ENDOCYTE INC
Form 10-Q
May 12, 2014

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington , D.C. 20549

Form 10-Q

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

For the quarterly period ended March 31, 2014

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	**35-1969-140**
(State or other jurisdiction of incorporation or organization)	*(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 R 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 R No ¨

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

Large accelerated filer ¨	Accelerated filer R	Non-accelerated filer ¨	Smaller reporting company ¨
		(Do not check if a smaller reporting company)	

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

Number of shares of the registrant's Common Stock, $0.001 par value, outstanding on April 30, 2014: 41,504,778

PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

ENDOCYTE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2013	March 31, 2014 (unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$52,846,940	$32,854,940
Short-term investments	70,434,148	91,318,737
Receivables	6,353,180	5,354,334
Prepaid expenses	3,200,924	4,552,488
Other assets	496,338	953,607
Total current assets	133,331,530	135,034,106
Long-term investments	25,571,659	7,370,093
Property and equipment, net	3,839,426	3,856,117
Other noncurrent assets	114,961	219,563
Total assets	$162,857,576	$146,479,879
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$5,435,473	$3,665,307
Accrued wages and benefits	3,065,905	1,663,316
Accrued clinical trial expenses	3,728,015	3,932,758
Accrued expenses	1,668,944	2,709,418
Deferred revenue	59,746,952	45,733,922
Current portion of other liabilities	18,168	18,225
Total current liabilities	73,663,457	57,722,946
Other liabilities, net of current portion	33,458	29,545
Deferred revenue, net of current portion	931,940	919,440
Total liabilities	74,628,855	58,671,931
Stockholders' equity:		
Common stock: $0.001 par value, 100,000,000 shares authorized; 36,155,509 and 36,302,600 shares issued and outstanding at December 31, 2013 and March 31, 2014	36,156	36,303
Additional paid-in capital	262,060,590	264,789,476

Accumulated other comprehensive income	56,691	48,344
Retained deficit	(173,924,716)	(177,066,175)
Total stockholders' equity	88,228,721	87,807,948
Total liabilities and stockholders' equity	$162,857,576	$146,479,879

See accompanying notes.

ENDOCYTE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three Months Ended March 31,	
	2013	**2014**
	(unaudited)	
Revenue:		
Collaboration revenue	$14,514,144	$17,268,651
Total revenue	14,514,144	17,268,651
Operating expenses:		
Research and development	12,258,639	12,986,763
General and administrative	6,256,002	7,501,394
Total operating expenses	18,514,641	20,488,157
Loss from operations	(4,000,497)	(3,219,506)
Other income (expense), net:		
Interest income	139,736	84,688
Interest expense	(774)	(384)
Other income (expense), net	(136)	(6,257)
Net loss	(3,861,671)	(3,141,459)
Net loss per share – basic and diluted	$(0.11)	$(0.09)
Items included in other comprehensive loss:		
Unrealized gain on foreign currency translation	630	510
Unrealized loss on available-for-sale securities	(40,214)	(8,857)
Other comprehensive (loss)	(39,584)	(8,347)
Comprehensive loss	$(3,901,255)	$(3,149,806)
Weighted-average number of common shares used in net loss per share calculation – basic and diluted	35,930,265	36,193,942

See accompanying notes.

ENDOCYTE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Retained	
	Shares	Amount	Capital	Income (Loss)	Deficit	Total
Balances, December 31, 2013	36,155,509	$36,156	$262,060,590	$ 56,691	$(173,924,716)	$88,228,721
Exercise of stock options	147,091	147	481,062	—	—	481,209
Stock-based compensation	—	—	2,182,211	—	—	2,182,211
Employee stock purchase plan	—	—	65,613	—	—	65,613
Net loss	—	—	—	—	(3,141,459)	(3,141,459)
Unrealized gain on foreign currency translation	—	—	—	510	—	510
Unrealized loss on securities	—	—	—	(8,857)	—	(8,857)
Balances, March 31, 2014 (unaudited)	36,302,600	$36,303	$264,789,476	$ 48,344	$(177,066,175)	$87,807,948

See accompanying notes.

