

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

Form 10-Q

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

For the quarterly period ended September 30, 2017

OR

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

For the transition period from to

Commission file number 001-35050

ENDOCYTE, INC.

(Exact name of Registrant as specified in its charter)

Delaware
*(State or other jurisdiction of
incorporation or organization)*

35-1969-140
*(I.R.S. Employer
Identification Number)*

**3000 Kent Avenue, Suite A1-100
West Lafayette, IN 47906**

(Address of Registrant's principal executive offices)

Registrant's telephone number, including area code: (765) 463-7175

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

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

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

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

Number of shares of the registrant's Common Stock, \$0.001 par value, outstanding on October 31, 2017: 47,881,033

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

**ENDOCYTE, INC.
CONDENSED BALANCE SHEETS**

	December 31, 2016	September 30, 2017
Assets		(unaudited)
Current assets:		
Cash and cash equivalents	\$ 31,228,192	\$ 47,178,505
Short-term investments	106,979,224	55,901,729
Receivables	55,074	27,746
Prepaid expenses	1,737,308	1,159,139
Other assets	255,912	125,435
Total current assets	140,255,710	104,392,554
Property and equipment, net	3,205,077	2,445,550
Other noncurrent assets	33,567	7,067
Total assets	\$ 143,494,354	\$ 106,845,171
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,381,545	\$ 395,046
Accrued wages and benefits	2,705,475	1,542,864
Accrued clinical trial expenses	861,293	1,360,587
Accrued expenses and other liabilities	613,861	1,048,764
Total current liabilities	5,562,174	4,347,261
Other liabilities, net of current portion	2,873	—
Deferred revenue, net of current portion	781,944	744,444
Total liabilities	6,346,991	5,091,705
Stockholders' equity:		
Common stock: \$0.001 par value, 100,000,000 shares authorized; 42,377,522 and 47,859,381 shares issued and outstanding at December 31, 2016 and September 30, 2017	42,378	47,860
Additional paid-in capital	390,768,742	402,100,682
Accumulated other comprehensive loss	(41,196)	(4,560)
Retained deficit	(253,622,561)	(300,390,516)
Total stockholders' equity	137,147,363	101,753,466
Total liabilities and stockholders' equity	\$ 143,494,354	\$ 106,845,171

See accompanying notes.

ENDOCYTE, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2017	2016	2017
	(unaudited)		(unaudited)	
Revenue:				
Collaboration revenue	\$ 32,500	\$ 32,500	\$ 57,500	\$ 57,500
Total revenue	32,500	32,500	57,500	57,500
Operating expenses:				
Research and development	5,985,230	4,089,677	19,304,124	20,739,170
General and administrative	2,987,168	3,011,176	14,201,399	10,061,722
Acquired in-process research and development	—	16,493,132	—	16,493,132
Total operating expenses	8,972,398	23,593,985	33,505,523	47,294,024
Loss from operations	(8,939,898)	(23,561,485)	(33,448,023)	(47,236,524)
Other income (expense), net:				
Interest income, net	232,240	264,932	629,289	734,065
Other income (expense), net	262	29,735	(4,062)	2,328
Net loss	(8,707,396)	(23,266,818)	(32,822,796)	(46,500,131)
Net loss per share – basic and diluted	\$ (0.21)	\$ (0.55)	\$ (0.78)	\$ (1.09)
Items included in other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	(64,606)	30,303	111,039	36,636
Other comprehensive income (loss)	(64,606)	30,303	111,039	36,636
Comprehensive loss	\$ (8,772,002)	\$ (23,236,515)	\$ (32,711,757)	\$ (46,463,495)
Weighted-average number of common shares used in net loss per share calculation – basic and diluted	42,263,311	42,636,567	42,184,182	42,525,693

See accompanying notes.

ENDOCYTE, INC.

CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Deficit	Total
	Shares	Amount				
Balances December 31, 2016	42,377,522	\$ 42,378	\$390,768,742	\$ (41,196)	\$(253,622,561)	\$ 137,147,363
Reclassification of impact of ASU 2016-09 (See Note 3)	—	—	267,824	—	(267,824)	—
Balances at January 1, 2017	42,377,522	\$ 42,378	\$391,036,566	\$ (41,196)	\$(253,890,385)	\$ 137,147,363
Exercise of stock options	52,258	52	109,690	—	—	109,742
Issuance of common stock in connection with development and license agreement	2,000,000	2,000	2,818,000	—	—	2,820,000
Issuance of common stock in connection with exercise of warrant to purchase common stock	3,278,000	3,278	5,501,925	—	—	5,505,203
Stock-based compensation	114,365	115	2,586,131	—	—	2,586,246
Employee stock purchase plan	37,236	37	48,370	—	—	48,407
Net loss	—	—	—	—	(46,500,131)	(46,500,131)
Unrealized gain on securities	—	—	—	36,636	—	36,636
Balances September 30, 2017	47,859,381	\$ 47,860	\$402,100,682	\$ (4,560)	\$(300,390,516)	\$ 101,753,466

See accompanying notes.

ENDOCYTE, INC.

CONDENSED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,	
	2016	2017
	(unaudited)	
Operating activities		
Net loss	\$ (32,822,796)	\$ (46,500,131)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	679,675	701,133
Stock-based compensation	7,889,999	2,680,873
Acquired in-process research and development	—	16,493,132
Loss on disposal of property and equipment	—	114,042
Accretion of bond premium	331,881	1,399
Change in operating assets and liabilities:		
Receivables	170,934	157,805
Prepaid expenses and other assets	(490,175)	770,892
Accounts payable	104,079	(1,160,801)
Accrued wages, benefits and other liabilities	(1,933,414)	(633,288)
Deferred revenue	(37,500)	(37,500)
Net cash used in operating activities	<u>(26,107,317)</u>	<u>(27,412,444)</u>
Investing activities		
Purchases of property and equipment	(664,673)	(46,833)
Purchases of investments	(114,900,851)	(51,318,003)
Purchase of acquired in-process research and development	—	(12,322,349)
Proceeds from sale and maturities of investments	160,865,053	102,430,000
Net cash provided by investing activities	<u>45,299,529</u>	<u>38,742,815</u>
Financing activities		
Stock repurchase	(158,283)	(94,627)
Proceeds from exercise of warrant to purchase common stock	—	4,556,420
Proceeds from the exercise of stock options	129,306	109,742
Proceeds from stock purchases under employee stock purchase plan	137,925	48,407
Net cash provided by financing activities	<u>108,948</u>	<u>4,619,942</u>
Net increase in cash and cash equivalents	19,301,160	15,950,313
Cash and cash equivalents at beginning of period	15,431,622	31,228,192
Cash and cash equivalents at end of period	<u>\$ 34,732,782</u>	<u>\$ 47,178,505</u>

See accompanying notes.

ENDOCYTE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

1. Nature of Business and Organization

Endocyte, Inc. (the "Company") is a biopharmaceutical company and leader in developing targeted therapies for the treatment of cancer. The Company uses drug conjugation technology to create novel therapeutics and companion imaging agents for personalized targeted therapies. The Company's agents actively target receptors that are over-expressed on diseased cells relative to healthy cells, such as prostate specific membrane antigen ("PSMA"), in prostate cancer. This targeted approach is designed to safely enable the delivery of highly potent drug payloads. The companion imaging agents are designed to identify patients whose disease over-expresses the target of the therapy and who are therefore more likely to benefit from treatment.

In June 2017, the Company ended clinical development of EC1456 and stopped enrollment in its EC1456 phase 1b trial as the assessment of trial data did not yield the level of clinical activity necessary to support continued advancement of EC1456. The Company is, however, continuing enrollment of a small number of patients in its EC1456 ovarian cancer surgical trial. In addition, in June 2017, the Company narrowed the focus of its EC1169 development program, refocused its efforts on pre-clinical programs, and reduced its workforce by approximately 40% to align resources to focus on the Company's highest value opportunities while maintaining key capabilities.

In September 2017, the Company entered into a Development and License Agreement (the "License Agreement") with ABX advanced biochemical compounds – Biomedizinische Forschungsreagenzien GmbH ("ABX"), pursuant to which the Company acquired exclusive worldwide rights to develop and commercialize PSMA-617 agents, including the product candidate known as ¹⁷⁷Lu-PSMA-617, a radioligand therapeutic ("RLT"). The Company intends to seek regulatory approval to initiate, in the first half of 2018, a phase 3 clinical trial of ¹⁷⁷Lu-PSMA-617 in patients with metastatic castration-resistant prostate cancer ("mCRPC").

2. Significant Accounting Policies

Basis of Presentation

The accompanying condensed financial statements are prepared in conformity with U.S. generally accepted accounting principles ("GAAP") for interim financial information to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the accompanying condensed financial statements have been included. Interim results for the three and nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2017 or any other future period. These condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016. Subsequent events have been evaluated through the date of issuance, which is the same as the date this Form 10-Q is filed with the Securities and Exchange Commission.

Segment Information

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. All long-lived assets are held in the U.S. The Company views its operations and manages its business in one operating segment.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual amounts may differ from those estimates.

Cash and Cash Equivalents

The Company considers cash and all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents consist primarily of money market instruments, U.S. government treasury obligations, corporate debt securities and repurchase agreements that are maintained by an investment manager.

Investments

Investments consist primarily of investments in U.S. Treasuries and corporate debt securities, which could also include commercial paper, that are maintained by an investment manager. Management determines the appropriate classification of marketable securities at the time of purchase and reevaluates such classification as of each balance sheet date. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in other income. The Company considers and accounts for other-than-temporary impairments according to the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 320, *Investments — Debt and Equity Securities* ("ASC 320"). The cost of securities sold is based on the specific-identification method. Discounts and premiums on debt securities are amortized to interest income and expensed over the term of the security.

Revenue Recognition

The Company recognizes revenues from license and collaboration agreements when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the fee is fixed or determinable, and there is reasonable assurance that the related amounts are collectible in accordance with ASC Topic 605, *Revenue Recognition* ("ASC 605"). The Company's license and collaboration agreements may contain multiple elements, including grants of licenses to intellectual property rights, agreement to provide research and development services and other deliverables. The deliverables under such arrangements are evaluated under ASC Subtopic 605-25, *Multiple-Element Arrangements* ("ASC 605-25"). Under ASC 605-25, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has "stand-alone value" to the customer. The arrangement's consideration that is fixed or determinable, excluding contingent milestone payments and royalties, is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables.

Upfront payments for licensing the Company's intellectual property are evaluated to determine if the licensee can obtain stand-alone value from the license separate from the value of the research and development services and other deliverables in the arrangement to be provided by the Company. If at the inception of an arrangement the Company determines that the license does not have stand-alone value separate from the research and development services or other deliverables, the license, services and other deliverables are combined as one unit of account and upfront payments are recorded as deferred revenue on the balance sheet and are recognized in a manner consistent with the final deliverable. Subsequent to the inception of an arrangement, the Company evaluates the remaining deliverables for separation as items in the arrangement are delivered. When stand-alone value is identified, the related consideration is recorded as revenue in the period in which the license or other intellectual property rights are delivered.

In those circumstances where research and development services or other deliverables are combined with the license, and multiple services are being performed such that a common output measure to determine a pattern of performance cannot be discerned, the Company recognizes amounts received on a straight line basis over the performance period. Such amounts are recorded as collaboration revenue. Any subsequent reimbursement payments, which are contingent upon the Company's future research and development expenditures, will be recorded as collaboration revenue and will be recognized on a straight-line basis over the performance period using the cumulative catch up method. The costs associated with these activities are reflected as a component of research and development expense in the statements of operations in the period incurred. In the event of an early termination of a collaboration agreement, any deferred revenue is recognized in the period in which all obligations of the Company under the agreement have been fulfilled.

Milestone payments under collaborative arrangements are triggered either by the results of the Company's research and development efforts, achievement of regulatory goals or by specified sales results by a third-party collaborator. Milestones related to the Company's development-based activities may include initiation of various phases of clinical trials and applications and acceptance for product approvals by regulatory agencies. Due to the uncertainty involved in meeting these development-based milestones, the determination is made at the inception of the collaboration agreement whether the development-based milestones are considered to be substantive (i.e. not just achieved through passage of time). In addition, the amounts of the payments assigned thereto are considered to be commensurate with the enhancement of the value of the delivered intellectual property as a result of the Company's performance. Because the Company's involvement is necessary to the achievement of development-based milestones, the Company would account for development-based milestones as revenue upon achievement of the substantive milestone events. Milestones related to sales-based activities may be triggered upon events such as first commercial sale of a product or when sales first achieve a defined level. Since these sales-based milestones would be achieved after the completion of the Company's development activities, the Company would account for the sales-based milestones in the same manner as royalties, with revenue recognized upon achievement of the milestone. Royalties based on reported sales of licensed products will be recognized based on contract terms when reported sales are reliably measurable and collectability is reasonably assured. To date, none of the Company's products have been approved and therefore the Company has not earned any royalty revenue from product sales. In territories where the Company and a collaborator may share profit, the revenue would be recorded in the period earned.

The Company often is required to make estimates regarding drug development and commercialization timelines for compounds being developed pursuant to a collaboration agreement. Because the drug development process is lengthy and the Company's collaboration agreements typically cover activities over several years, this approach often results in the deferral of significant amounts of revenue into future periods. In addition, because of the many risks and uncertainties associated with the development of drug candidates, the Company's estimates regarding the period of performance may change in the future. Any change in the Company's estimates or a termination of the arrangement could result in substantial changes to the period over which the revenues are recognized.

Research and Development Expenses

Research and development expenses represent costs associated with the ongoing development of novel therapeutics and companion imaging agents for personalized targeted therapies and include salaries and employee benefits, supplies, facility costs related to research activities, and expenses for clinical trials. The Company records accruals for clinical trial expenses based on the estimated amount of work completed. The Company monitors patient enrollment levels and related activities to the extent possible through internal reviews, correspondence, and discussions with research organizations. In the event that a clinical trial is terminated early, the Company records, in the period of termination, an accrual for the estimated remaining costs to complete and close out the trial pursuant to ASC Topic 420, *Exit or Disposal Cost Obligations*, as a terminated trial does not provide any future economic benefit to the Company. See Note 10 – Restructuring Costs of the Notes to Condensed Financial Statements contained herein for costs incurred during the three and nine months ended September 30, 2017 related to the Company's restructuring activities in June 2017.

