to adjustment based on our actual costs pursuant to the agreement with the NIH and NIAID.

We have recorded revenue of \$38.1 million through June 30, 2018 under the NIH and NIAID contract. This contract is the only arrangement under which we have generated substantial revenue.

### **Development and Commercialization Agreements**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The agreement expired on June 30, 2018. As of June 30, 2018, we accrued \$2.0 million for development and production services performed by Cellscript under the development and supply agreement.

### **Manufacturing**

We currently have a manufacturing suite located at our Technology Drive leased facility in Durham, North Carolina. However, we have determined to cease the manufacture of Arcelis-based product candidates. Primarily due to our decision to cease support for the Phase 2 trial of AGS-004 for the eradication of HIV, we elected to close our Patriot Center facility, a manufacturing facility we previously leased in Durham, North Carolina, during the second quarter of 2018.

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

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

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

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

## Results of Operations

### Comparison of the Three and Six Months Ended June 30, 2017 with the Three and Six Months Ended June 30, 2018

The following table summarizes the results of our operations for each of the three and six month periods ended June 30, 2017 and 2018, together with the changes in those items in dollars and as a percentage:

	Three Months Ended		\$	%	Six Months Ended		\$	%
	June 30,				June 30,			
	2017	2018	Change	Change	2017	2018	Change	Change
	(in thousands)							
Revenue	\$ 70	\$ 54	\$ (15)	(22.2)%	\$ 175	\$ 5,987	\$ 5,812	*
Operating expenses								
Research and development	5,121	3,924	(1,197)	(23.4)%	13,035	9,469	(3,565)	(27.4)%
General and administrative	2,680	2,496	(184)	(6.9)%	6,643	4,995	(1,648)	(24.8)%
Impairment of property and equipment	—	—	—	—	27,204	—	(27,204)	(100.0)%
Restructuring costs	344	—	(344)	(100.0)%	5,353	—	(5,353)	(100.0)%
Total operating expenses	8,145	6,420	(1,725)	(21.2)%	52,235	14,464	(37,771)	(72.3)%
Loss from operations	(8,076)	(6,366)	1,710	21.2%	(52,060)	(8,477)	43,583	83.7%
Interest income	9	20	11	124.4%	39	38	(1)	(3.8)%
Interest expense	(294)	(152)	142	48.4%	(1,023)	(301)	722	70.6%
Gain on early extinguishment of debt	—	—	—	—	249	—	(249)	100.0%
Change in fair value of warrant liability	(178)	19	196	*	20,180	168	(20,012)	*
Other expense	—	1	—	100.0%	(5)	(18)	(13)	*
Net loss	\$ (8,539)	\$ (6,479)	\$ 2,060	24.1%	\$ (32,619)	\$ (8,590)	\$ 24,029	73.7%

\* Not meaningful

**Revenue**

To date, we have not generated revenue from the sale of any products. Substantially all of our revenue has been derived from our NIH and NIAID contract and our license agreements with Medinet and Lummy HK.

Revenue was \$54,000 for the three months ended June 30, 2018, compared with \$70,000 for the three months ended June 30, 2017, a decrease of \$15,000, or 22.2%. The decrease for the three months ended June 30, 2018 compared with the three months ended June 30, 2017 resulted from lower reimbursement under our NIH and NIAID contract.

Revenue was \$5.9 million for the six months ended June 30, 2018, compared with \$0.1 million for the six months ended June 30, 2017, an increase of \$5.8 million. The \$5.8 million increase for the six months ended June 30, 2018 resulted from the recognition of \$5.8 million of revenue from milestone payments from Medinet that had previously been recorded as deferred revenue as a result of our decision to irrevocably forego our revocation right under our license agreement with Medinet.