ENDOCYTE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Months Ended March 31,	
	2013	2014
	(unaudited)	
Operating activities		
Net loss	$(3,861,671)	$(3,141,459)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	144,406	201,600
Stock-based compensation	1,145,454	2,247,824
Accretion of bond premium	277,402	341,243
Non cash interest expense	—	—
Loss on disposal of property and equipment	—	2,619
Change in operating assets and liabilities:		
Receivables	1,559,178	126,748
Prepaid expenses and other assets	(60,362)	(1,330,669)
Accounts payable	(1,622,135)	(1,555,926)
Accrued interest, wages, benefits and other liabilities	212,474	(306,429)
Deferred revenue	(12,998,096)	(13,170,993)
Net cash used in operating activities	(15,203,350)	(16,585,442)
Investing activities		
Purchases of property and equipment	(77,607)	(665,829)
Purchases of investments	(53,886,316)	(15,073,013)
Proceeds from sale of investments	71,080,711	12,039,890
Net cash provided by (used in) investing activities	17,116,788	(3,698,952)
Financing activities		
Proceeds from the exercise of stock options	121,791	291,884
Net cash provided by financing activities	121,791	291,884
Effect of exchange rate	630	510
Net increase (decrease) in cash and cash equivalents	2,035,859	(19,992,000)
Cash and cash equivalents at beginning of period	33,996,866	52,846,940
Cash and cash equivalents at end of period	$36,032,725	$32,854,940

See accompanying notes.

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ENDOCYTE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Organization

Endocyte, Inc. (the "Company") is a biopharmaceutical company developing targeted therapies for the treatment of cancer and inflammatory diseases. The Company uses its proprietary technology to create novel small molecule drug conjugates ("SMDCs"), and companion imaging agents. The SMDCs actively target receptors that are over-expressed on diseased cells, relative to healthy cells. This targeted approach is designed to enable the treatment of patients with a highly active drug at greater doses, delivered more frequently, and over longer periods of time than would be possible with the untargeted drug alone. The Company is also developing companion imaging agents for each of its SMDCs that are designed to identify the patients whose disease over-expresses the target of the therapy and who are therefore more likely to benefit from treatment.

The Company has two wholly-owned subsidiaries, Endocyte Europe B.V. and Endocyte Europe GmbH, which have been formed to assist with the administration of the pending applications with the European Commission ("EC") and commercial pre-launch activities in Europe.

2. Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of Endocyte, Inc. and its subsidiaries and all intercompany amounts have been eliminated. The condensed consolidated 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 consolidated financial statements have been included. Interim results for the three months ended March 31, 2014 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2014 or any other future period. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013. 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. The Company is performing clinical trials globally and has established a subsidiary in The Netherlands to assist in the administration of filing applications in Europe and a subsidiary in Switzerland for commercial launch activities in Europe. 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 could 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 that are maintained by an investment manager.

Investments

Investments consist primarily of investments in U.S. Treasuries, U.S. Government agency obligations 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 expense over the term of the security.

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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.* 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, 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 in 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.

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 the collaborator will share profit, the revenue will be recorded in the period earned.

Research and Development Expenses

Research and development expenses represent costs associated with the ongoing development of SMDCs and companion imaging agents and include salaries, supplies, 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.

Upfront payments made in connection with business collaborations and research and development arrangements are evaluated under ASC Subtopic 730-20, *Research and Development Arrangements*. Upfront payments made in connection with business development collaborations are expensed as research and development costs, as the assets acquired do not have alternative future use. 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 March 31, 2014, the Company had approximately $3.7 million of capitalized research and development costs included in prepaid expenses and other noncurrent assets.