Upfront payments made in connection with business collaborations and research and development arrangements are evaluated under ASC Subtopic 730-20, *Research and Development Arrangements*. Amounts related to future research and development are capitalized as prepaid research and development and are expensed over the service period based upon the level of services provided. As of September 30, 2017, the Company had approximately \$0.2 million of capitalized research and development costs included in prepaid expenses.

Acquired In-Process Research and Development Expense

The Company has acquired and may continue to acquire the rights to develop and commercialize new drug candidates. In accordance with ASC Subtopic 730-25, *Accounting for Research and Development Costs*, the up-front payments to acquire a new drug compound, as well as future milestone payments when paid or payable, are immediately expensed as acquired in-process research and development ("IPR&D") in transactions other than a business combination provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Upon obtaining regulatory approval for marketing, any related milestone payments may be capitalized and amortized over the life of the asset.

Stock-Based Compensation

The Company accounts for its stock-based compensation pursuant to ASC Topic 718, *Compensation — Stock Compensation* (“ASC 718”), which requires the recognition of the fair value of stock-based compensation in net income. Stock-based compensation consists of stock options, which are granted at exercise prices at or above the fair market value of the Company’s common stock on the dates of grant, service-based restricted stock units (“RSUs”), performance-based RSUs (“PRSUs”), and shares available for purchase under the Company’s 2010 Employee Stock Purchase Plan (“ESPP”). For PRSUs issued by the Company, stock-based compensation expense would be recognized if and when the Company determines that it is probable that the performance conditions will be achieved. For RSUs and stock options issued by the Company, stock-based compensation expense is recognized ratably over the service period. The Company recognizes compensation cost based on the grant-date fair value estimated in accordance with the provisions of ASC 718.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method and the if-converted method. For purposes of this calculation, stock options, warrants, PRSUs, RSUs and shares to be purchased under the ESPP are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Common stock equivalents

As of September 30, 2016 and 2017, the following number of potential common stock equivalents were outstanding:

	As of September 30,	
	2016	2017
Outstanding common stock options	6,544,738	6,265,333
Outstanding warrants	34,647	756,647
Outstanding RSUs	414,018	478,087
Shares to be purchased under the ESPP	34,853	18,323
Total	<u>7,028,256</u>	<u>7,518,390</u>

These common stock equivalents were excluded from the determination of diluted net loss per share due to their anti-dilutive effect on earnings. The increase in outstanding warrants is due to warrants issued in connection with the License Agreement. For additional information on the outstanding warrants, see Note 8 – Warrants of the Notes to Condensed Financial Statements contained herein.

3. New Accounting Pronouncements

Recently Issued Accounting Standards

In January 2017, the FASB issued Accounting Standards Update (“ASU”) 2017-01, *Clarifying the Definition of a Business*, an update to ASC Topic 805, *Business Combinations*. This guidance is intended to clarify the definition of a business as it relates to the evaluation of whether a set of transferred assets and activities are accounted for as a business combination or as an asset acquisition. This update was effective for the Company in the three and nine months ended September 30, 2017, as the Company elected early adoption. As a result, the Company considered ASU 2017-01 when evaluating the License Agreement. In the three and nine months ended September 30, 2017, the Company determined that the set of transferred assets and activities included in the License Agreement did not meet the definition of a business and accounted for the License Agreement as an asset acquisition. The adoption of this guidance did not have a material impact on the Company’s financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, an update to ASC Topic 718, *Stock Compensation*. This guidance involves improving several aspects of the accounting for share-based payment transactions, including classification of awards as either equity or liabilities, classification on the

statement of cash flows, the method of accounting for forfeitures and requiring entities to recognize all income tax effects of awards in the income statement when the awards vest or are settled. This update was effective for the Company for interim and annual reporting periods beginning January 1, 2017. In the nine months ended September 30, 2017, the Company adopted this guidance using the modified retrospective method. As a result, the Company has elected to account for forfeitures as they occur and no longer estimates the number of awards expected to be forfeited. The cumulative effect related to the change in accounting for forfeitures was a \$0.3 million increase to the opening balance of retained deficit at January 1, 2017. Additionally, as a result of the adoption, the Company recognized the excess tax benefits of awards that have vested or settled that had previously not been recognized as the related tax deduction had increased the Company's net operating loss carryforward. The Company determined, consistent with its accounting for existing net operating losses, that a full valuation allowance was required for the excess tax benefits. As such, the Company recognized an increase in its net operating loss carryforward deferred tax asset of \$1.7 million and the valuation allowance against the net operating loss carryforward was also increased by \$1.7 million, which resulted in no impact to the financial statements. The adoption of this guidance did not have a material impact on the Company's financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*, an update to ASC Topic 842, *Leases*. This guidance requires lessees to recognize leases as assets and liabilities on their balance sheets but recognize expenses on their income statements in a manner similar to the current accounting guidance. For lessors, the guidance also modifies the classification criteria and the accounting for sales-type and direct finance leases. This update is effective for the Company for interim and annual reporting periods beginning January 1, 2019 unless it elects early adoption. The Company is currently evaluating the impact, if any, the adoption of this guidance will have on its financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606), to clarify the principles used to recognize revenue for all entities. Under ASU 2014-09, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In order to do so, an entity would follow the five-step process for in-scope transactions: 1) identify the contract with a customer, 2) identify the separate performance obligations in the contract, 3) determine the transaction price, 4) allocate the transaction price to the separate performance obligations in the contract, and 5) recognize revenue when (or as) the entity satisfies a performance obligation. In August 2015, the FASB issued ASU 2015-14, which defers the effective date of ASU 2014-09 by one year. Therefore, ASU 2014-09 will become effective for the Company for interim and annual reporting periods beginning after December 15, 2017. Early adoption is permitted, but not any earlier than the original effective date of December 15, 2016. An entity can apply the new revenue standard retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings. In April 2016, the FASB issued ASU 2016-10, an update to Topic 606, which clarifies how entities should identify performance obligations and evaluate licensing. In May 2016, the FASB issued ASU 2016-12, an update to Topic 606, which clarifies guidance on transition, collectability, noncash consideration and the presentation of sales and other similar taxes. In December 2016, the FASB issued ASU 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*, which affects narrow aspects of the guidance issued in ASU 2014-09. The Company currently has a limited number of contracts with customers and only one revenue stream, which relates to collaboration and licensing arrangements, and which represents all of the revenue earned in the three and nine months ended September 30, 2017. While the Company has begun the review of its collaboration and licensing arrangements, it is not yet able to estimate the anticipated impact of the adoption of the new standard to its financial statements. The Company will continue to evaluate the impact, if any, the adoption of this guidance will have on its financial statements.

4. Other Comprehensive Income (Loss)

The following tables summarize the accumulated balances related to each component of other comprehensive income (loss) for three months ended September 30, 2016 and 2017:

	Unrealized Net Gains (Losses) on Securities	Accumulated Other Comprehensive Gains (Losses)
Balance at June 30, 2016	\$ 96,246	\$ 96,246
Unrealized loss	(65,901)	(65,901)
Net amount reclassified to net loss	1,295	1,295
Other comprehensive loss	(64,606)	(64,606)
Balance at September 30, 2016	<u>\$ 31,640</u>	<u>\$ 31,640</u>

	Unrealized Net Gains (Losses) on Securities	Accumulated Other Comprehensive Gains (Losses)
Balance at June 30, 2017	\$ (34,863)	\$ (34,863)
Unrealized gain	30,303	30,303
Net amount reclassified to net loss	—	—
Other comprehensive income	30,303	30,303
Balance at September 30, 2017	<u>\$ (4,560)</u>	<u>\$ (4,560)</u>

The following tables summarize the accumulated balances related to each component of other comprehensive income for the nine months ended September 30, 2016 and 2017:

	Unrealized Net Gains (Losses) on Securities	Accumulated Other Comprehensive Gains (Losses)
Balance at December 31, 2015	\$ (79,399)	\$ (79,399)
Unrealized gain	109,744	109,744
Net amount reclassified to net loss	1,295	1,295
Other comprehensive income	111,039	111,039
Balance at September 30, 2016	<u>\$ 31,640</u>	<u>\$ 31,640</u>

	Unrealized Net Gains (Losses) on Securities	Accumulated Other Comprehensive Gains (Losses)
Balance at December 31, 2016	\$ (41,196)	\$ (41,196)
Unrealized gain	36,636	36,636
Net amount reclassified to net loss	—	—
Other comprehensive income	36,636	36,636
Balance at September 30, 2017	<u>\$ (4,560)</u>	<u>\$ (4,560)</u>

5. Investments

The Company applies the fair value measurement and disclosure provisions of ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC 820"). ASC 820, which defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. Investments consist primarily of investments with original maturities greater than three months, but no longer than 24 months when purchased.

ASC 820 establishes a three-level valuation hierarchy for fair value measurements. These valuation techniques are based upon the transparency of inputs (observable and unobservable) to the valuation of an asset or liability as of the measurement date. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company's market assumptions. These two types of inputs create the following fair value hierarchy:

Level 1 — Valuation is based on quoted prices for identical assets or liabilities in active markets.

Level 2 — Valuation is based on quoted prices for similar assets or liabilities in active markets, or other inputs that are observable for the asset or liability, either directly or indirectly, for the full term of the financial instrument.

Level 3 — Valuation is based upon other unobservable inputs that are significant to the fair value measurement.

The fair value of the Company's fixed income securities is based on a market approach using quoted market values.

The following table summarizes the fair value of cash and cash equivalents and investments as of December 31, 2016:

Description	Cost	Level 1	Level 2	Fair Value (Carrying Value)
Cash				
Cash	\$ 6,249,703	\$ 6,249,703	\$ —	\$ 6,249,703
Cash equivalents (original maturity of 3 months or less)				
FDIC insured deposits and money market funds	24,978,489	24,978,489	—	24,978,489
Cash and cash equivalents	\$ 31,228,192	\$ 31,228,192	\$ —	\$ 31,228,192
Short-term investments (due within 1 year)				
U.S. government treasury obligations	\$ 86,078,622	\$ 86,053,755	\$ —	\$ 86,053,755
Corporate obligations	20,941,799	—	20,925,469	20,925,469
Total short-term investments	\$ 107,020,420	\$ 86,053,755	\$ 20,925,469	\$ 106,979,224

The following table summarizes the fair value of cash and cash equivalents and investments as of September 30, 2017:

Description	Cost	Level 1	Level 2	Fair Value (Carrying Value)
Cash				
Cash	\$ 6,110,170	\$ 6,110,170	\$ —	\$ 6,110,170
Cash equivalents (original maturity of 3 months or less)				
Repurchase agreements	15,000,000	—	15,000,000	15,000,000
Money market funds	14,573,254	14,573,254	—	14,573,254
U.S. government treasury obligations	9,495,984	9,496,720	—	9,496,720
Corporate obligations	1,998,361	—	1,998,361	1,998,361
Cash and cash equivalents	\$ 47,177,769	\$ 30,180,144	\$ 16,998,361	\$ 47,178,505
Short-term investments (due within 1 year)				
U.S. government treasury obligations	\$ 36,957,883	\$ 36,953,105	\$ —	\$ 36,953,105
Corporate obligations	18,949,143	—	18,948,624	18,948,624
Total short-term investments	\$ 55,907,026	\$ 36,953,105	\$ 18,948,624	\$ 55,901,729

All securities held at December 31, 2016 and September 30, 2017, were classified as available-for-sale as defined by ASC 320.

Total unrealized gross gains were \$8,257 and \$2,623 as of December 31, 2016 and September 30, 2017, respectively. Total unrealized gross losses were \$49,453 and \$7,183 as of December 31, 2016 and September 30, 2017, respectively. The Company does not consider any of the unrealized losses to be other-than-temporary impairments because the Company has the intent and ability to hold investments until they recover in value. Total realized gross losses were \$53 for the three and nine months ended September 30, 2016. There were no total realized gross gains for the three or nine months ended September 30, 2016. There were no total realized gross gains or total realized gross losses for the three or nine months ended September 30, 2017.

6. Collaboration and Other Arrangements

ABX Development and License Agreement

In September 2017, the Company entered into the License Agreement with ABX that grants the Company exclusive worldwide rights to develop and commercialize PSMA-617 agents. Under the terms of the License Agreement, the Company will be responsible for, and bear the future costs of, worldwide development and commercialization of PSMA-617. As consideration for the exclusive license, the Company made an upfront cash payment on September 29, 2017 of approximately \$11.9 million to ABX, consisting of \$12.0 million less an immaterial expense reimbursement amount, and issued to ABX 2,000,000 shares of the Company's common stock (see Note 7 – Stockholders' Equity (Deficit) of the Notes to Condensed Financial Statements for additional information regarding this issuance) and two warrants to purchase, in the aggregate, 4,000,000 shares of the Company's common stock (see Note 8 – Warrants of the Notes to Condensed Financial Statements for additional information regarding the warrants). The License Agreement also obligates the Company to pay ABX regulatory milestone payments of up to \$25.0 million, sales milestone payments of up to \$135.0 million, and tiered royalties, beginning in the mid-teens and not to exceed the mid-twenties, based on percentages of net sales.

The Company has accounted for the License Agreement as an asset acquisition and as a result, the upfront payment was expensed in the three months ended September 30, 2017 as acquired IPR&D expense. Any future regulatory milestone payments when paid or payable will be expensed as acquired IPR&D, provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. If the Company obtains regulatory approval for marketing for ¹⁷⁷Lu-PSMA-617 or any other PSMA-617 agents, any related milestone payments may be capitalized as an intangible asset and amortized over the life of the asset. The Company recorded \$16.5 million of acquired IPR&D expenses related to the License Agreement for the three months ended September 30, 2017 consisting of the following:

- \$12.0 million related to the upfront payment to ABX;
- \$3.8 million related to the fair value of common stock and warrant shares issued; and
- \$0.7 million of acquisition costs consisting primarily of legal and professional fees.

The Company intends to seek regulatory approval to initiate, in the first half of 2018, a phase 3 clinical trial of ¹⁷⁷Lu-PSMA-617 in patients with mCRPC. In October 2017, the Company entered into an agreement with RadioMedix, Inc., a biotechnology company focused on innovative targeted radiopharmaceuticals for diagnosis, monitoring and therapy of cancer, which enables the transfer of a U.S. Investigational New Drug application of ¹⁷⁷Lu-PSMA-617 from the current sponsor, RadioMedix, to the Company.