**Research and Development Expenses**

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

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

The table below summarizes our direct research and development expenses by program for the periods indicated. Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, including in connection with our clinical trials, and related clinical trial fees. Research and development expenses also include commercial manufacturing development costs consisting primarily of costs incurred under our Invetech Development Agreement to develop and provide prototypes of the automated production system to be used for the manufacture of our Arcelis-based products and our Saint-Gobain Development Agreement to develop a range of disposables to be used in both our manual and automated manufacturing processes. We had 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,	
	2017	2018	2017	2018
	(in thousands)			
Direct research and development expense by program:				
Rocapuldencel-T	\$ 2,151	\$ 446	\$ 4,554	\$ 3,569
AGS-004	21	12	77	25
Total direct research and development program expense	2,172	458	4,631	3,594
Commercial manufacturing development expense	—	—	(373)	—
Indirect research and development expense	2,949	3,466	8,777	5,875
Total research and development expense	<u>\$ 5,121</u>	<u>\$ 3,924</u>	<u>\$ 13,035</u>	<u>\$ 9,469</u>

*Three months ended June 30, 2017 and 2018.*

Research and development expenses were \$3.9 million for the three months ended June 30, 2018, compared with \$5.1 million for the three months ended June 30, 2017, a decrease of \$1.2 million, or 23.4%. The decrease in research and development expense reflects a \$1.7 million decrease in direct research and development expense partially offset by a \$0.5 million increase in indirect research and development expense.

Direct research and development expense for rocapuldencel-T was \$0.4 million in the three months ended June 30, 2018, compared with \$2.2 million for the three months ended June 30, 2017, a decrease of \$1.7 million. This decrease reflects a reduction of costs for the ADAPT trial following the termination of this trial in April 2018.

Direct research and development expense for AGS-004 was not significantly different in the three months ended June 30, 2018 compared with the three months ended June 30, 2017.

*Six Months ended June 30, 2017 and 2018.*

Research and development expenses were \$9.5 million for the six months ended June 30, 2018, compared with \$13.0 million for the six months ended June 30, 2017, a decrease of \$3.6 million, or 27.4%. The decrease in research and development expense reflects a \$1.0 million decrease in direct research and development expense and a \$2.9 million decrease in indirect research and development expense, partially offset by a credit of \$0.4 million during the six months ended June 30, 2017 related to our Saint Gobain Development Agreement.

The decrease in direct research and development expenses for rocapuldencel-T and AGS-004 resulted primarily from the following:

- Direct research and development expense for rocapuldencel-T decreased to \$3.6 million in the six months ended June 30, 2018 from \$4.6 million for the six months ended June 30, 2017. This decrease primarily reflects a reduction of costs for the ADAPT trial.
- Direct research and development expense with respect to AGS-004 was not significantly different in the six months ended June 30, 2018 compared with the six months ended June 30, 2017.

During the six months ended June 30, 2017, we recorded a credit of \$0.4 million related to amounts owed under our Saint-Gobain Development Agreement, which we recorded as a reduction of research and development expense. No commercial manufacturing development expense was recorded for the six months ended June 30, 2018.

The decrease in indirect research and development expense was primarily due to the reduction in the size of our workforce engaged in research and development activities. As of June 30, 2018, we had 21 employees engaged in such activities, compared with 36 employees engaged in such activities as of June 30, 2017.

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

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

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. If the FDA or another regulatory authority were to require additional clinical trials or if there were significant delays in enrollment, significant additional financial resources and time would be expended on the completion of clinical development.

#### ***General and Administrative Expenses***

General and administrative expenses were \$2.5 million for the three months ended June 30, 2018, compared with \$2.7 million for the three months ended June 30, 2017, a decrease of \$0.2 million or 6.9%. This decrease was primarily due to a reduction in personnel costs consisting primarily of stock-based compensation.

General and administrative expenses were \$5.0 million for the six months ended June 30, 2018, compared with \$6.6 million for the six months ended June 30, 2017, a decrease of \$1.6 million or 24.8%. This decrease was primarily due to a reduction in personnel costs consisting primarily of salaries and stock-based compensation.