Stock-Based Compensation

The Company accounts for its stock options pursuant to ASC Topic 718, *Compensation — Stock Compensation* ("ASC 718"), which requires the recognition of the fair value, or calculated value for nonpublic entities, 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. The Company has issued performance-based restricted stock units ("PRSUs") for which stock-based compensation expense will be recognized when the Company determines that it is probable that the performance conditions will be achieved. The Company has also issued service-based restricted stock units ("RSUs") for which stock-based compensation expense is recognized ratably over the service period. The Company used the calculated value method to measure its stock-based compensation prior to its initial public offering. The Company recognizes compensation cost based on the grant-date 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 and RSUs 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.

The following tables and discussion provide a reconciliation of the numerator and denominator of the basic and diluted net loss per share computations. The calculation below provides net loss, weighted-average common shares outstanding, and the resultant net loss per share on both a basic and diluted basis for the three months ended March 31, 2013 and 2014.

Historical net loss per share

	Three Months Ended March 31,	
	2013	2014
Numerator:		
Net loss	$ (3,861,671)	$ (3,141,459)
Denominator:		
Weighted-average common shares outstanding	35,930,265	36,193,942

Basic and diluted net loss per share	$ (0.11)	$ (0.09)

Common stock equivalents

As of March 31, 2013 and 2014, the following number of potential common stock equivalents were outstanding:

	As of March 31,	
	2013	2014
Outstanding common stock options	4,962,887	5,939,710
Outstanding warrants	133,968	34,647
Outstanding PRSUs	272,750	270,649
Outstanding RSUs	—	196,710
Total	5,369,605	6,441,716

These common stock equivalents were excluded from the determination of diluted net loss per share due to their anti-dilutive effect on earnings.

3. New Accounting Pronouncements

Recently Adopted Accounting Standards

In July 2013, the FASB issued ASU No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists,* an update to ASC Topic 740, *Income Taxes.* This amendment provides clarification regarding the presentation of an unrecognized tax benefit related to a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. Under this new standard, the liability related to an unrecognized tax benefit, or a portion thereof, should be presented in the financial statements as a reduction to a deferred tax asset if available under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position. Otherwise, the unrecognized tax benefit should be presented in the financial statements as a separate liability. The assessment is based on the unrecognized tax benefit and deferred tax asset that exist at the reporting date. The provisions of the new standard were effective on a prospective basis beginning in 2014 for annual and interim reporting periods. This update became effective for the Company beginning January 1, 2014. The adoption did not have a material impact on the Company's interim consolidated financial statements.

4. Other Comprehensive Income (Loss)

The accumulated balances related to each component of other comprehensive income (loss) were as follows:

	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2013	$ (11,816)	$ 68,507	$ 56,691
Unrealized gain (loss)	510	(8,857)	(8,347)
Net amount reclassified to net loss	—	—	—
Other comprehensive income (loss)	510	(8,857)	(8,347)
Balance at March 31, 2014	$ (11,306)	59,650	48,344

The assets and liabilities of foreign operations are translated into U.S. dollars using the current exchange rate. For those operations, changes in exchange rates generally do not affect cash flows, which results in translation adjustments being made in stockholders' equity rather than to net loss.

For the three months ended March 31, 2014, there were no amounts reclassified out of Accumulated Other Comprehensive Income.

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, 2013:

Description	Cost	Level 1	Level 2	Fair Value (Carrying Value)
Cash				
Cash	$7,887,502	$7,887,502	$—	$7,887,502
Cash equivalents				
Money market funds	44,959,438	44,959,438	—	44,959,438
Cash and cash equivalents	$52,846,940	$52,846,940	$—	$52,846,940
Short-term investments (due within 1 year)				
U.S. government treasury obligations	$5,009,194	$5,013,850	$—	$5,013,850
U.S. government agency obligations	33,598,370	33,609,886	—	33,609,886
Corporate obligations	31,789,117	—	31,810,412	31,810,412
Total short-term investments	$70,396,681	$38,623,736	$31,810,412	$70,434,148
Long-term investments (due after 1 year through 2 years)				
U.S. government agency obligations	$14,807,642	$14,821,065	$—	$14,821,065
Corporate obligations	10,743,707	—	10,750,594	10,750,594
Total long-term investments	$25,551,349	$14,821,065	$10,750,594	$25,571,659