In addition, under a three-party agreement, entered into in October 2017, among the Company, the University of Sydney (the "University") and ANZUP, a cooperative cancer trials group operating in Australia and New Zealand pursuing research in genito-urinary malignancies, ANZUP will sponsor and undertake jointly with the University a randomized phase 2 multi-center TheraP trial of ¹⁷⁷Lu-PSMA-617 versus cabazitaxel in 200 mCRPC patients. Under the three-party agreement, the Company will provide the PSMA-617 precursor molecule and financial support for the trial. The Company will have access to data generated from the trial, which is a potentially important supportive trial for future regulatory submissions. The primary financial obligations of the trial, along with labeling PSMA-617 with Lutetium-177, will be the responsibility of the University and ANZUP.

NMP License and Commercialization Agreement

In August 2013, the Company entered into a license and commercialization agreement with Nihon Medi-Physic Co., LTD. ("NMP") that grants NMP the right to develop and commercialize etarfolatide in Japan for use in connection with any folate receptor-targeted SMDC in Japan. The Company received a \$1.0 million non-refundable upfront payment, is eligible for up to \$4.5 million based on the successful achievement of regulatory goals for etarfolatide in five different cancer indications and is eligible to receive double-digit percentage royalties on sales of etarfolatide in Japan.

For revenue recognition purposes, the Company viewed the agreement with NMP as a multiple element arrangement. Multiple element arrangements are analyzed to determine whether the various performance obligations, or elements, can be separated or whether they must be accounted for as a single unit of accounting. The Company has identified the deliverables related to the collaboration with NMP, which include the license granted to NMP, as well as the obligation to provide pre-clinical and clinical supply of etarfolatide, to provide rights to NMP if a product is developed that replaces etarfolatide, the obligation for the Company to provide clinical data to NMP during the contract period and the coordination of development and commercialization efforts between the Company for any folate receptor-targeted SMDC, and NMP for etarfolatide in Japan. The Company's deliverables will be accounted for as a single unit of account, therefore the non-refundable upfront payment is being recognized on a straight-line basis over the performance period. This determination was made because the successful development of etarfolatide in Japan requires the ongoing participation by the Company, including the development of the related folate receptor-targeted SMDC therapeutic drug. The performance period over which the revenue will be recognized continues from the date of execution of the agreement through the end of 2033, the estimated termination date of the contract which is when the Company's performance obligations will be completed. Any significant changes in the timing of the performance period could result in a change in the revenue recognition period. The Company had deferred revenue related to the agreement of approximately \$0.8 million at September 30, 2017. Subsequent to the inception of the NMP arrangement, the Company evaluates the remaining deliverables for separation as items in the arrangement are delivered.

The arrangement with NMP includes milestone payments of up to approximately \$4.5 million and the milestones are based on the commencement of clinical trials in Japan for specific and non-specific indications and filing for approval in Japan for specific and non-specific indications. The Company evaluated each of these milestone payments and believes that all of the milestones are substantive as there is substantial performance risk that must occur in order for them to be met because the Company must complete additional clinical trials which show a positive outcome or receive approval from a regulatory authority and would be commensurate with the enhancement of value of the underlying intellectual property. To date, the products have not been approved in Japan and no revenue has been recognized related to the regulatory milestones or royalties as continued development of any folate receptor-targeted SMDC is still an opportunity that the Company could pursue in the future.

NMP has the right to terminate the collaboration agreement on 90 days notice prior to the first commercial sale in Japan and six months notice after the first commercial sale in Japan. NMP also has the right to terminate the agreement on six months notice if the Company fails to launch any folate receptor-targeted SMDC therapeutic drug after receiving regulatory approval in Japan. NMP and the Company each have the right to terminate the agreement due to the material breach or insolvency of the other party. Upon termination of the agreement depending on the circumstances, the parties have varying rights and obligations with respect to licensing and related regulatory materials and data.

7. Stockholders' Equity (Deficit)

Issuances Related to the License Agreement

In connection with the License Agreement, the Company issued to ABX on September 29, 2017, 2,000,000 unregistered shares of the Company's common stock and two warrants to purchase up to 4,000,000 shares of the Company's common stock, one of which warrants to purchase 3,278,000 shares was exercised on that same day. Pursuant to a Registration Rights Agreement entered into with ABX, the Company was required to file, within 45 days of September 29, 2017, a registration statement with U.S. Securities and Exchange Commission (the "SEC") to register the resale of the 6,000,000 shares of common stock issued on September 29, 2017 or issuable pursuant to the warrants issued to ABX, and to use its commercially reasonable efforts to cause the registration statement to be declared effective by the SEC as soon as practicable. On October 12, 2017, the Company filed a Registration Statement on Form S-3, which was declared effective by the SEC on October 24, 2017.

Stock-Based Compensation Plans

The Company has had stock-based compensation plans since 1997. The awards made under the plans adopted in 1997 and 2007 consisted of stock options. The 2010 Equity Incentive Plan (the "2010 Plan"), which is the only plan under which awards may currently be made, authorizes awards in the form of stock options, stock appreciation rights, restricted stock, RSUs, PRSUs and performance units and performance shares. Awards under the 2010 Plan may be made to employees, directors and certain consultants as determined by the compensation committee of the board of directors. There were 11,003,563 and 11,850,563 shares of common stock authorized and reserved under these plans at December 31, 2016 and September 30, 2017, respectively.

Stock Options

Under the various plans, employees have been granted incentive stock options, while directors and consultants have been granted non-qualified options. The plans allow the holder of an option to purchase common stock at the exercise price, which was at or above the fair value of the Company's common stock on the date of grant.

Generally, options granted under the 1997 and 2007 plans in connection with an employee's commencement of employment vested over a four-year period with one-half of the shares subject to the grant vesting after two years of employment and remaining options vesting monthly over the remainder of the four-year period. Options granted under the 1997 and 2007 plans for performance or promotions vested monthly over a four-year period. Generally, options granted under the 2010 Plan vest annually over a three-year or four-year period. Unexercised stock options terminate on the tenth anniversary date after the date of grant. The Company recognizes stock-based compensation expense over the requisite service period of the individual grantees, which generally equals the vesting period. The Company utilizes a Black-Scholes option-pricing model to estimate the value of stock options. The Black-Scholes model allows the use of a range of assumptions related to volatility, risk-free interest rate, employee exercise behavior and dividend yield. Expected volatilities used in the model beginning in 2015 are based on historical volatility of the Company's stock prices.

The Company is using the "simplified" method for "plain vanilla" options to estimate the expected term of the stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option. The risk-free interest rate assumption is derived from the weighted-average yield of a U.S. Treasury security with the same term as the expected life of the options, and the dividend yield assumption is based on historical experience and the Company's estimate of future dividend yields.

The weighted-average value of the individual options granted during the three and nine months ended September 30, 2016 and the nine months ended September 30, 2017 were determined using the following assumptions. There were no options granted during the three months ended September 30, 2017.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2017	2016	2017
Expected volatility	95.9 %	—	99.0 %	92.7 %
Risk-free interest rate	1.27 %	—	1.47 %	2.15 %
Weighted-average expected life (in years)	6.3	—	6.6	6.9
Dividend yield	0.00 %	—	0.00 %	0.00 %

The Company's stock option activity and related information are summarized as follows:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value ⁽¹⁾
Outstanding at January 1, 2017	6,447,594	\$ 6.41		
Granted during period	653,842	2.17		
Exercised during period	(7,757)	2.10		
Expired during period	(163,836)	8.82		
Forfeited during period	(68,875)	5.59		
Outstanding at March 31, 2017	6,860,968	\$ 5.96	6.27	\$ 282,786
Exercisable at March 31, 2017	5,085,833	\$ 6.72	5.33	\$ 29,895
Outstanding at April 1, 2017	6,860,968	5.96		
Granted during period	198,350	2.27		
Exercised during period	(44,501)	2.10		
Expired during period	(123,874)	8.41		
Forfeited during period	(225,402)	4.15		
Outstanding at June 30, 2017	6,665,541	\$ 5.89	6.09	\$ —
Exercisable at June 30, 2017	5,083,084	\$ 6.63	5.22	\$ —
Outstanding at July 1, 2017	6,665,541	5.89		
Granted during period	—	—		
Exercised during period	—	—		
Expired during period	(336,625)	7.08		
Forfeited during period	(63,583)	4.71		
Outstanding at September 30, 2017	6,265,333	\$ 5.84	5.83	\$ —
Exercisable at September 30, 2017	4,770,246	6.59	4.94	—

- (1) The aggregate intrinsic value of the stock options was calculated by identifying those stock options that had a lower exercise price than the closing market price of our common stock on the applicable date and multiplying the difference between the closing market price of our common stock and the exercise price of each of those stock options by the number of shares subject to those stock options that were outstanding or exercisable, as applicable. Since the closing market price of our common stock on June 30, 2017 and September 30, 2017 was lower than the exercise price of all outstanding stock options and exercisable stock options as of those dates, the aggregate intrinsic value of those stock options was zero.

As of September 30, 2017, the total remaining unrecognized compensation cost related to stock options granted was \$2.6 million, which is expected to be recognized over a weighted average period of approximately 1.5 years.

Restricted Stock Units

In May 2011, the Company adopted and granted awards under a performance-based RSU program (the "2011 PRSU Program") under the 2010 Plan. All PRSU awards expired in the second quarter of 2016 when the performance deadline of May 26, 2016 passed.

RSUs are service-based awards that will vest and be paid in the form of one share of the Company's common stock for each RSU, generally in two, three or four equal annual installments beginning on the first anniversary of the date of grant of an RSU. As of September 30, 2017, the Company had 478,087 RSU awards outstanding. As of September 30, 2017, the total remaining unrecognized compensation cost related to RSUs was \$1.0 million, which is expected to be recognized over a weighted average period of approximately 1.6 years.

The following table sets forth the number of RSUs that were granted, vested and forfeited in the periods indicated:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2017	394,132	\$ 4.96
Granted during period	367,985	2.17
Vested during period	(128,225)	5.77
Forfeited during period	(16,980)	3.50
Outstanding at March 31, 2017	<u>616,912</u>	\$ 3.17
Outstanding at April 1, 2017	616,912	\$ 3.17
Granted during period	26,400	2.27
Vested during period	(23,950)	3.25
Forfeited during period	(94,569)	3.06
Outstanding at June 30, 2017	<u>524,793</u>	\$ 3.14
Outstanding at July 1, 2017	524,793	\$ 3.14
Granted during period	—	—
Vested during period	(5,937)	4.85
Forfeited during period	(40,769)	3.20
Outstanding at September 30, 2017	<u>478,087</u>	\$ 3.11

On October 4, 2017, the Company granted approximately 890,000 RSUs to employees at a weighted-average grant date fair value of \$6.10 per RSU.

Employee Stock Purchase Plan

At January 1, 2017, 825,154 common shares were available for issuance under the ESPP. Shares may be issued under the ESPP twice a year. In the nine months ended September 30, 2017, plan participants purchased 37,236 shares of common stock under the ESPP at an average purchase price of \$1.30 per share. There were no purchases in the three months ended September 30, 2017. At September 30, 2017, there were 787,918 common shares available for issuance under the ESPP.

8. Warrants

In connection with the License Agreement, the Company issued to ABX on September 29, 2017, two warrants to purchase up to 4,000,000 shares of the Company's common stock, at a per share exercise price of \$1.39, which is equal to the average closing price of the Company's common stock during the 30 calendar days prior to September 29, 2017. The Company accounted for the warrants at fair value in stockholders' equity. The warrants contain a conversion feature in the case of certain mergers or consolidations by the Company. Immediately upon issuance, ABX assigned the warrants to an affiliate and certain related parties, which exercised a warrant for 3,278,000 shares on September 29, 2017, resulting in proceeds to the Company in the amount of approximately \$4.6 million. The remaining warrant, covering an aggregate of 722,000 shares, remained outstanding as of September 30, 2017, is exercisable until September 29, 2027, and is subject to restrictions on transfer. This warrant was valued using the Black-Scholes model utilizing a ten-year term, the Company's historic volatility of 91.1%, and an interest rate of 2.28% which is the risk free interest rate of a treasury bond with the same term as the warrants.

As of September 30, 2017, there was also outstanding a separate warrant to purchase 34,647 shares of the Company's common stock, exercisable on or before December 31, 2017 at an exercise price per share of \$8.12. This warrant does not contain a conversion feature.

9. Income Taxes

The Company accounts for income taxes under the liability method in accordance with the provisions of ASC Topic 740, *Income Taxes*. The Company recognizes future tax benefits, such as net operating losses, to the extent those benefits are expected to be realized in future periods. Due to uncertainty surrounding the realization of its deferred tax assets, the Company has recorded a valuation allowance against its net deferred tax assets. The Company experienced a change in ownership as defined under Section 382 of the U.S. Internal Revenue Code (the "Code") in August 2011. As a result, the future use of its net operating losses and credit equivalents is currently limited to approximately \$218.7 million for 2017. Any available but unused amounts will become available for use in successive years, only if the Company generates future taxable income prior to their expiration, which will begin in 2021. Furthermore, the utilization of the net operating loss carryforwards could be limited beyond the Company's generation of taxable income if an additional change in the underlying ownership of the Company's common stock has occurred, resulting in a limitation on the amounts that could be utilized in any given period under Section 382 of the Code.

10. Restructuring Costs

In June 2017, the Company refocused its clinical development efforts and aligned its resources to focus on the Company's highest value opportunities while maintaining key capabilities. The Company's restructuring activities included a reduction of its workforce by approximately 40%, as well stopping enrollment in its EC1456 phase 1b trial as the assessment of trial data did not yield the level of clinical activity necessary to support continued advancement of EC1456. Pursuant to ASC Topic 420, *Exit or Disposal Cost Obligations*, the Company recorded \$2.3 million of restructuring expenses in the nine months ended September 30, 2017 as follows:

- included in research and development expenses were expenses for employee termination benefits of \$0.9 million, \$0.9 million for the remaining EC1456 phase 1b trial expenses, including site close-out expenses, \$0.3 million related to other restructuring expenses, and \$0.1 million related to fixed asset impairment charges; and
- included in general and administrative expenses were expenses for employee termination benefits of \$0.1 million.

As of September 30, 2017, the Company had paid all severance related to the restructuring activities, had a clinical trial accrual balance related to the EC1456 phase 1b trial termination of \$0.4 million, and an accrual balance related to other restructuring expenses of \$37,600, both of which accrual balances are expected to be fully paid by the end of the first quarter of 2018.

The following tables summarize the restructuring accruals for the three and nine months ended September 30, 2017.