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 did not recognize an impairment loss on property and equipment for the three and six months ended June 30, 2018, and the three months ended June 30, 2017. We recognized an impairment loss on property and equipment of \$27.2 million for the six months ended June 30, 2017. 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 six months ended June 30, 2017 that we no longer planned to develop our Centerpoint facility. Accordingly, we recorded an impairment loss of \$18.3 million for the Construction-in-progress on the property.

Additionally, we determined during the six months ended June 30, 2017 that we would no longer need to develop various equipment included in Construction-in-progress under our current manufacturing plans. As such, we entered into agreements and understandings with various vendors to attempt to sell or dispose this equipment at prices less than our carrying value. Accordingly, we determined that the fair value of this equipment held for sale was \$0.7 million as of March 31, 2017 and recorded an impairment loss of \$1.1 million as of March 31, 2017. Additionally, we recorded a \$6.1 million impairment loss on other equipment included in Construction-in-progress that had to be abandoned or had no net realizable value. Finally, we recorded an impairment loss of \$0.9 million on Construction-in-progress that was abandoned at the CTI facility.

#### *Impairment of Capital Leases*

In August 2016, we entered into two agreements, or the Power Generation Agreements, with an electric utility company. The Power Generation Agreements were accounted for as capital leases for financial reporting purposes. Under the lease agreements, the electric utility company agreed to design, procure, install, own and maintain electrical equipment at Centerpoint to provide required electrical loads. Property, plant and equipment included \$2.4 million as of December 31, 2016 under the Power Generation Agreements in the Construction-in-progress account. As of 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 and \$0.1 million during the three and six months ended June 30, 2017, respectively.

#### *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 the three and six months ended June 30, 2018, respectively. The restructuring costs and impairment charges during the three and six months ended June 30, 2017 were related to the restructuring of our operations following the recommendation by the IDMC to discontinue the ADAPT study in February 2017.

#### *Workforce Action Plan*

On March 10, 2017, we enacted a workforce action plan designed to streamline operations and reduce our operating expenses. Under this plan, we reduced our workforce by 58 employees during the six months ended June 30, 2017. During the three and six months ended June 30, 2017, we recognized \$0.1 million and \$1.1 million in severance costs, respectively, and \$0.2 and \$2.6 million in stock compensation cost, respectively, from the acceleration of vesting of stock options held by the terminated employees.

#### *CTI Lease Agreement*

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

In March 2017 the landlord of our CTI facility notified us that it was terminating the lease due to nonpayment of invoices for up-fit costs, effective immediately. On March 31, 2017, we entered into a termination agreement with the landlord terminating the lease as of March 17, 2017. From the \$2.4 million letter of credit, the landlord drew down \$0.7 million to cover unpaid construction costs in March 2017 and \$1.7 million in April 2017 for lease termination damages and agreed to return \$0.1 million in consideration for being able to salvage some of the construction costs. Pursuant to the termination agreement, we have no further obligations under the lease. During the 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 \$0.2 million for the three months ended June 30, 2018, compared with \$0.3 million for the three months ended June 30, 2017, a decrease of \$0.1 million or 48.4%. The decrease primarily resulted from the termination of the Power Generation Agreements on November 21, 2017, 2018 that were accounted for as capital leases.

Interest expense was \$0.3 million for the six months ended June 30, 2018, compared with \$1.0 million for the six months ended June 30, 2017, a decrease of \$0.7 million or 70.6%. The decrease resulted primarily from our repayment of the balance outstanding under the Loan Agreement on March 6, 2017 and the termination of the Power Generation Agreements that were accounted for as capital leases.