The following table summarizes the fair value of cash and cash equivalents and investments as of March 31, 2014:

Description	Cost	Level 1	Level 2	Fair Value (Carrying Value)
Cash				
Cash	$9,048,029	$9,048,029	$—	$9,048,029
Cash equivalents				
Money market funds	23,806,911	23,806,911	—	23,806,911
Cash and cash equivalents	$32,854,940	$32,854,940	$—	$32,854,940
Short-term investments (due within 1 year)				
U.S. government treasury obligations	$5,004,745	$5,008,000	$—	$5,008,000
U.S. government agency obligations	51,005,003	51,021,550	—	51,021,550
Corporate obligations	35,256,158	—	35,289,187	35,289,187
Total short-term investments	$91,265,906	$56,029,550	$35,289,187	$91,318,737
Long-term investments (due after 1 year through 2 years)				
U.S. government treasury obligations	$2,995,377	$2,998,140	$—	$2,998,140
U.S. government agency obligations	1,301,728	1,304,173	—	1,304,173
Corporate obligations	3,066,168	—	3,067,780	3,067,780
Total long-term investments	$7,363,273	$4,302,313	$3,067,780	$7,370,093

All securities held at December 31, 2013 and March 31, 2014, were classified as available-for-sale as defined by ASC 320.

Total unrealized gross gains were $58,888 and $ 79,258 for the three months ended March 31, 2013 and 2014, respectively. Total unrealized gross losses were $21,342 and $19,608 for the three months ended March 31, 2013 and 2014, 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.

6. Collaborations

Merck Collaboration Agreement

In April 2012, the Company entered into a worldwide collaboration agreement with Merck Sharp & Dohme Research GmbH, a subsidiary of Merck & Co, Inc. (“Merck”), regarding the development and commercialization of vintafolide. The agreement grants Merck worldwide rights to develop and commercialize vintafolide and the right to use etarfolatide. The Company received a $120.0 million non-refundable upfront payment and a $5.0 million milestone

payment in 2012 and is eligible for additional milestone payments of up to $875.0 million based on the successful achievement of development, regulatory and commercialization goals for vintafolide in a total of six different cancer indications. Depending on clinical trial data results, the near-term potential milestones that could be reached are for the commencement of the first Phase 3 clinical trial of vintafolide for the treatment of non-small cell lung cancer ("NCSLC"), and for marketing authorization approval by the EC for vintafolide for the treatment of patients with platinum resistant ovarian cancer ("PROC"). In addition, the collaboration agreement with Merck provides that in the event of regulatory approval and launch of vintafolide, the Company would split U.S. earnings under the collaboration arrangement on a 50/50 basis with Merck and would receive a double-digit percentage royalty on sales of the product in the rest of the world. The Company has retained the right (which it can opt out of) to co-promote vintafolide with Merck in the U.S. and Merck has the exclusive right to promote vintafolide in the rest of the world. The Company is responsible for the majority of funding and completion of the Phase 3 PROCEED clinical trial of vintafolide for the treatment of patients with PROC. The Company is responsible for the execution of the Phase 2b TARGET trial of vintafolide for the treatment of second line NCSLC, which is now substantially complete, pending the receipt of overall survival results. Merck is responsible for the costs of the TARGET trial and for all other development activities and costs and will have all decision rights with respect to the development and commercialization of vintafolide. The Company is responsible for the development, manufacture and commercialization worldwide of etarfolatide.

For revenue recognition purposes, the Company viewed the collaboration with Merck 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 evaluated whether the delivered elements under the arrangement have value on a stand-alone basis and whether objective and reliable evidence of fair value of the undelivered element exists. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition. For a single unit of accounting, payments received are recognized in a manner consistent with the final deliverable. The Company has determined that the deliverables related to the collaboration with Merck, including the licenses granted to Merck, as well as the Company performance obligations to provide various research and development services, will be accounted for as a single unit of account. This determination was made because the successful development of the therapeutic drug, vintafolide, is dependent on the companion diagnostic, etarfolatide, to select patients who are most likely to receive the most benefit from vintafolide. Given the nature of the combined benefit of the companion diagnostic and the therapeutic drug, the ongoing research and development services to be provided by the Company are essential to the overall arrangement as the Company has significant knowledge and technical know-how that is important to realizing the value of the licenses granted. Subsequent to the inception of the Merck arrangement, the Company evaluates the remaining deliverables for separation as items in the arrangement are delivered.