	Employee Termination Accrual	EC1456 Phase 1b Trial Termination Accrual	Other Restructuring Costs Accrual	Total
Balance, June 30, 2017	\$ 181,500	\$ 778,100	\$ 45,100	\$ 1,004,700
Charges for the three months ended September 30, 2017	—	—	—	—
Amounts paid in the three months ended September 30, 2017	(181,500)	(409,764)	(7,500)	(598,764)
Balance, September 30, 2017	<u>\$ —</u>	<u>\$ 368,336</u>	<u>\$ 37,600</u>	<u>\$ 405,936</u>

	Employee Termination Accrual	EC1456 Phase 1b Trial Termination Accrual	Other Restructuring Costs Accrual	Total
Balance, January 1, 2017	\$ —	\$ —	\$ —	\$ —
Charges for the nine months ended September 30, 2017	1,029,400	947,100	126,500	2,103,000
Amounts paid in the nine months ended September 30, 2017	(1,029,400)	(578,764)	(88,900)	(1,697,064)
Balance, September 30, 2017	<u>\$ —</u>	<u>\$ 368,336</u>	<u>\$ 37,600</u>	<u>\$ 405,936</u>

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

This quarterly report on Form 10-Q contains certain statements that are forward-looking statements within the meaning of federal securities laws. When used in this report, the words "may," "will," "should," "could," "would," "anticipate," "estimate," "expect," "plan," "believe," "predict," "potential," "project," "target," "forecast," "intend," "working to" and similar expressions are intended to identify forward-looking statements. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These risks and uncertainties include the important risks and uncertainties that may affect our future operations as discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, in this Quarterly Report on Form 10-Q and in any other filings made with the Securities and Exchange Commission. Readers of this report are cautioned not to place undue reliance on these forward-looking statements. While we believe the assumptions on which the forward-looking statements are based are reasonable, there can be no assurance that these forward-looking statements will prove to be accurate. This cautionary statement is applicable to all forward-looking statements contained in this report.

Overview

We are a biopharmaceutical company and leader in developing targeted therapies for the treatment of cancer. We use drug conjugation technology to create novel therapeutics and companion imaging agents for personalized targeted therapies. Our agents actively target receptors that are over-expressed on diseased cells relative to healthy cells, such as prostate specific membrane antigen, or PSMA, in prostate cancer. This targeted approach is designed to safely enable the delivery of highly potent drug payloads. The companion imaging agents are designed to identify patients whose disease over-expresses the target of the therapy and who are therefore more likely to benefit from treatment.

On September 29, 2017, we entered into a Development and License Agreement, or the License Agreement, with ABX advanced biochemical compounds – Biomedizinische Forschungsreagenzien GmbH, or ABX, pursuant to which we acquired exclusive worldwide rights to develop and commercialize PSMA-617 agents, including the product candidate known as ¹⁷⁷Lu-PSMA-617, a radioligand therapeutic, or RLT. Under the terms of the License Agreement, we will be responsible for, and bear the future costs of, worldwide development and commercialization of PSMA-617. As consideration for the exclusive license, we made an upfront cash payment on September 29, 2017 of approximately \$11.9 million to ABX, consisting of \$12.0 million less an immaterial expense reimbursement amount, and issued to ABX 2,000,000 shares of our common stock and warrants to purchase, in the aggregate, 4,000,000 shares of our common stock. The License Agreement also obligates us to pay ABX regulatory milestone payments of up to \$25.0 million, sales milestone payments of up to \$135.0 million, and tiered royalties, beginning in the mid-teens and not to exceed the mid-twenties, based on percentages of net sales. We recorded \$16.5 million of acquired in-process research and development, or IPR&D expenses related to the License Agreement for the three months ended September 30, 2017 consisting of the following:

- \$12.0 million related to the upfront payment to ABX;
- \$3.8 million related to the fair value of common stock and warrant shares issued; and
- \$0.7 million of acquisition costs consisting primarily of legal and professional fees.

In October 2017, we announced our plan to focus our resources on the development of ¹⁷⁷Lu-PSMA-617 and on a very targeted effort to generate proof-of-concept data for our CAR T-cell therapy program, and to explore out-licensing opportunities for all other development programs, including EC2629, our dual-targeted folate-pro pyrrrolobenzodiazepine, or pro-PBD, DNA crosslinker drug.

We intend to seek regulatory approval to initiate, in the first half of 2018, a phase 3 clinical trial of ¹⁷⁷Lu-PSMA-617 in patients with metastatic castration-resistant prostate cancer, or mCRPC. ¹⁷⁷Lu-PSMA-617 utilizes a high affinity targeting ligand to direct potent radiotherapy to prostate cancer cells. The specific targeting of this therapy comes from the "ligand" portion of the RLT, which is a small molecule designed to bind to PSMA, a protein highly expressed on the cell surface of most prostate cancer cells but absent on most normal cells. The PSMA targeting ligand in ¹⁷⁷Lu-PSMA-617 is chemically attached to a therapeutic radioactive atom called Lutetium-177 (¹⁷⁷Lu), which releases an energetic beta particle designed to precisely deliver cell-killing radiation to the site of disease. Unlike traditional external beam radiotherapy, ¹⁷⁷Lu-PSMA-617, which is administered as a systemic injection, has been designed to directly target multiple sites of PSMA-positive prostate cancer throughout the body, including the bone and soft tissue, while bypassing the PSMA-negative healthy cells. Prior to treatment with ¹⁷⁷Lu-PSMA-617, the patient's expression of PSMA can be

determined using imaging technology, allowing for personalization of treatment so that the optimum course of therapy might be selected. As highlighted in roughly 20 peer reviewed publications of trials in the post-chemotherapy compassionate use setting, ¹⁷⁷Lu-PSMA-617 demonstrated a prostate-specific antigen, or PSA, response (defined as greater than 50% decline from baseline) in 40% to 60% of patients, and a Response Evaluation Criteria in Solid Tumors, or RECIST, response rate in soft tissue disease of between 40% and 50%.

In October 2017, we entered into an agreement with RadioMedix, Inc., a biotechnology company focused on innovative targeted radiopharmaceuticals for diagnosis, monitoring and therapy of cancer, which enables the transfer of a U.S. Investigational New Drug application of ¹⁷⁷Lu-PSMA-617 from the current sponsor, RadioMedix, to us. This transfer is expected to be formally acknowledged by the U.S. Food and Drug Administration in the coming weeks and will accelerate our end-of-phase 2 trial meeting with the agency to confirm our phase 3 trial design and protocol for ¹⁷⁷Lu-PSMA-617.

At the European Society for Medical Oncology Congress in September 2017, Dr. Michael Hofman of the Peter MacCallum Cancer Center in Melbourne, Australia presented the results of an open-label, single-arm, non-randomized pilot trial of ¹⁷⁷Lu-PSMA-617 in 30 mCRPC patients. Primary endpoints included safety and efficacy as defined by PSA response, quality of life, and imaging response. The results showed a 57% PSA response rate (>50% reduction) and 71% interim RECIST response rate in soft tissue lesions in patients who had previously failed such conventional therapies as docetaxel, cabazitaxel, enzalutamide and abiraterone. Median overall survival was 12.7 months. The drug was well-tolerated, with a grade 3 or higher hematotoxicity attributable to ¹⁷⁷Lu-PSMA-617 occurring in five (17%) patients and no renal toxicity. Significantly improved quality of life scores and reduction in pain scores were recorded in 37% and 43% of patients, respectively. This trial has subsequently been expanded to 50 patients from the original 30, with updated results expected to be presented in 2018.

In addition, we entered into a three-party agreement in October 2017, with the University of Sydney, or the University, and ANZUP, a cooperative cancer trials group operating in Australia and New Zealand pursuing research in genito-urinary malignancies, in which ANZUP will sponsor and undertake jointly with the University a randomized phase 2 multi-center TheraP trial of ¹⁷⁷Lu-PSMA-617 versus cabazitaxel in 200 mCRPC patients. Under the three-party agreement, we will provide the PSMA-617 precursor molecule and financial support for the trial. We will have access to data generated from the trial, which is a potentially important supportive trial for future regulatory submissions. The primary financial obligations of the trial, along with labeling PSMA-617 with Lutetium-177, will be the responsibility of the University and ANZUP.

We are also developing a unique therapeutic approach that involves the re-targeting of potent immune cells, called chimeric antigen receptor T-cells, or CAR T-cells, to fight cancer. Traditional CAR T-cell therapies rely on the activity and specificity of T-cells that have been engineered to recognize a single naturally expressed target that, ideally, is only present on cancer cells, with no cross-reactivity to or targeting of healthy tissues. Our alternative strategy relies on a single universal CAR T-cell that expresses a high affinity for a molecule called fluorescein isothiocyanate, or FITC, which is not naturally present in the human body. The activity and specificity of these universal CAR T-cells is dependent upon the administration of our proprietary cell adaptor molecules, or CAMs, that “paint” a patient’s cancer cells with FITC by conjugating it to a tumor-homing ligand. The FITC molecule then attracts the universal CAR T-cell to the site of disease, causing the anti-cancer immune response of a traditional CAR T-cell therapy. However, unlike existing CAR T-cell technologies, our unique CAM-dependent technology makes possible the engineering of a single universal CAR T-cell that can be used to treat a wide range of cancer types. This is accomplished through the use of multiple CAMs, each of which is designed to bind the FITC molecule to a specific cancer type. In addition to enabling the treatment of multiple cancer types with a single universal CAR T-cell, this adaptor technology is also designed to facilitate novel control strategies intended to increase the safety of CAR T-cell therapy. In March 2017, we announced our collaboration with Seattle Children’s Research Institute, or SCRI, and Dr. Michael Jensen for the development of our technology in the CAR T-cell immunotherapy setting. The aim of the research collaboration is to join our adaptor technology with the CAR T-cell immunotherapy research efforts at the Ben Towne Center for Childhood Cancer Research at SCRI, to move these potentially enabling technologies more quickly to patients in the clinic. In October 2017, we announced that we are limiting the scope our CAR T-cell therapy program to a very targeted effort to generate proof-of-concept data.

In June 2017, we ended clinical development of EC1456 and stopped enrollment in our EC1456 phase 1b trial as the assessment of trial data did not yield the level of clinical activity necessary to support continued advancement of EC1456. We are, however, continuing enrollment of a small number of patients in our EC1456 ovarian cancer surgical trial. In addition, in June 2017, we narrowed the focus of our EC1169 development program, refocused our efforts on

pre-clinical programs, and reduced our workforce by approximately 40% to align resources to focus on our highest value opportunities while maintaining key capabilities. We recorded \$2.3 million of restructuring expenses for the nine months ended September 30, 2017, as follows:

- included in research and development expenses were expenses for employee termination benefits of \$0.9 million, \$0.9 million for the remaining EC1456 phase 1b trial expenses, including site close-out expenses, \$0.3 million related to other restructuring expenses, and \$0.1 million related to fixed asset impairment charges; and
- included in general and administrative expenses were expenses for employee termination benefits of \$0.1 million.

As of September 30, 2017, we had paid all severance related to the restructuring activities, had a clinical trial accrual balance related to the EC1456 phase 1b trial termination of \$0.4 million, and an accrual balance related to other restructuring expenses of \$37,600, both of which accrual balances are expected to be fully paid by the end of the first quarter of 2018.

For the nine months ended September 30, 2017, we had a net loss of \$46.5 million compared to a net loss of \$32.8 million for the nine months ended September 30, 2016. We had a retained deficit of \$300.4 million at September 30, 2017. We expect to continue to incur significant operating expenses for the next several years as we pursue the advancement of our product candidates through the research, development, regulatory and, potentially, the commercialization processes. Our operating costs were higher for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 primarily due to an increase in acquired IPR&D expenses related to the License Agreement for PSMA-617, and, to a lesser extent, an increase in trial expenses related to EC1169, an increase in expenses related to pre-clinical work and general research, including the development of EC2629, and an increase in expenses related to the termination of the EC1465 phase 1b trial, including remaining trial and site close-out expenses. These increases were partially offset by a decrease in compensation expense due to the resignation of our former Chief Executive Officer, P. Ron Ellis, in June 2016, lower compensation expense, including stock compensation expense, in the nine months ended September 30, 2017 due to employee terminations, including terminations as a result of the workforce reduction, and a decrease in trial and manufacturing expenses for EC1456 unrelated to the trial termination.

As of September 30, 2017, our cash, cash equivalents and investments were \$103.1 million. We believe that our current cash balance will be sufficient to fund our current operating plan for the next 12 months, which includes our narrow focus on clinical development of ¹⁷⁷Lu-PSMA-617 and the generation of proof-of-concept data on our CAR T-cell therapy program.

Critical Accounting Policies

Our significant accounting policies are described in more detail in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016. Other than the adoption of ASU 2016-09 effective January 1, 2017 and the adoption of ASU 2017-01 effective in the three and nine months ended September 30, 2017 as discussed in Note 3 – New Accounting Pronouncements of the Notes to Condensed Financial Statements contained in Part I, Item 1 herein, and except as set forth below, there were no changes in the three and nine months ended September 30, 2017 to the application of the accounting policies that are critical to the judgments and estimates used in the preparation of our condensed financial statements.

Acquired In-Process Research and Development Expense

We have acquired and may continue to acquire the rights to develop and commercialize new drug candidates. In accordance with Accounting Standards Codification, or ASC, Subtopic 730-25, *Accounting for Research and Development Costs*, the up-front payments to acquire a new drug compound, as well as future milestone payments when paid or payable, are immediately expensed as acquired IPR&D in transactions other than a business combination provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Upon obtaining regulatory approval for marketing, any related milestone payments may be capitalized and amortized over the life of the asset.

Results of Operations

Comparison of Three Months Ended September 30, 2016 to Three Months Ended September 30, 2017

	Three Months Ended		\$ Increase/ (Decrease)	% Increase/ (Decrease)
	September 30, 2016	September 30, 2017		
	(In thousands)			
Statement of operations data:				
Collaboration revenue	\$ 33	\$ 33	\$ —	—
Operating expenses:				
Research and development	5,985	4,090	(1,895)	(32)%
General and administrative	2,988	3,011	23	1 %
Acquired in-process research and development	—	16,493	16,493	100 %
Total operating expenses	8,973	23,594	14,621	163 %
Loss from operations	(8,940)	(23,561)	(14,621)	(164)%
Interest income, net	232	265	33	14 %
Other income, net	—	29	29	100 %
Net loss	<u>\$(8,708)</u>	<u>\$(23,267)</u>	\$ (14,559)	(167)%

Revenue

Our revenue of \$32,500 in the three months ended September 30, 2017 and the three months ended September 30, 2016 related to the amortization of the \$1.0 million non-refundable upfront payment from Nihon Medi-Physic Co., LTD, or NMP, as well as an annual minimum royalty payment received in each of the three months ended September 30, 2017 and 2016.