### ***Gain on Early Extinguishment of Debt***

We recognized a gain on early extinguishment of debt of \$0 and \$0.2 million for the three and six months ended June 30, 2017, respectively. We recognized no gain on early extinguishment of debt for the three and six months ended June 30, 2018. On March 3, 2017, we entered into a payoff letter with the Lenders, pursuant to which we paid on March 6, 2017, a total of \$23.1 million to the Lenders, representing the principal balance and accrued interest outstanding under the Loan Agreement in repayment of our outstanding obligations under the Loan Agreement. In addition, we issued to the Lenders five year warrants to purchase an aggregate of 5,000 shares of our common stock at an exercise price of \$26.00 per share in consideration of the Lenders accepting the \$23.1 million as repayment in full.

### ***Change in Fair Value of Warrant Liability***

The gain (loss) from the change in fair value of the warrant liability was \$0.01 million and \$0.2 million for the three and six months ended June 30, 2018, respectively, compared with \$(0.2) million and \$20.2 million for the three and six months ended June 30, 2017, respectively. These amounts represent the change in the fair value of our warrant liability for the warrants issued in August 2016. The August 2016 warrants contain provisions that could require cash settlement and are recorded as a liability at fair value on the date of issuance and as of the end of each reporting period. The fair value of the August 2016 warrants declined primarily due to a significant decline in the price of our common stock and a shorter expected life of the warrants. As of June 30, 2018, the fair value of the August 2016 warrants was \$0.

### ***Liquidity and Capital Resources***

#### ***Sources of Liquidity***

As of June 30, 2018, we had cash and cash equivalents of \$12.1 million.

Since our inception in May 1997 through June 30, 2018, we have funded our operations principally with \$360.7 million from the sale of common stock, convertible debt, warrants and preferred stock, \$32.9 million from the licensing of our technology, \$107.3 million from government contracts, grants and license and collaboration agreements, and \$25.0 million from the Loan Agreement.

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

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

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

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

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

The maturity date for the payment of principal and interest under the note is September 30, 2020. The note bears interest at a rate of 6.0% per annum, which interest will compound quarterly. For the quarterly periods ended December 31, 2017, March 31, 2018, and June 30, 2018, we paid Saint-Gobain \$270,000, \$270,000 and \$185,000, respectively, in cash under the note. For the fiscal quarter ending September 30, 2018, we are required to make a quarterly installment payment under the note, in the aggregate amount of up to \$245,000, consisting of (i) cash in the amount of \$125,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to \$120,000 of shares of our common stock. For the fiscal quarters ending December 31, 2018 and March 31, 2019, we are required to make quarterly installment payments under the note, each in an aggregate amount of up to \$220,000, consisting of (i) cash in the amount of \$100,000 and (ii) if certain specified conditions are met as of the corresponding payment date, up to \$120,000 of shares of our common stock. For the fiscal quarters ending December 31, 2017, March 31, 2018, June 30, 2018, September 30, 2018, December 31, 2018 and March 31, 2019, if the conditions required for the issuance of common stock are not met solely because the price of the common stock at the time is less than \$4.058 per share (as adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction), then are required to pay in each such quarter cash equal to 50% of the value of the common stock that would otherwise have been issued. For the fiscal quarters ending June 30, 2019 through June 30, 2020, we are required to make quarterly installment payments under the note, each in an amount of \$100,000, payable in cash.

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

***Venture Loan and Security Agreement.***

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

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

***At-the-market Offering.***

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

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

Under the Sales Agreement, we paid Cowen a commission of up to 3% of the gross proceeds. During the six months ended June 30, 2018, the Company sold 4,135,993 shares of common stock pursuant to the Sales Agreement, resulting in proceeds of \$7.5 million, net of commissions and issuance costs. However, upon the delisting of our common stock from The Nasdaq Capital Market in April 2018, we ceased to sell any additional shares under the Sales Agreement.

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

**Convertible Note.**

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

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

Pharmstandard is our largest stockholder, and beneficially owned, in the aggregate, shares representing approximately 14.49% of our outstanding common stock as of August 17, 2018. In addition, two members of our board of directors are closely associated with Pharmstandard.