The Company has been recognizing the non-refundable $120.0 million upfront payment, the $5.0 million milestone payment and funding from the research and development services on a straight-line basis over the performance period, which started at the date of execution of the agreement. The Company recognized approximately $17.3 million of collaboration revenue during the three months ended March 31, 2014. Though accounted for as a single unit of account for presentation purposes, the Company has made an allocation of revenue recognized as collaboration revenue between the license and the services. This allocation is based upon the relative selling price of each deliverable. For the three months ended March 31, 2014, license revenue was approximately $13.7 million while research and development services were approximately $3.6 million of the collaboration revenue.

The collaboration arrangement with Merck includes milestone payments of approximately $880.0 million. These milestones consist of development milestones of approximately $380.0 million and sales-based milestones of approximately $500.0 million. The development milestones range from $5.0 million to $45.0 million each and are based on the commencement of a new phase of clinical trials for specific indications, filing for approval in the U.S. or major countries in Europe for specific indications and approval in the U.S. and other major countries. The Company evaluated each of these milestone payments and believes that all but one of the milestones are substantive as there is substantial performance risk that must occur in order for them to be met as it 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. The non-substantive milestone is $5.0 million and was received in the fourth quarter of 2012. This milestone payment of $5.0 million is being combined with the other consideration received in the arrangement, being the license and research and development reimbursements, and under the cumulative catch-up approach is being recognized on a straight-line basis. The $500.0 million of sales-based milestones will occur after development milestones are achieved, and the Company will account for these in the same manner as royalties. The sales-based milestones would be achieved if certain sales thresholds are exceeded for worldwide sales of vintafolide and etarfolatide. To date, the products have not been approved and no revenue has been recognized related to the earnings split on U.S sales, development milestones, sales-based milestones or royalties.

Merck has the right to terminate the collaboration agreement on 90 days notice. Merck and the Company each have the right to terminate the agreement due to the material breach or insolvency of the other party. The Company has the right to terminate the agreement in the event that Merck challenges an Endocyte patent right relating to vintafolide. Upon termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of vintafolide and, in the case of termination for cause by Merck, certain royalty obligations and U.S. profit and loss sharing.

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 vintafolide 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 preclinical and clinical supply of etarfolatide, to provide rights to NMP if a product is developed that replaces etarfolatide, obligation for the Company to provide clinical data to NMP during the contract period and coordination of development and commercialization efforts between Merck for vintafolide 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 will be 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 coordination with Merck and the development of the related therapeutic drug, vintafolide. 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 $1.0 million at March 31, 2014. 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.

NMP has the right to terminate the collaboration agreement on 90 days notice prior to 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 and/or Merck fail to launch vintafolide 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)

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, PRSUs, performance units and performance shares, and RSUs. 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 6,625,563 and 8,071,563 shares of common stock authorized and reserved at December 31, 2013 and March 31, 2014 under these plans, 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 vest 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 vest monthly over a four-year period. Generally, options granted under the 2010 Plan vest annually over a four-year period. Unexercised stock options terminate on the tenth anniversary date after the date of grant. The Company recognizes the 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. Prior to 2013, since the Company did not have sufficient history as a publicly traded company to evaluate volatility, the Company used an average of several peer companies' volatilities to determine a reasonable estimate of volatility. Beginning in 2013, the Company utilizes a combination of peer volatility and company volatility. For purposes of identifying peer companies, the Company considered characteristics such as industry, length of trading history, market capitalization and similar product pipelines.