Research and Development

The decrease in research and development expenses for the three months ended September 30, 2017 compared to the three months ended September 30, 2016 was primarily attributable to: a decrease of \$1.1 million in compensation expense as a result of employee terminations since September 30, 2016, including those resulting from the restructuring activities in June 2017; a decrease of \$0.5 million in expenses related to trial and manufacturing costs for EC1456; a decrease of \$0.4 million in expenses related to pre-clinical work and general research, including the development of EC2629; and a \$0.2 million decrease in manufacturing expense for EC1169. These decreases were partially offset by an increase in expenses of \$0.4 million related to the phase 1b trial expense for EC1169.

Included in research and development expenses were stock-based compensation charges of \$0.9 million and \$0.3 million for the three months ended September 30, 2016 and 2017, respectively.

Research and development expenses included expenses of \$0.3 and \$0.2 million for the three months ended September 30, 2016 and 2017, respectively, for company-funded research at Purdue University, the primary employer of our Chief Science Officer.

General and Administrative

General and administrative expenses remained largely consistent in the three months ended September 30, 2017 compared to the three months ended September 30, 2016, as a slight increase in expenses related to legal and professional fees was mostly offset by a slight decrease in expenses related to stock compensation expense due to employee terminations as a result of the Company's restructuring activities in June 2017.

Included in general and administrative expenses were stock-based compensation charges of \$0.4 million for each of the three months ended September 30, 2016 and 2017.

Acquired In-Process Research and Development

The increase in acquired IPR&D expenses in the three months ended September 30, 2017 compared to the three months ended September 30, 2016 related to the expenses incurred as a result of the License Agreement. We recorded \$16.5 million of acquired IPR&D expenses in the three months ended September 30, 2017 which included \$12.0 million for an upfront payment to ABX, \$3.8 million related to the fair value of common stock and warrant shares issued, and \$0.7 million related to acquisition costs consisting primarily of legal and professional fees.

Interest Income, Net

The increase in interest income, net in the three months ended September 30, 2017 compared to the three months ended September 30, 2016 resulted from an increase of \$165,000 in the interest rate yield during the three months ended September 30, 2017 as compared to the three months ended September 30, 2016, partially offset by a decrease of \$132,000 due to the lower average short-term investment balances. There were no long-term investment balances at September 30, 2016 or 2017.

Comparison of Nine Months Ended September 30, 2016 to Nine Months Ended September 30, 2017

	Nine Months Ended September 30,		\$ Increase/ (Decrease)	% Increase/ (Decrease)
	2016	2017		
	(In thousands)			
Statement of operations data:				
Collaboration revenue	\$ 58	\$ 58	\$ —	—
Operating expenses:				
Research and development	19,304	20,739	1,435	7 %
General and administrative	14,202	10,062	(4,140)	(29)%
Acquired in-process research and development	—	16,493	16,493	100 %
Total operating expenses	33,506	47,294	13,788	41 %
Loss from operations	(33,448)	(47,236)	(13,788)	(41)%
Interest income, net	629	734	105	17 %
Other income (expense), net	(4)	2	6	150 %
Net loss	<u>\$(32,823)</u>	<u>\$(46,500)</u>	\$ (13,677)	(42)%

Revenue

Our revenue of \$57,500 in the nine months ended September 30, 2017 and the nine months ended September 30, 2016 related to the amortization of the \$1.0 million non-refundable upfront payment from NMP, as well as an annual minimum royalty payment received in each of the nine months ended September 30, 2017 and 2016.

Research and Development

The increase in research and development expenses for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 was primarily attributable to an increase of \$1.7 million related to the phase 1b trial expense for EC1169, an increase of \$1.5 million in pre-clinical work and general research, including the development of EC2629, and an increase of \$0.9 million in expenses related to the termination of the EC1456 phase 1b trial, including remaining trial expenses and site close-out expenses. The increases were partially offset by a decrease of \$1.8 million related to stock compensation expense due to employee terminations since September 30, 2016, including those resulting from the restructuring activities in June 2017, and a decrease of \$0.9 million in manufacturing expenses related to EC1169 and EC1456.

Included in research and development expenses were stock-based compensation charges of \$3.2 million and \$1.4 million for the nine months ended September 30, 2016 and 2017, respectively.

Research and development expenses included expenses of \$0.8 million and \$0.6 million for the nine months ended September 30, 2016 and 2017, respectively, for company-funded research at Purdue University, the primary employer of our Chief Science Officer.

General and Administrative

The decrease in general and administrative expenses in the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 was primarily due to a \$4.4 million decrease in compensation expense, of which \$3.6 million related to the resignation of our former Chief Executive Officer, P. Ron Ellis, in June of 2016, which included \$2.8 million of stock compensation expense and \$0.8 million of severance expense, and \$0.9 million of the decrease in compensation expense related to a decrease in employee compensation and stock compensation expenses as a result of the workforce reduction in June 2017. The decreases were partially offset by an increase of \$0.3 million related to professional fees.

Included in general and administrative expenses were stock-based compensation charges of \$4.6 million and \$1.2 million for the nine months ended September 30, 2016 and 2017, respectively.

Acquired In-Process Research and Development

The increase in acquired IPR&D expenses in the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 related to the expenses incurred as a result of the License Agreement. We recorded \$16.5 million of acquired IPR&D expenses in the nine months ended September 30, 2017 which included \$12.0 million for an upfront payment to ABX, \$3.8 million related to the fair value of common stock and warrant shares issued, and \$0.7 million related to acquisition costs consisting primarily of legal and professional fees.

Interest Income, Net

The increase in interest income, net in the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 resulted from an increase of \$365,000 in the interest rate yield during the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016, partially offset by a decrease of \$260,000 due to the lower average short-term investment balances. There were no long-term investment balances at September 30, 2016 or 2017.

Liquidity and Capital Resources

We have funded our operations principally through sales of equity and debt securities, revenue from strategic collaborations, grants, and loans. As of September 30, 2017, we had cash, cash equivalents and investments of \$103.1 million. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Nine Months Ended	
	September 30,	
	2016	2017
	(in thousands)	
Net cash used in operating activities	\$ (26,107)	\$ (27,413)
Net cash provided by investing activities	45,299	38,743
Net cash provided by financing activities	109	4,620
Net increase in cash and cash equivalents	<u>\$ 19,301</u>	<u>\$ 15,950</u>

Operating Activities

The cash used in operating activities for the nine months ended September 30, 2016 and 2017 primarily resulted from our net loss adjusted for non-cash items and changes in operating assets and liabilities.

Investing Activities

The cash provided by investing activities during the nine months ended September 30, 2016 was due to the net result of maturities and purchases of investments, which was partially offset by capital expenditures for equipment of

\$665,000. The cash provided by investing activities during the nine months ended September 30, 2017 was due to the net result of maturities and purchases of investments, which was partially offset by acquired IPR&D of \$12.3 million and capital expenditures for equipment of \$47,000.

Financing Activities

The cash provided by financing activities during the nine months ended September 30, 2016 consisted of proceeds from the exercise of stock options and from stock purchases under our employee stock purchase plan, which were partially offset by stock repurchases for restricted stock units, or RSUs that vested during the period. The cash provided by financing activities during the nine months ended September 30, 2017 consisted of proceeds from the exercise of a warrant and stock options and from stock purchases under our employee stock purchase plan, which were partially offset by stock repurchases for RSUs that vested during the period.

Operating Capital Requirements

We expect to continue to incur significant operating losses for the next several years as we pursue the advancement of our product candidates through the research, development, regulatory and, potentially, the commercialization processes.

As of September 30, 2017, our cash, cash equivalents and investments were \$103.1 million. We believe that our current cash balance will be sufficient to fund our current operating plan for the next 12 months, which includes our narrow focus on clinical development of ¹⁷⁷Lu-PSMA-617 and the generation of proof-of-concept data on our CAR T-cell therapy program, but because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including but not limited to:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates and conducting pre-clinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing any product candidates we successfully commercialize;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, payments, receipts and amount of sales of, or royalties on, our product candidates, if any; and
- the costs we may incur and revenues we may generate in connection with in-licensing and out-licensing activities.

We may seek to sell additional equity or debt securities or obtain new loans or credit facilities. We have an effective shelf Registration Statement on Form S-3 that, in addition to the registration of 6,000,000 shares of our common stock that may be resold by certain stockholders from time to time, also registers up to \$150 million of equity and debt securities that may be offered and sold by us from time to time. The sale of additional equity securities by us may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or convertible preferred stock, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

Contractual Obligations and Commitments

There have been no significant changes during the nine months ended September 30, 2017 to the items that we disclosed as our contractual obligations and commitments in our Form 10-K for the year ended December 31, 2016.

Off-Balance Sheet Arrangements

None.

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

We are exposed to market risk related to changes in interest rates. As of September 30, 2017, we had cash, cash equivalents and investments of \$103.1 million. The investments consisted of U.S. government treasury obligations, U.S. corporate debt securities and cash equivalents. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Our short-term investments are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10 percent change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our short-term investments until maturity, and therefore we do not expect that our results of operations or cash flows would be adversely affected by any change in market interest rates on our investments. We carry our investments based on publicly available information. We do not currently have any investment securities for which a market is not readily available or active.

We do not believe that any credit risk is likely to have a material impact on the value of our assets and liabilities.

Item 4. *Controls and Procedures*

Conclusion Regarding Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the three months ended September 30, 2017, 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

None.

Item 1A. Risk Factors

You should carefully consider the risks and uncertainties we describe below and elsewhere in this Quarterly Report on Form 10-Q and in our other SEC filings before deciding to invest in, or retain, shares of our common stock. Additional risks and uncertainties not presently known to us or that are currently not believed to be significant to our business may also affect our actual results and could harm our business, financial condition, results of operations, cash flows or stock price. If any of these risks or uncertainties actually occurs, our business, financial condition, results of operations, cash flows or stock price could be materially and adversely affected.

Risks Related to Our Business and Industry

We have incurred significant losses in each year since our inception, other than in 2014, and we anticipate that we will continue to incur significant losses for the foreseeable future. We may never again achieve or sustain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have not generated any revenue from product sales to date. For the nine months ended September 30, 2017, we had a net loss of \$46.5 million and a retained deficit of \$300.4 million. Other than in 2014, we have incurred significant losses in each year since our inception in December 1995. We expect to continue to incur significant operating expenses for the next several years as we pursue the advancement of our product candidates through the research, development, regulatory and commercialization processes. As such, we are subject to all of the risks incident to the creation of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. If our product candidates fail in clinical trials, or do not gain regulatory approval, or fail to achieve market acceptance, we may never again be profitable. Even if we achieve profitability again in the future, we may not be able to sustain profitability in subsequent periods.

We currently have no approved products, which makes it difficult to assess our future viability.

To date, we have not derived any revenue from the sales of our products. Our operations to date have been limited to acquiring, developing and securing our technology, undertaking pre-clinical studies and clinical trials of our product candidates and engaging in research and development under collaboration agreements. We have not yet demonstrated an ability to obtain regulatory approval, formulate and manufacture commercial-scale products, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, it is difficult to predict our future success and the viability of any commercial programs that we may choose to take forward. While we have in the past derived revenues from payments under collaboration agreements, all of such agreements have been terminated, and we have no current sources of revenue.

Our restructuring activities and refocused development program efforts may not be successful, and our restructuring activities and changes in our development program efforts may cause uncertainty regarding the future of our business and may adversely impact employee hiring and retention, our stock price and our results of operations and financial condition.

In June 2017, we discontinued clinical development of EC1456, our second-generation folate-targeted SMDC, and narrowed the focus of our clinical development of EC1169, a PSMA-targeted SMDC, to include only the cohort of taxane-exposed mCRPC patients, for which a top-line efficacy assessment of the expansion phase of this phase 1 trial is expected before the end of 2017. In addition, in June 2017, we reduced our workforce by approximately 40% to align resources to focus on our highest value opportunities while maintaining key capabilities. On October 2, 2017, we announced our plan to focus our resources on the development of ¹⁷⁷Lu-PSMA-617 and on a very targeted effort to generate proof-of-concept data for our CAR T-cell therapy program, and to explore out-licensing opportunities for all other development programs.

Our ability to achieve the anticipated benefits, including the anticipated levels of cost savings and efficiency, of our restructuring activities within expected timeframes is subject to many estimates, assumptions and uncertainties. Additional restructuring or reorganization activities may also be required in the future, which could further increase the risks associated with these activities. There is no assurance that we will successfully implement, or fully realize the anticipated impact of, our restructuring or execute successfully on our refocused development program, in the timeframes we desire or at all. If we fail to realize the anticipated benefits from these measures, or if we incur charges or costs in amounts that are greater than anticipated, our financial condition and operating results may be adversely affected.

In addition, the changes in focus of our development program may not be successful and we may have to terminate other clinical and pre-clinical efforts. Further, although the workforce reduction is intended to align resources to focus on highest value opportunities while maintaining key capabilities, those opportunities may not prove to be of high value and those capabilities may not be sufficient.

The changes to our development program and the workforce reduction measures, as well as the potential for additional changes or activities in the future, may introduce uncertainty regarding our prospects and may result in disruption of our business. As a result of these actions, we incurred significant expenses and charges, including site close-out expenses, employee termination benefits and fixed asset impairment charges, and we may incur additional expenses and charges related to these actions. In addition, these changes and measures could distract our employees, decrease employee morale and make it more difficult to retain and hire new talent, and harm our reputation. These changes and activities caused our stock price to decline, and may cause it to further decline in the future. As a result of these or other similar risks, our business, results of operations and financial condition may be adversely affected.

We are highly dependent on the success of PSMA - 617 product candidates, and we cannot give any assurance that we will successfully complete its clinical development, or that it will receive regulatory approval or be successfully commercialized.