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

**Cash Flows**

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

	<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2018</b>
	<b>(in thousands)</b>	
Net cash (used in) provided by:		
Operating activities	\$ (24,145)	\$ (10,778)
Investing activities	(2,138)	610
Financing activities	(17,357)	7,110
Effect of exchange rate changes on cash	4	(5)
Net increase (decrease) in cash and cash equivalents	<u>\$ (43,636)</u>	<u>\$ (3,063)</u>

*Operating Activities.*

Net cash used in operating activities of \$10.8 million during the six months ended June 30, 2018 was primarily a result of our \$8.6 million net loss and an increase in net operating assets of \$5.1 million, partially offset by non-cash items of \$2.9 million.

The increase in net operating assets reflects a decrease in deferred revenue of \$4.9 million, a decrease in accounts payable of \$0.9 million and an increase in prepaid expenses and other receivables of \$0.6 million, partially offset by an increase in accrued expenses of \$1.3 million.

The non-cash items primarily reflect compensation expense related to stock options of \$1.4 million, depreciation and amortization expense of \$0.9 million, interest accrued on long term debt of \$0.3 million and issuance of common stock for a license option of \$0.2 million, partially offset by a decrease in the fair value of the warrant liability of \$0.2 million.

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 increase in net operating assets reflects a decrease in accounts payable of \$2.4 million, a decrease in accrued expenses of \$1.9 million, 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.

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.

*Investing Activities.*

Net cash provided by investing activities was \$0.6 million during the six months ended June 30, 2018, consisting of proceeds of \$0.6 million from the sale of property and equipment.

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.

*Financing Activities.*

Net cash provided by financing activities was \$7.1 million during the six months ended June 30, 2018, consisting primarily of \$7.5 million of proceeds from the issuance of common stock through our at-the-market offering and the sale of \$0.4 million of common stock to Lummy HK, partially offset by \$0.8 million of debt amortization payments.

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 convertible note issued to Pharmstandard and \$0.3 million of proceeds from the issuance of common stock through our at-the-market offering.

### **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, a product candidate.

As of June 30, 2018, we had cash and cash equivalents of \$12.1 million. We do not currently have sufficient cash resources to pay all of our accrued obligations in full or to continue our business operations beyond the end of 2018. As a result, in order to continue to operate our business beyond that time, we will need to raise additional funds. However, there can be no assurance that we will be able to generate funds on terms acceptable to us, on a timely basis, or at all.

In light of the termination of the development of rocapuldencel-T, cessation of our research and development activities and our cash resources, and based on a review of the status of our internal programs, resources and capabilities, we are exploring a wide range of strategic alternatives that may include a potential merger or sale of our company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some or all of our assets or proprietary technologies, among other potential alternatives. There can be no assurance that we will be able to enter into a strategic transaction or transactions on a timely basis, on terms that are favorable to us, or at all. If we are unable to successfully conclude a strategic transaction in the near future, we expect that we will seek protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of our company. If we decide to seek protection under the bankruptcy laws, and if we decide to wind down the company under the bankruptcy laws or otherwise, it is unclear to what extent we will be able to pay our obligations to creditors, and, whether and to what extent any resources will be available for distributions to our stockholders. However, based on our current resources, we believe that it is unlikely that any resources will be available for distributions to our stockholders and that a likely outcome of our wind-down and potential bankruptcy proceeding will be the cancellation or extinguishment of all outstanding shares in the company without any payment or other distribution on account of those shares.