Due to insufficient history as a public company, the Company is using the "simplified" method for "plain vanilla" options to estimate the expected term of the stock options 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 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 months ended March 31, 2013 and 2014 were determined using the following assumptions:

	Three Months Ended March 31,	
	2013	2014
Weighted-average volatility	101 %	102 %
Risk-free interest rate	1.07 %	1.92 %
Weighted-average expected life (in years)	6.3	6.3
Dividend yield	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
Outstanding at January 1, 2014	5,246,465	$ 6.76		
Granted during period	856,261	11.13		
Exercised during period	(147,091)	3.27		
Expired during period	—	—		
Forfeited during period	(15,925)	16.42		
Outstanding at March 31, 2014	5,939,710	$ 7.45	7.6	$97,181,600
Exercisable at March 31, 2014	2,697,802	$ 5.10	6.2	$50,465,826

As of March 31, 2014, the total remaining unrecognized compensation cost related to stock options was $20.6 million, which is being amortized over the remaining requisite service period. The expense is expected to be recognized over a weighted average period of 2.0 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. Each unit represents an amount equal to one share of the Company's common stock. The PRSUs will be earned, in whole or in part, based on performance and service conditions. The performance condition is based upon whether the Company receives regulatory approval to sell a therapeutic product, and the

awards include a target number of PRSUs that will vest upon a First Commercial Approval, and a maximum number of PRSUs that will vest upon a Second Commercial Approval. Any earned PRSUs will vest fifty percent based on the performance condition of commercial approval and fifty percent one year thereafter to fulfill the service condition, which requires the employee to remain employed by the Company.

As of March 31, 2014, the Company had 270,649 PRSU awards outstanding. The unrecorded stock compensation expense is based on number of units granted, less estimated forfeitures based on the Company's historical forfeiture rate of 6.49%, and the closing market price of the Company's common stock at the grant date. As of March 31, 2014, the performance condition of obtaining regulatory approval had not been achieved, therefore, no vesting had occurred. The awards are being accounted for under ASC 718, and compensation expense is to be recorded if the Company determines that it is probable that the performance conditions will be achieved. As of March 31, 2014, it was not probable that the performance conditions will be achieved, therefore, no compensation expense related to the PRSUs was recorded for the three months ended March 31, 2014. Unrecorded compensation expense for the 2011 PRSU program as of March 31, 2014 was $2.7 million.

As of March 31, 2014, the Company had 196,710 RSU awards outstanding under the 2010 Plan which were granted during the three months ended March 31, 2014. The RSUs are service-based awards that will vest and be paid in four equal installments annually beginning in February 2015 in the form of one share of the Company's common stock for each RSU. The awards were granted at a weighted average fair value of $11.11 per share. As of March 31, 2014, the total remaining unrecognized compensation cost related to RSUs was $2.1 million, which is being amortized over the remaining requisite service period, and had a weighted average remaining life of 2.4 years.

8. 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 an equal and offsetting 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 in August 2011. As a result, the future use of its net operating losses and credit equivalents is currently limited to approximately $ 133.2 million for 2014, $39.0 million for 2015, $29.7 million for 2016 and $16.8 million for 2017. Any available but unused amounts will become available for use in all successive years.

9. Subsequent Events

On April 2, 2014, the Company issued 5,175,000 shares of its common stock in a public offering and received net proceeds of approximately $101.8 million.

Following the completion of the pre-specified interim futility analysis of the PROCEED trial, on April 30, 2014, the Data and Safety Monitoring Board (“DSMB”) recommended that the PROCEED trial be stopped because vintafolide did not demonstrate efficacy on the pre-specified outcome of progression free survival (“PFS”). In May 2014, the Company suspended screening and enrollment for the PROCEED trial pending review of the interim data, while continuing to treat patients already participating in the trial. Pending additional review of the PROCEED trial interim data, the EC is not expected to take further action on the pending applications for conditional marketing authorizations in Europe for vintafolide for the treatment of PROC, and etarfolatide and folic acid for patient selection. In the event that the Company decides to terminate the PROCEED trial, the Company would record a charge in the period of termination for the remaining expenses of the trial, including prepaid research and development expenses and site close-out expenses.