In September 2017, we entered into a License Agreement with ABX, pursuant to which we acquired exclusive worldwide rights to develop and commercialize PSMA - 617, including the drug candidate known as ¹⁷⁷Lu-PSMA - 617, an RLT. We intend to seek regulatory approval to initiate, in the first half of 2018, a phase 3 clinical trial of ¹⁷⁷Lu-PSMA - 617 in patients with mCRPC. The regulatory approval required to initiate this trial may be conditioned on various factors, including that we undertake additional pre-clinical studies or earlier phase clinical trials prior to initiating the phase 3 clinical trial. A requirement to undertake additional trials could delay the initiation of the phase 3 clinical trial of ¹⁷⁷Lu-PSMA - 617 beyond the first half of 2018. If initiated, the phase 3 trial may not be successful, and ¹⁷⁷Lu-PSMA - 617 may never receive regulatory approval or be successfully commercialized. We may fail to obtain necessary marketing approvals for ¹⁷⁷Lu-PSMA - 617 from the U.S. Food and Drug Administration, or the FDA, or other regulatory authorities if our clinical development programs for ¹⁷⁷Lu-PSMA - 617 fail to demonstrate that it is safe and effective to the satisfaction of such authorities, or if we have inadequate financial or other resources to advance ¹⁷⁷Lu-PSMA - 617 through the necessary development activities. Even if ¹⁷⁷Lu-PSMA - 617 receives regulatory approval, we may not be successful in marketing it for a number of reasons, including the introduction by our competitors of more clinically-effective or cost-effective alternatives or failure in our sales and marketing efforts. Any failure to obtain approval of ¹⁷⁷Lu-PSMA - 617 and successfully commercialize it would have a material and adverse impact on our business.

We cannot give any assurance that we will successfully complete the clinical development of any of our other product candidates, or that they will receive regulatory approval or be successfully commercialized.

We have terminated or significantly limited the development programs for product candidates other than PSMA - 617 product candidates. With respect to any other product candidates that we may pursue, they may never receive regulatory approval or be successfully commercialized. We may fail to obtain necessary marketing approvals from the FDA or other regulatory authorities if our clinical development programs fail to demonstrate that they are safe and effective to the satisfaction of such authorities, or if we have inadequate financial or other resources to advance our product candidates through the necessary development activities. Even if any of our product candidates receive regulatory approval, we may not be successful in marketing them for a number of reasons, including the introduction by our competitors of more clinically-effective or cost-effective alternatives or failure in our sales and marketing efforts.

The results of clinical trials may not be predictive of future results, and those trials may not satisfy the requirements of the FDA or other regulatory authorities.

The clinical trials of our product candidates are, and the manufacturing and marketing of any approved products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States, Europe and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through pre-clinical testing and clinical trials that the product candidate is safe and effective for use in each indication for which we intend to market such product candidate. This process takes many years and requires the expenditure of substantial financial and human resources and may include post-marketing trials and surveillance. To date, we have not completed any randomized phase 3 clinical trials.

Positive results from pre-clinical studies and early clinical trials, such as those of ¹⁷⁷Lu-PSMA-617, should not be relied upon as evidence that later-stage or large-scale clinical trials will succeed. Like our past history with respect to certain product candidates, a number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, even after promising results in earlier trials. We will be required to demonstrate with substantial evidence through adequate and well-controlled clinical trials that our product candidates are safe and effective for use in the target population before the regulatory authorities will approve our product candidates for commercial sale, and we cannot assure you that we will be able to do so.

In addition to the phase 3 clinical trial of ¹⁷⁷Lu-PSMA-617 that we intend to initiate in the first half of 2018, certain third party investigators, including Dr. Michael Hofman of the Peter MacCallum Cancer Center in Melbourne, Australia, are conducting clinical trials of ¹⁷⁷Lu-PSMA-617 and other product candidates containing PSMA-617. In addition, the German institutions that own the patent rights to PSMA-617 have retained the right, under their license to ABX (under which we are the exclusive sublicensee), to conduct clinical trials of compounds containing PSMA-617 at their premises in Heidelberg, Germany, subject to our approval of the trial protocol. Current or possible future clinical trials of compounds containing PSMA-617 that are conducted by third party investigators outside of our control (in whole or in part) may generate clinical data that hinders our ability to obtain regulatory approvals for the development and/or commercialization of ¹⁷⁷Lu-PSMA-617.

Further, our product candidates may not be approved even if they achieve the primary endpoints in phase 3 clinical trials or registration trials. The FDA or other regulatory authorities may disagree with our trial design or the interpretation of data from pre-clinical studies and clinical trials. In addition, the FDA and other regulatory authorities may change requirements for the approval of our product candidates even after reviewing and providing non-binding comments on a protocol for a pivotal phase 3 clinical trial that has the potential to result in approval. Regulatory authorities may also approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

There is a high risk that our development and clinical activities will not result in commercial products, and we may be required to invest significant additional resources in our current development and clinical programs, to the exclusion of others, before it is known whether one or more of our product candidates will receive regulatory approval or be commercially introduced.

Our product candidates are in various stages of development and are prone to the risks of failure inherent in biopharmaceutical development. Development of our product candidates could be discontinued due to insufficient efficacy or unacceptable toxicity. In many cases, even if we ultimately obtain regulatory approval to market a product candidate, we will need to complete significant additional clinical trials before we can demonstrate that the product candidate is safe and effective to the satisfaction of the regulatory authorities involved. Clinical trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process. Further, even if a product candidate receives the required regulatory approvals, we cannot assure you that it will be successful commercially. In addition, while we invest in the technology and indications that we believe are most promising, financial and resource

constraints may require us to forego or delay opportunities that may ultimately have greater commercial potential than those programs we are currently actively developing.

We may not achieve research, development and commercialization goals in the time frames that we publicly estimate, which could have an adverse impact on our business and could cause our stock price to decline.

We set goals, and make public statements regarding our expectations, regarding the timing of certain accomplishments, developments and milestones under our research and development programs. The actual timing of these events can vary significantly due to a number of factors, including, without limitation, the amount of time, effort and resources committed to our programs by us and any collaborators and the uncertainties inherent in the regulatory approval process. As a result, there can be no assurance that we or any collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or any collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our programs. If we or any collaborators fail to achieve one or more of the milestones described above as planned, our business could be materially adversely affected and the price of our common stock could decline.

The coverage and reimbursement status of newly approved biopharmaceuticals is uncertain, and failure to obtain adequate coverage and adequate reimbursement of our product candidates could limit our ability to generate revenue.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. The commercial success of our product candidates, if approved, in both domestic and international markets will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, and managed care organizations. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our product candidates are less safe, less effective or less cost-effective than existing or later introduced products, and third-party payors may not approve our product candidates for coverage and reimbursement or may cease providing coverage and reimbursement for these product candidates. Because each country has one or more payment systems, obtaining reimbursement in the United States and internationally may take significant time and cause us to spend significant resources. The failure to obtain coverage and adequate reimbursement for our product candidates or healthcare cost containment initiatives that limit or deny reimbursement for our product candidates may significantly reduce any future product revenue.

In the United States and in other countries, there have been and we expect there will continue to be a number of legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. International, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Such government-adopted reform measures may adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. In addition, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. The continuing efforts of U.S. and other governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set satisfactory prices for our products, to generate revenues, and to achieve and maintain profitability.

In some countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

Our development activities could be delayed or stopped for a number of reasons, many of which are outside our control, which could materially harm our financial results and the commercial prospects for our product candidates.

Each of our clinical trials requires the investment of substantial expense and time, and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes. We do not know whether our current clinical trials will be completed on schedule, or at all, and we cannot guarantee that our future planned clinical trials will begin on time, or at all. Clinical trials must be conducted in accordance with FDA or applicable foreign government guidelines and are subject to oversight by the FDA, foreign governmental agencies and independent institutional review boards, or IRBs, at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under current Good Manufacturing Practice, or cGMP, and other requirements in foreign countries, and may require large numbers of test patients. Our current and planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable sites to conduct our clinical trials;
- government or regulatory delays and changes in regulatory requirements, policy and guidelines;
- delay or failure to obtain sufficient supplies of the product candidate for, or other drugs used in, our clinical trials as a result of our suppliers' non-compliance with cGMP, or for other reasons
- delay or failure to reach agreement on acceptable clinical trial agreement terms with prospective sites or investigators; and
- delay or failure to obtain IRB approval to conduct a clinical trial at a prospective site.

The completion of our clinical trials could also be substantially delayed or prevented by several factors, including:

- slower than expected rates of patient recruitment and enrollment;
- unforeseen safety issues;
- lack of efficacy evidenced during clinical trials, which risk may be heightened given the advanced state of disease and lack of response to prior therapies of patients in certain clinical trials;
- termination of our clinical trials by an IRB at one or more clinical trial sites;
- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols; and
- inability to monitor patients adequately during or after treatment or high patient dropout rates.

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities or us. For example, in June 2017 we ended clinical development of EC1456 and stopped enrollment in our EC1456 phase 1b trial, as the assessment of trial data did not yield the level of clinical activity necessary to support continued advancement of EC1456. We cannot assure you that we will not terminate our current and future development programs.

Failure or significant delay in completing clinical trials for our product candidates could materially harm our financial results and the commercial prospects for our product candidates.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization.

Common side effects of our product candidates include abdominal pain, vomiting, constipation, nausea, fatigue, loss of appetite, hematologic events and peripheral sensory neuropathy. Because our product candidates have been tested in relatively small patient populations and for limited durations to date, additional side effects may be observed as their development progresses.

¹⁷⁷Lu-PSMA-617 is designed to target PSMA, a protein highly expressed on the surface of most prostate cancer cells but absent on most normal cells. However, the fact that PSMA is expressed on *some* normal cells may result in off-target toxicity due to the delivery of ¹⁷⁷Lu, the cell-killing radioactive atom in ¹⁷⁷Lu-PSMA-617, to those normal cells.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or discontinue clinical trials and could result in the denial, cancellation or withdrawal of regulatory

approval by the FDA or other regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing our product candidates and generating revenues from their sale. In addition, if one of our products receives marketing approval and we or others later identify undesirable side effects caused by that product:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall the product, change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- the product may be rendered less competitive and sales may decrease; or
- our reputation may suffer generally both among clinicians and patients.

Any one or a combination of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating revenues from the sale of the product.

We may not obtain government regulatory approval to market our product candidates.

We may seek approval to market certain of our product candidates in both the United States and in non-U.S. jurisdictions. Prior to commercialization, each product candidate will be subject to an extensive and lengthy governmental regulatory approval process in the United States and in other countries. In order to market our products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We may not receive the approvals necessary to commercialize our product candidates in any market and we may withdraw applications for approval before acted upon by the regulatory authority.

We may not be able to obtain regulatory approval for any product candidates, or even if approval is obtained, the labeling for such products may place restrictions on their use that could materially negatively impact the marketability and profitability of the product subject to such restrictions. Satisfaction of these regulatory requirements, which includes satisfying regulatory authorities that the product is both safe and effective for its intended uses, typically takes several years or more depending upon the type, complexity, novelty and safety profile of the product and requires the expenditure of substantial resources. Uncertainty with respect to meeting the regulatory requirements governing our product candidates may result in excessive costs or extensive delays in the regulatory approval process, adding to the already lengthy review process.

Also, the approval procedure varies among countries and can involve additional testing and data review. The time and safety and efficacy data required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in any jurisdiction could materially harm our business.

We may require substantial additional funding which may not be available to us on acceptable terms, or at all.

As we work to advance product candidates through pre-clinical and clinical development, our future funding requirements will depend on many factors, including but not limited to:

- our need to expand our research and development activities;
- the rate of progress and cost of our clinical trials and the need to conduct clinical trials beyond those planned;
- the costs associated with establishing a sales force and commercialization capabilities;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- the costs and timing of seeking and obtaining approval from regulatory authorities;
- our ability to maintain, defend and expand the scope of our intellectual property portfolio;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments; and

- the economic and other terms and timing of collaboration, licensing or other arrangements into which we have entered or may enter into in the future.

Until we can generate a sufficient amount of revenue to finance our cash requirements, which we may never do, and if we would require additional funding, we expect to finance future cash needs primarily through public or private equity or debt financings or other sources. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs, or enter into collaboration or other arrangements with other companies to provide such funding for one or more of such clinical trials or programs in exchange for our affording such partner commercialization or other rights to the product candidates that are the subject of such clinical trials or programs.

Furthermore, we may incur unexpected expenses, experience timing delays or encounter other circumstances that result in us needing additional funds sooner than planned. Also, we may seek additional capital due to favorable market conditions or other strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

We may seek the additional capital necessary to fund our operations through public or private equity or debt financings or other sources, such as strategic partnerships or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of the current stockholders will be diluted and the terms may include liquidation or other preferences that adversely affect their rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends, or which impose financial covenants on us that limit our operating flexibility to achieve our business objectives. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. In addition, we cannot assure you that additional funds will be available to us on favorable terms or at all.

If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address various types of cancer and other indications we treat or may treat in the future. We are currently developing cancer therapeutics that will compete with other drugs and therapies that currently exist or are being developed. Also, certain of our product candidates may be clinically developed not as an initial first line therapy but as a therapy for patients whose tumors have developed resistance to first line chemotherapy, which limits its potential addressable market. Products we may develop in the future are also likely to face competition from other drugs and therapies.

Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large biopharmaceutical companies, in particular, have extensive experience in clinical testing and in obtaining regulatory approvals for drugs. Additional mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated by our competition. Competition may increase further as a result of advances in the commercial applicability of technologies currently being developed and a greater availability of capital investment in those fields. These companies may also have significantly greater research and marketing capabilities than we do. Some of the companies developing products which may compete with our product candidates include Adaptimmune Therapeutics PLC; Affimed N.V.; AstraZeneca PLC ; Atara Biotherapeutics, Inc.; Atridia Pty LTD; Autolus Limited; Bayer AG; Bellicum Pharmaceuticals, Inc.; BioNTech AG; Bluebird Bio Inc.; Cancer Targeted Technology; Collectis S.A.; Celyad S.A.; Editas Medicine, Inc.; ESSA Pharma, Inc.; Gilead Sciences, Inc.; GlaxoSmithKline PLC; Immutics Biotechnology GmbH; Immunocore Limited; Innocrin Pharmaceuticals, Inc.; Intellia Therapeutics, Inc.; Intrexon Corporation; Janssen Biotechnology, Inc.; Johnson & Johnson; Juno Therapeutics, Inc.; MedImmune, Inc.; Merck & Co., Inc.; MorphoSys AG; Novartis AG; Progenics Pharmaceutical, Inc.; Roche Holdings; Suzhou Kintor Pharmaceuticals, Inc.; Takara Bio, Inc.; TRACON Pharmaceuticals, Inc.; Unum Therapeutics, Inc.; Zenith Pharmaceuticals LTD; and Zymeworks, Inc. In addition, many universities and private and public research

institutes are active in cancer research, the results of which may result in direct competition with our product candidates. For example, the German Center of Cancer Research and University Medical Center Heidelberg, the owners of the patent rights to PSMA-617 (which have been exclusively licensed to ABX and, in turn, exclusively sublicensed to us under the License Agreement), may continue to engage in research relating to RLTs or other cancer therapies, which could result in competition for ¹⁷⁷Lu-PSMA-617 or other product candidates that we advance from PSMA-617.