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

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

### **Critical Accounting Estimates**

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

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

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

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

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

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

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

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

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

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

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

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

#### **Contractual Obligations**

During the six months ended June 30, 2018, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

#### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

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

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

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

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

#### **Item 4. Controls and Procedures**

##### ***Evaluation of Disclosure Controls and Procedures***

Under the supervision of and with the participation of our management, including our chief executive officer, who is our principal executive officer, and our chief financial officer, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2018. The term “disclosure controls and procedures,” as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to 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 periods specified in the rules and forms promulgated by the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2018, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

### **Changes in Internal Control over Financial Reporting**

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

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

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

### **Item 1A. Risk Factors**

*Investing in our securities involves a high degree of risk. In addition to the information contained elsewhere in this report and under this Item 1A, you should carefully consider the factors discussed in "Part I, Item 1A. Risk Factors" in our Annual Report filed on Form 10-K for the year ended December 31, 2017, and any updates thereto contained in the Quarterly Report on form 10-Q for the period ending March 31, 2018, which could materially affect our business, financial condition or future results.*

**If we decide to seek protection under the bankruptcy laws, and if we decide to wind down the company under the bankruptcy laws or otherwise, risks and uncertainties associated with a potential bankruptcy proceeding and a wind-down may lead to adverse effects on recoveries for our stakeholders.**

Due to the risks and uncertainties associated with a potential bankruptcy proceeding and a wind-down of our company, we cannot assure our creditors or stockholders of any recovery, or any specific level of recovery, on their claims and interests if we determine to seek protection under the bankruptcy laws or wind down the company. Our wind-down and potential bankruptcy proceeding, and any distributions made in connection with our wind-down and bankruptcy proceeding, will be affected by a number of factors, including:

- the timing, duration, and cost of the wind-down and potential bankruptcy process;
- our ability to effectuate transactions, if any, in the course of our wind-down and potential bankruptcy proceeding, and the value to be realized in any such transactions;
- our ability to obtain bankruptcy court approval with respect to motions we file in the potential bankruptcy proceeding and the impact of bankruptcy court rulings on the case in general;
- motions and other papers filed by third parties in the bankruptcy proceeding, and the bankruptcy court's reaction to the same; and
- our ability to conclude the bankruptcy proceeding through a plan of liquidation or other means.

Notwithstanding these and other variables, based on our current resources, we believe that it is unlikely that any resources will be available for distributions to our stockholders and that a likely outcome of our wind-down and potential bankruptcy proceeding will be the cancellation or extinguishment of all outstanding shares in the company without any payment or other distribution on account of those shares.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

In January 2018, the Company entered into a stock purchase agreement with Lummy HK under which the Company agreed to issue and sell to Lummy HK in a private financing 375,000 shares of the Company's common stock for an aggregate purchase price of \$1.5 million. On March 23, 2018, the Company and Lummy HK amended the stock purchase agreement to reduce the aggregate price for the shares to \$450,000. Concurrent with such amendment, the Company entered into a third amendment to its license agreement with Lummy HK pursuant to which Lummy HK agreed to pay the Company a \$1.05 million milestone payment. During April, 2018, the Company received from Lummy HK \$450,000 for the purchase of the 375,000 shares and a \$1.05 million milestone payment. Based in part upon the representations of Lummy HK, the shares were issued and sold in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act") set forth in Section 4(a)(2) of the Securities Act. The securities have not been registered under the Securities Act or any state securities laws, and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from the registration requirements.

**Item 6. Exhibits**

**Exhibit**

**Number**

**Description of Exhibit**

---

<a href="#"><u>31.1*</u></a>	<a href="#"><u>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</u></a>
<a href="#"><u>31.2*</u></a>	<a href="#"><u>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</u></a>
<a href="#"><u>32.1#</u></a>	<a href="#"><u>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</u></a>
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.

**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 20, 2018

## 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.

Date: August 20, 2018

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

## 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.

Date: August 20, 2018

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

**CERTIFICATIONS PURSUANT TO 18 U.S.C. 1350**

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

(a) the Quarterly Report on Form 10-Q of the Company for the period ended June 30, 2018 filed on the date hereof with the Securities and Exchange Commission (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

August 20, 2018

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

August 20, 2018

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