The Company may accelerate the recognition of the balance of deferred revenue of $45.7 million associated with the Merck collaboration in the second quarter of 2014. This deferred revenue is a combination of a portion of the upfront payment from Merck, a $5.0 million milestone payment and reimbursable services provided by the Company for the development of vintafolide which, through the end of the first quarter of 2014, was being recognized over the performance period. The potential acceleration would be the result of the completion of certain obligations associated with the Merck collaboration agreement, the transfer of knowledge and know-how to Merck and as a result of the completion of the enrollment of the 250th FR(100%) patient (patients in which 100 percent of their target lesions over-expressed the folate receptor as determined by an etarfolatide scan) in the PROCEED trial. If the remaining deferred revenue balance is recognized in the second quarter of 2014, any future reimbursable research and development services will be recognized as revenue in the period in which the services are performed.

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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," "anticipa "estimate," "expect," "plan," "believe," "predict," "potential," "project," "target," "forecast," "intend" and similar expre 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 Part II — Item 1A of this Quarterly Report on Form 10-Q and 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 developing targeted therapies for the treatment of cancer and inflammatory diseases. We use our proprietary technology to create novel small molecule drug conjugates, or SMDCs, and companion imaging agents. Our SMDCs actively target receptors that are over-expressed on diseased cells, relative to healthy cells. This targeted approach is designed to enable the treatment of patients with highly active drugs at greater doses, delivered more frequently, and over longer periods of time than would be possible with the untargeted drug alone. We are also developing companion imaging agents for each of our SMDCs that are designed to identify the patients whose disease over-expresses the target of the therapy and who are therefore more likely to benefit from treatment. This combination of an SMDC with its companion imaging agent is designed to personalize the treatment of patients by delivering effective therapy, selectively to diseased cells, in the patients most likely to benefit.

One of our lead SMDC candidates, vintafolide, targets the folate receptor, which is frequently over-expressed on cancer cells. We initially chose platinum-resistant ovarian cancer, or PROC, a highly treatment-resistant disease, as our lead indication for development of vintafolide because of the high unmet need in treating this patient population and the high percentage of ovarian cancer patients whose tumors over-express the targeted folate receptor. We conducted a multicenter, open-label randomized phase 2 clinical trial of vintafolide in 149 women with PROC, referred to as the PRECEDENT trial. Based upon our findings from the PRECEDENT trial, we initiated enrollment of our PROCEED trial, a phase 3 registration trial in women with PROC, in the first half of 2011. PROCEED is a randomized, double-blinded trial of vintafolide in combination with pegylated liposomal doxorubicin, or PLD (marketed in the U.S. under the brand name DOXIL® and in Europe under the brand name CAELYX®), compared to PLD plus placebo. In the first quarter of 2013, we announced our decision to amend the PROCEED trial design to incorporate a progression free survival, or PFS, analysis on 250 FR(100%) patients (patients in which 100 percent of their target lesions over-expressed the folate receptor as determined by an etarfolatide scan) which was to be evaluated by the Data and Safety Monitoring Board, or DSMB. On April 30, 2014, the DSMB recommended that the PROCEED trial be stopped after the interim futility analysis was performed because vintafolide did not demonstrate

efficacy on the pre-specified outcome of PFS. In May 2014, we suspended screening and enrollment for the PROCEED trial pending review of the interim data, while continuing to treat patients already participating in the trial. In the event that we decide to terminate the PROCEED trial, we would record a charge in the period of termination for the remaining expenses of the PROCEED trial, including prepaid research and development expenses and site close-out expenses. Merck is responsible for the future development of vintafolide, and has previously announced its intention to initiate a randomized trial for vintafolide in folate-receptor positive, triple negative breast cancer, expected to begin in the second quarter of 2014. It is possible that this could be delayed as Merck evaluates clinical trial data from other trials.