In certain instances, the drugs which will compete with our product candidates are widely available or established, existing standards of care. To compete effectively with these drugs, our product candidates will need to demonstrate advantages that lead to improved clinical safety or efficacy compared to these competitive products. We cannot assure you that we will be able to achieve competitive advantages versus alternative drugs or therapies. If our competitors' market products are more effective, safer or less expensive than our product candidates or reach the market sooner than our product candidates, we may not achieve commercial success.

We believe that our ability to successfully compete will depend on, among other things:

- our ability to design and successfully execute appropriate clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the results of our clinical trials and the efficacy and safety of our product candidates;
- the speed at which we develop our product candidates;
- achieving and maintaining compliance with regulatory requirements applicable to our business;
- the timing and scope of regulatory approvals, including labeling;
- adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect intellectual property rights related to our product candidates;
- our ability to commercialize and market any of our product candidates that may receive regulatory approval;
- our ability to have any partners manufacture and sell commercial quantities of any approved product candidates to the market;
- acceptance of our product candidates by physicians, other healthcare providers and patients; and
- the cost of treatment in relation to alternative therapies.

In addition, the biopharmaceutical industry is characterized by rapid technological change. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. Also, because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively.

If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

Our success as a specialized scientific business depends on our continued ability to attract, retain and motivate highly qualified management and scientific and clinical personnel. The loss of the services of any of our senior management could delay or prevent the commercialization of our product candidates.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. In addition, the impact on employee morale experienced in connection with our workforce reduction in June 2017, in which we reduced our workforce by approximately 40%, could make it more difficult for us to retain current employees or to attract new employees when needed. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede the achievement of our research and development objectives, our ability to raise additional capital and our ability to implement our business strategy.

If we evolve from a company primarily involved in clinical development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

If we are able to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand, we expect that we may need to manage additional relationships with such third parties, as well as additional collaborators and suppliers.

Maintaining these relationships and managing our future growth will impose significant added responsibilities on members of our management and other personnel. We must be able to: manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; improve our managerial, development, operational and finance systems; and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure. We may also begin to expand our capabilities or enter into contractual relationships during the later stage clinical trial or regulatory approval process, and then have to reduce our capabilities or terminate those relationships if the trials or approval processes are terminated.

Even if we are able to obtain regulatory approval of our products, we may be unable to successfully market and sell them unless we establish sales, marketing and distribution capabilities.

We currently have no sales or distribution capabilities and only limited marketing capabilities. If any of our product candidates receive regulatory approval, we intend to build a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue is likely to be lower than if we directly marketed or sold our products and will depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We rely on third parties to conduct clinical trials for our product candidates and plan to rely on third parties to conduct future clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, it may cause delays in commencing and completing clinical trials of our product candidates or we may be unable to obtain regulatory approval for or commercialize our product candidates.

Clinical trials must meet applicable FDA and foreign regulatory requirements. We do not have the ability to independently conduct phase 2 or phase 3 clinical trials for any of our product candidates. We rely on third parties, such as medical institutions, clinical investigators and contract laboratories, to conduct all of our clinical trials of our product candidates; however, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and other regulatory authorities require us to comply with regulations and standards, commonly referred to as Good Clinical Practices, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements.

We or the third parties we rely on may encounter problems in clinical trials that may cause us or the FDA or foreign regulatory agencies to delay, suspend or terminate our clinical trials at any phase. These problems could include the possibility that we may not be able to manufacture sufficient quantities of materials for use in our clinical trials, conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites, or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, we, the FDA or foreign regulatory agencies may suspend clinical trials of our product candidates at any time if we or they believe the subjects

participating in the trials are being exposed to unacceptable health risks, whether as a result of adverse events occurring in our trials or otherwise, or if we or they find deficiencies in the clinical trial process or conduct of the investigation.

The FDA and foreign regulatory agencies could also require additional clinical trials before or after granting marketing approval for any products, which would result in increased costs and significant delays in the development and commercialization of such products and could result in the withdrawal of such products from the market after obtaining marketing approval. Our failure to adequately demonstrate the safety and efficacy of a product candidate in clinical development could delay or prevent obtaining marketing approval of the product candidate and, after obtaining marketing approval, data from post-approval trials could result in the product being withdrawn from the market, either of which would have a material adverse effect on our business.

We rely on third parties to manufacture and supply our product candidates.

We do not currently own or operate manufacturing facilities for the clinical or commercial production of our product candidates. We lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. Although we intend to enter into an agreement with ABX for the supply to us of PSMA-617, we do not have any long-term supply arrangements with any third-party manufacturers and we obtain our raw materials on a purchase order-basis. We expect to continue to depend on third-party contract manufacturers for the manufacture of our product candidates for the foreseeable future. If for some reason our contract manufacturers cannot perform as agreed, we may be unable to replace them in a timely manner and the production of our product candidates would be interrupted, resulting in delays in clinical trials and additional costs. We have no experience with managing the manufacturing of commercial quantities of any of our product candidates and scaling-up production to commercial quantities could take us significant time and result in significant costs. Switching manufacturers may be difficult because the number of potential manufacturers is limited and the FDA and other regulatory authorities must approve any replacement manufacturer prior to manufacturing our product candidates. Such approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our product candidates after receipt of regulatory approval to manufacture any of our product candidates.

To date, our product candidates have been manufactured in small quantities for pre-clinical studies and clinical trials by third-party manufacturers. If the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of any approved product candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation trials, which the regulatory agencies must review and approve. Additionally, any third-party manufacturer we retain to manufacture our product candidates on a commercial scale must pass a pre-approval inspection for conformance to the cGMP before we can obtain approval of our product candidates. If we are unable to successfully increase the manufacturing capacity for a product candidate in conformance with cGMP, the regulatory approval or commercial launch of such products may be delayed or there may be a shortage in supply.

Our product candidates require precise, high quality manufacturing. Failure by our contract manufacturers to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could seriously harm our business. Contract manufacturers may encounter difficulties involving production yields, quality control and assurance. These manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and non-U.S. authorities to ensure strict compliance with cGMP and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party manufacturers' compliance with these regulations and standards.

We are subject to risks associated with the availability of key raw materials, such as the radioisotopes used in the manufacture of our products.

The manufacture of our RLTs and companion imaging agents requires the use of raw materials which are subject, at times, to global supply constraints that have the potential to delay our work on the products incorporating those raw materials. For example, any limitation on our ability to source adequate supply of lutetium-177 for ¹⁷⁷Lu-PSMA-617 could prevent us from gathering sufficient data in clinical trials, or to the extent that we obtain regulatory approval for marketing for this product candidate, a limited supply may prevent us from meeting commercial demands. Supply

constraints for Lutetium-177 could also materially increase the manufacturing costs of ¹⁷⁷Lu-PSMA-617, which would increase the cost of our clinical trials and reduce the commercial potential of the product candidate.

In addition, we plan to use etarfolatide that employs Tc-99m in our development of imaging capabilities and there have been historical periods in which global supply was not sufficient to satisfy worldwide demand for use in various nuclear medicine diagnostics utilized by healthcare providers. If we are not able to obtain sufficient quantities of Tc-99m for use in etarfolatide, we may not be able to gather sufficient data on etarfolatide to use in future clinical trials or to possibly seek the approval of etarfolatide. In addition, to the extent the approval of our product candidates depends on the screening and monitoring of the patient population with a companion imaging agent such as etarfolatide in our clinical trials, we would experience a corresponding delay in approval and commercialization of these product candidates if we are not able to obtain sufficient Tc-99m.

If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, we could be forced to pay substantial damage awards.

The use of any of our product candidates in clinical trials, and the sale of any approved products, may expose us to product liability claims. We currently maintain product liability insurance coverage in an amount which we believe is adequate for our clinical trials currently in progress and those recently completed. We monitor the amount of coverage we maintain as the size and design of our clinical trials evolve and intend to adjust the amount of coverage we maintain accordingly. However, we cannot assure you that such insurance coverage will fully protect us against some or all of the claims to which we might become subject. We might not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct financial and managerial resources to such defense and adverse publicity could result, all of which could harm our business.

Each of our product candidates will remain subject to ongoing regulatory review even if it receives marketing approval. If we or any collaborators and contractors fail to comply with continuing regulations, we or they may be subject to enforcement action that could adversely affect us.

If any of our product candidates become approved products, they will continue to be subject to pervasive regulation by the FDA and other regulatory authorities. We and any collaborators and contractors will continue to be subject to regulatory requirements governing among other things the manufacture, packaging, sale, promotion, adverse event reporting, storage and recordkeeping of our approved products. Although we have not received any notice that we are the subject of any regulatory enforcement action, it is possible that we may be in the future and that could have a material adverse effect on our business. We may be slow to adapt, or may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements. If we or any collaborators or contractors fail to comply with the requirements of the FDA and other applicable governmental or regulatory authorities or previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we or the collaborator or contractor could be subject to administrative or judicially imposed sanctions, including: fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

We deal with hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our activities involve the controlled storage, use, and disposal of hazardous materials, including corrosive, explosive and flammable chemicals, biologic waste and various radioactive compounds. We are subject to federal, state, and local laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. Although we believe that our safety procedures for the handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials.

In the event of an accident, state or federal authorities may curtail our use of these materials, and we could be liable for any civil damages, which may exceed our financial resources and may seriously harm our business. We currently maintain insurance covering hazardous waste clean-up costs in an amount we believe to be sufficient for typical risks

regarding our handling of these materials, however, this amount of coverage may not be sufficient to cover extraordinary or unanticipated events. Additionally, an accident could damage, or force us to temporarily shut down, our operations.

Risks Related to Intellectual Property

We may be at risk for cyber attacks or other security breaches that could compromise our intellectual property, trade secrets or other sensitive business information and expose us to liability, which would cause our business and reputation to suffer.

Cyber attacks or security breaches could compromise confidential, business critical information, cause a disruption in our operations, harm our reputation or increase our stock trading risk. We have attractive information assets, including intellectual property, trade secrets and other sensitive, business critical information, including personally identifiable information of our employees. Our employees, some of whom have access to such information, frequently receive “phishing” emails intended to trick recipients into surrendering their user names and passwords. Phishing is a fraud method in which the perpetrator sends out legitimate-looking emails in an attempt to gather personal, business, financial or other information from recipients. To date, we have found no evidence of unauthorized access to our employees’ accounts, but cannot preclude the possibility that sensitive information has been accessed, publicly disclosed, lost or stolen.

We have cybersecurity technologies, processes and practices that are designed to protect networks, computers, programs and data from attack, damage or unauthorized access, but we cannot assure you that they will be effective or will work as designed. Our cybersecurity is continuously reviewed, maintained and upgraded in response to possible security breach incidents. Notwithstanding these measures, a cyber attack could compromise our networks and data centers and/or result in access, disclosure, or other loss of information, which could result in legal claims or proceedings, investigations, potential liabilities under laws that protect the privacy of personal information, delays and impediments to our discovery and development efforts, damage to our reputation and a negative impact on our financial results.

Our proprietary rights may not adequately protect our technologies and product candidates.

Our commercial success will depend in part on our ability to obtain additional patents and protect our existing patent position as well as our ability to maintain adequate protection of other intellectual property for our technologies, product candidates, and any future products in the United States and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The laws of some foreign countries do not protect our proprietary rights to the same extent or in the same manner as U.S. laws, and we may encounter significant problems in protecting and defending our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We apply for patents covering both our technologies and product candidates, as we deem appropriate. However, we may fail to apply for patents on important technologies or product candidates in a timely fashion, or at all. The existing patent rights that we own or license, and any future patents rights, may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. We cannot be certain that patent applications will be approved or that any patents issued will adequately protect our or our licensors’ intellectual property. With respect to PSMA-617 and CAR T-cell therapies, for example, patents have yet to issue and the patents may not issue at all, or if they do issue, they may be challenged. In addition, we often do not ultimately control the patent prosecution of subject matter that we license from others, including those licensed from Purdue Research Foundation, a non-profit organization which manages the intellectual property of Purdue University. In addition, we have licensed intellectual property from other third parties, such as ABX, where we were not involved in preparing, drafting or filing the patent applications. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we would over our own and would need to involve such third parties in legal proceedings to enforce these intellectual property rights. Moreover, the patent positions of biopharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles are often evolving and remain unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, we do not know whether:

- we or our licensors were the first to make the inventions covered by each of our issued patents and pending patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- any of our product candidates will be Orange Book eligible;
- others will independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' pending patent applications will result in issued patents;
- any of our or our licensors' patents will be valid or enforceable;
- any patents issued to us or our licensors and collaboration partners will provide us with any competitive advantages, or will be challenged by third parties;
- we will develop additional proprietary technologies that are patentable;
- the U.S. government will exercise any of its statutory rights to our intellectual property that was developed with government funding; or
- our business may infringe the patents or other proprietary rights of others.

The actual protection afforded by a patent varies based on products or processes, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country, the validity and enforceability of the patent and the financial ability of us or a third party to enforce the patent and other intellectual property. Our ability to maintain and solidify our proprietary position for our products will depend on our success in obtaining effective claims and enforcing those claims once granted. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, narrowed, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products. Due to the extensive amount of time required for the development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We also rely upon unpatented proprietary know-how and continuing technological innovation and other trade secrets in connection with the development of our technologies and product candidates. While it is our policy to enter into agreements imposing confidentiality obligations upon our employees and third parties, including our collaboration partners, to protect our intellectual property, these confidentiality obligations may be breached, may not provide meaningful protection for our trade secrets or proprietary know-how, or adequate remedies may not be available in the event of an unauthorized access, use or disclosure of our trade secrets and know-how. In addition, others could obtain knowledge of our trade secrets through independent development or other access by legal means. Further, non-U.S. courts are sometimes less willing than U.S. courts to protect trade secrets.

The failure of patent rights or confidentiality agreements to protect our processes, technology, trade secrets or proprietary know-how or the failure of adequate legal remedies for related actions could have a material adverse effect on our business, results of operations, financial condition and liquidity.

The intellectual property protection for our product candidates is dependent on third parties.

While we do have the right and responsibility under the License Agreement to control the prosecution and maintenance of the patent rights covering PSMA-617, we are subject to certain consent and cooperation obligations to ABX and/or the owners of the patent rights. With respect to patent applications relating to our product candidates that incorporate patents licensed from Purdue Research Foundation, the right and obligation to prosecute and maintain the patents and patent applications covered by these license agreements are generally retained by Purdue Research Foundation. Generally, we do not have the right to prosecute and maintain such patents in our territories, unless Purdue Research Foundation elects not to file, prosecute or maintain any or all of such patents, however, our most recent master license agreement for future potential technology provides us lead prosecution responsibility. We would need to determine, with our other potential partners, who would be responsible for the prosecution of patents relating to any joint inventions. If any of our licensing partners who maintain such rights fail to appropriately prosecute and maintain patent protection for any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

If we breach any of the agreements under which we license commercialization rights to our product candidates or technology from third parties, we could lose license rights that are important to our business.

We license the use, development and commercialization rights for some of our product candidates, and we expect to enter into similar licenses in the future. For example, we licensed exclusive worldwide rights from ABX and Purdue Research Foundation, pursuant to license agreements, which enables us to use PSMA-617 and adaptor controlled CAR T-cell therapies, respectively, in the treatment of cancer. Under these licenses, we are subject to development and commercialization obligations, diligence obligations, sublicense revenue sharing requirements, royalty payments, and other obligations. If we fail to comply with any of these obligations or otherwise breach a license agreement or any other current or future licenses, our licensing partners may have the right to terminate the license in whole or in part or to terminate the exclusive nature of the license. In addition, if ABX fails to comply with its obligations under its license agreement with the owners of the patent rights covering PSMA-617, our rights under the License Agreement with ABX could be materially impaired. The loss of any current or future licenses or the exclusivity rights provided therein would materially harm our financial condition and operating results.

The patent protection for our product candidates may expire before we are able to maximize their commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

The patents for our product candidates have varying expiration dates and, if these patents expire, we may be subject to increased competition and we may not be able to recover our development costs or market any of our approved products profitably. In some of the larger potential market territories, such as the United States and Europe, patent term extension or restoration may be available to compensate for time taken during aspects of the product's development and regulatory review. However, we cannot be certain that such an extension will be granted, or if granted, what the applicable time period or the scope of patent protection afforded during any extension period will be. In addition, even though some regulatory authorities may provide some other exclusivity for a product under their own laws and regulations, we may not be able to qualify the product or obtain the exclusive time period. If we are unable to obtain patent term extension/restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of patents.

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

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where there is no patent protection for our product candidates to develop their own products and further, may export otherwise infringing products to territories where there is patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have rights to any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult to stop the infringement of the patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

If we are sued for infringing intellectual property rights of third parties, litigation will be costly and time-consuming and could prevent us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our not infringing the patents and proprietary rights of other parties and not breaching any collaboration or other agreements we have entered into with regard to our technologies and product candidates. Numerous third-party U.S. and non-U.S. issued patents and pending applications exist in the areas of targeted therapy and targeted diagnostics, including radioligand therapeutics, cytotoxic agents and other active compounds and formulations comprising such compounds.

Because patent applications can take several years to issue, if they are issued at all, there may currently be pending applications, unknown to us, that may result in issued patents that cover our technologies or product candidates. It is

uncertain whether the issuance of any third-party patent would require us to alter our products or processes, obtain licenses or cease activities related to the development or commercialization of our product candidates. If we wish to use the technology or compound claimed in issued and unexpired patents owned by others, we may need to obtain a license from the owner, enter into litigation to challenge the validity of the patents or incur the risk of litigation in the event that the owner asserts that any of our product candidates infringe its patents. The failure to obtain a license to technology or the failure to challenge an issued patent that we may require to discover, develop or commercialize our products may have a material adverse impact on us.

There is a substantial amount of litigation involving intellectual property in the biopharmaceutical industry generally. If a third party asserts that our products or technologies infringe its patents or other proprietary rights, we could face a number of risks that could seriously harm our results of operations, financial condition and competitive position, including:

- infringement and other intellectual property claims, which would be costly and time-consuming to defend, whether or not the claims have merit, and which could delay the regulatory approval process and divert management's attention from our business;
- substantial damages for past infringement, which we may have to pay if a court determines that our product candidates or technologies infringe a third party's patent or other proprietary rights;
- a court prohibiting us from selling or licensing our technologies or our product candidates unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties or lump sum payments or grant cross-licenses to our patents or other proprietary rights to obtain that license; and
- redesigning our products so they do not infringe, which may not be possible or may require substantial monetary expenditure and time.

Although we are not currently a party to any legal proceedings relating to our intellectual property, in the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert these claims against us or against the current or future licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend against these claims, whether they are with or without any merit, whether they are resolved in favor of or against us or our licensors, we may face costly litigation and diversion of management's attention and resources. As a result of these disputes, we may have to develop costly non-infringing technology, or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, if at all, which could seriously harm our business or financial condition.

One or more third-party patents or patent applications may conflict with patent applications to which we have rights. Any such conflict may substantially reduce the coverage of any rights that may issue from the patent applications to which we have rights. If third parties file patent applications in technologies that also claim technology to which we have rights, we may have to participate in interference proceedings with the U.S. Patent and Trademark Office, or USPTO, or non-U.S. patent regulatory authorities, as applicable, to determine priority of invention.

We may become involved in lawsuits to enforce patents or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe the patents or other intellectual property rights related to our product candidates. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. To the extent such claims relate to patent rights held by our licensors, they would have to file such an infringement lawsuit since we do not have the independent right to enforce those third parties' intellectual property. In addition, in an infringement proceeding, a court may decide that a patent is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of the patents at risk of being invalidated or interpreted narrowly and could put patent applications at risk of not issuing.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our current or future licensors or collaborators. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or

interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors or collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Risks Related to Ownership of Our Common Stock

The price of our common stock has been volatile and our shares may suffer a decline in value.

Since becoming a public company in February 2011, we have experienced volatility in the trading price of our common stock. Factors that could cause volatility in the market price of our common stock include, but are not limited to, the risk factors identified above as well as:

- results from, supplemental analyses of and any delays in, our current or planned clinical trials;
- announcements of approval or non-approval by any regulatory authorities of any of our product candidates, or delays in any regulatory authority review processes;
- other regulatory actions affecting us or our industry;
- litigation or public concern about the safety of our product candidates;
- failure or discontinuation of any of our research or clinical trial programs;
- withdrawal of regulatory approval applications;
- delays in the commercialization of our product candidates;
- our ability to effectively partner with collaborators to develop or sell our products;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- actual and anticipated fluctuations in our quarterly operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new products by us or our competitors;
- issues in supply or manufacturing of our product candidates;
- market acceptance of our product candidates;
- deviations in our operating results from the estimates of securities analysts;
- coverage and reimbursement policies of governments and other third-party payors;
- sales of our common stock by our officers, directors or significant stockholders;
- price and volume fluctuations in the overall stock market from time to time;
- general economic conditions and trends;
- major catastrophic events;
- our ability to expand our operations, domestically and internationally, and the amount and timing of expenditures related to this expansion; and
- additions or departures of key personnel.

In addition, the stock markets in general, and the markets for biopharmaceutical, pharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action and other litigation against the issuer.

Sales of substantial amounts of our shares could adversely affect the market price of our common stock.

Sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur, could cause the market price of our common stock to decline. These sales could also make it more difficult for us to raise capital by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

As of September 30, 2017, there were 47,859,381 shares of our common stock outstanding. All of the outstanding shares are freely transferable without restriction under the Securities Act 1933, as amended, or the Securities Act, unless held by our “affiliates” as that term is used in Rule 144 promulgated under the Securities Act or unless issued in an unregistered offering. Such shares may be sold in the public market pursuant to Rule 144, another exemption from registration or an effective registration statement under the Securities Act.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control all matters submitted to stockholders for approval and may take actions that may not be in the best interests of our other stockholders.

As of September 30, 2017, our executive officers, directors, stockholders who hold more than 5% of our outstanding common stock and their affiliates beneficially owned, in the aggregate, shares representing approximately 41% of our outstanding capital stock, which includes shares that the individuals and entities have the right to acquire within 60 days after September 30, 2017. As a result, if these stockholders were to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they act together, could control the election of directors and decisions on any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in management of our company with which our public stockholders disagree.

We do not intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

Provisions in our certificate of incorporation and bylaws and under Delaware law might discourage, delay or prevent a change of control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Our certificate of incorporation and bylaws contain provisions that could depress the trading price of our common stock by acting to discourage, delay or prevent a change of control of our company or changes in our management that our stockholders may deem advantageous. These provisions include:

- establishing a classified board so that not all members of our Board of Directors are elected at one time;
- authorizing “blank check” preferred stock that our Board of Directors could issue to increase the number of outstanding shares to discourage a takeover attempt;
- eliminating the ability of stockholders to call a special stockholder meeting;
- eliminating the ability of stockholders to act by written consent;
- being subject to provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers;
- providing that our Board of Directors is expressly authorized to make, alter or repeal our bylaws; and
- establishing advance notice requirements for nominations for elections to our Board of Directors or for proposing other matters that can be acted upon by stockholders at stockholder meetings.

If we fail to maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

We are subject to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, which requires management to assess and report annually on the effectiveness of internal control over financial reporting and identify any material

weaknesses in internal control over financial reporting, and our independent registered public accounting firm to issue an attestation report as to the effectiveness of internal control over financial reporting.

If we identify one or more material weaknesses in our internal control over financial reporting, or if we are unable to conclude that we have effective internal control over financial reporting or if our independent auditors are unwilling or unable to provide us with an attestation report on the effectiveness of internal control over financial reporting, investors may lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions.

Our ability to use net operating losses to offset future taxable income is subject to certain limitations.

Under Section 382 of the U.S. Internal Revenue Code, or Code, a corporation that experiences a more-than 50 percent ownership change over a three-year testing period is subject to limitations on its ability to utilize its pre-change net operating losses to offset future taxable income. We experienced such an ownership change in August 2011. As a result, the future use of our net operating losses, after giving effect to net unrealized built-in gains, is currently limited to approximately \$218.7 million for 2017. Any available but unused amounts will become available for use in all successive years, subject to certain limitations. Utilization of these net operating loss carryforwards would require us to generate future taxable income prior to their expiration. Furthermore, the utilization of the net operating loss carryforwards could be limited beyond our generation of taxable income if a change in the underlying ownership of our common stock has occurred, resulting in a limitation on the amounts that could be utilized in any given period under Section 382 of the Code. If not used, the net operating loss carryforwards will begin expiring in the year 2021. At December 31, 2016, we recorded a full valuation allowance against our deferred tax assets of approximately \$106.7 million, as we believe it is more likely than not that the deferred tax assets will not be fully realized.

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

Unregistered Sales of Securities

Information regarding sales of unregistered securities by us in the three months ended September 30, 2017 was disclosed in a Current Report on Form 8-K filed with the SEC on October 2, 2017.

Item 6. Exhibits

See the Exhibit Index immediately preceding the signature page to this Quarterly Report on Form 10-Q.

EXHIBIT INDEX

Exhibit Number	Description
3.1	<u>Amended and Restated Certificate of Incorporation of Endocyte, Inc. (incorporated by reference from Exhibit 3.1 to Annual Report on Form 10-K for the year ended December 31, 2010 filed March 18, 2011).</u>
3.2	<u>Amended and Restated Bylaws of Endocyte, Inc. (incorporated by reference to Exhibit 3.2 to Annual Report on Form 10-K for the year ended December 31, 2010 filed March 18, 2011).</u>
4.1	<u>Registration Rights Agreement, dated as of September 29, 2017, between Endocyte, Inc. and ABX advanced biochemical compounds – Biomedizinische Forschungsreagenzien GmbH (incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed October 2, 2017).</u>
4.2	<u>Form of Warrant to Purchase Shares of Common Stock, dated as of September 29, 2017 (incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed October 2, 2017).</u>
10.1*	<u>Development and License Agreement, dated as of September 29, 2017, between Endocyte, Inc. and ABX advanced biochemical compounds – Biomedizinische Forschungsreagenzien GmbH (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed October 2, 2017).</u>
31.1	<u>Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934 of the Chief Executive Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2	<u>Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934 of the Chief Financial Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1	<u>Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101	The following materials from Endocyte, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, formatted in Extensible Business Reporting Language (XBRL), includes: (i) Condensed Balance Sheets at December 31, 2016 and September 30, 2017, (ii) Condensed Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2016 and 2017, (iii) Condensed Statement of Stockholders' Equity (Deficit) for the nine months ended September 30, 2017, (iv) Condensed Statements of Cash Flows for the nine months ended September 30, 2016 and 2017 and (v) Notes to Condensed Financial Statements.

*The Securities and Exchange Commission has granted our request that certain provisions of this exhibit be treated as confidential. Such material has been redacted from the exhibit as filed.

SIGNATURES

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

ENDOCYTE, INC.

Date: November 7, 2017

By: /s/ Michael A. Sherman
Michael A. Sherman
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2017

By: /s/ Michael T. Andriole
Michael T. Andriole
Chief Financial Officer
(Principal Financial Officer)

Date: November 7, 2017

By: /s/ Beth A. Taylor
Beth A. Taylor
Vice President of Finance and Chief Accounting Officer
(Principal Accounting Officer)

**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES
EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002**

I, Michael A. Sherman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Endocyte, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with 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.

/s/ Michael A. Sherman
Michael A. Sherman
President and Chief Executive Officer

Date: November 7, 2017

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael T. Andriole, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Endocyte, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with 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.

/s/ Michael T. Andriole
Michael T. Andriole
Chief Financial Officer

Date: November 7, 2017

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael A. Sherman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Endocyte, Inc. on Form 10-Q for the quarter ended September 30, 2017 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Endocyte, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

November 7, 2017

/s/ Michael A. Sherman

Name: Michael A. Sherman

Title: *President and Chief Executive Officer*

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael T. Andriole, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Endocyte, Inc. on Form 10-Q for the quarter ended September 30, 2017 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Endocyte, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

November 7, 2017

/s/ Michael T. Andriole

Name: Michael T. Andriole

Title: *Chief Financial Officer*