We are also developing vintafolide for use in non-small cell lung cancer, or NSCLC. Based on results of our single-arm, single agent phase 2 clinical trial of vintafolide in patients with second line NSCLC, in 2012 we began enrollment in TARGET, a randomized phase 2b trial, which is now substantially complete. The trial is designed to enroll up to 200 patients with adenocarcinoma and squamous cell carcinoma of the lung who have failed one prior line of therapy and enrollment was completed in July 2013. Patients were selected based on etarfolatide scan results and only FR(100%) patients are included. The trial design is intended to evaluate the safety and efficacy of vintafolide in second line NSCLC as a single agent and in combination with docetaxel, a commonly used second line chemotherapy approved by the U.S. Food and Drug Administration, or the FDA. The study has three arms: docetaxel alone; vintafolide alone; and vintafolide plus docetaxel. The primary outcome measure will be PFS with secondary measures of overall survival, or OS, tumor response and duration of response. In October 2013, we announced the outcomes of the planned DSMB review of the interim futility analysis for the TARGET trial. The DSMB recommended the continuation of the vintafolide plus docetaxel arm and docetaxel alone arm of the trial. The DSMB also recommended investigators and patients be advised that the vintafolide alone arm is not likely to be declared superior to docetaxel in PFS at the end of the study, and patients currently on the vintafolide alone arm may continue treatment based on guidance from their investigator. In March 2014, we announced that the study met the primary endpoint of PFS for the combination vintafolide plus docetaxel arm, and demonstrated initial positive trends in secondary endpoints of OS and response rate. We expect to communicate the detailed data, including updated OS results, at a medical conference in the fall of 2014.

The recommendation of the DSMB regarding the PROCEED trial does not affect our plans to continue the TARGET trial or to advance our pipeline.

In September 2013, the FDA accepted the investigational new drug application, or IND, filed for EC1456, a folate-targeted tubulysin therapeutic. We are currently enrolling patients in a Phase 1 trial.

In March 2014, the FDA accepted the IND filed for EC1169, a tubulysin therapeutic targeting prostate-specific membrane antigen, or PSMA. We have initiated a Phase 1 trial in prostate cancer for EC1169.

In April 2012, we entered into a worldwide collaboration agreement with Merck Sharp & Dohme Research GmbH, a subsidiary of Merck & Co, Inc., or Merck, regarding the development and commercialization of vintafolide. The agreement grants Merck worldwide rights to develop and commercialize vintafolide. We received a non-refundable $120.0 million upfront payment and a $5.0 million milestone payment in 2012 and are eligible for additional milestone payments of up to $875.0 million based on the successful achievement of development, regulatory and commercialization goals for vintafolide in a total of six different cancer indications. In the event that there is regulatory approval and launch of vintafolide, we would split U.S. earnings under the collaboration arrangement on a 50/50 basis with Merck and would receive a double-digit percentage royalty on sales of the product in the rest of the world. We have retained the right (which we can opt out of) to co-promote vintafolide with Merck in the U.S. and Merck has the exclusive right to promote vintafolide in the rest of the world. We are responsible for the majority of funding and completion of the PROCEED trial. We are responsible for the execution of the TARGET trial of vintafolide for the treatment of second line NSCLC, which is now substantially complete, pending the receipt of OS results. Merck is responsible for the costs of the TARGET trial and for all other development activities and costs and has all decision rights with respect to the development and commercialization of vintafolide. We are responsible for the development, manufacture and commercialization worldwide of etarfolatide, the companion imaging diagnostic for vintafolide. Merck has the right to terminate the collaboration agreement on 90 days notice. Each party has the right to terminate the agreement due to the material breach or insolvency of the other party. We have the right to terminate the agreement in the event that Merck challenges an Endocyte patent right relating to vintafolide. Upon termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of vintafolide and, in the case of termination for cause by Merck, certain royalty obligations and U.S. profit and loss sharing. While Merck has not terminated the collaboration agreement as a result of the suspension of the PROCEED trial, the continuation and future success of the collaboration likely depends on the favorable results of ongoing and planned trials, including the final OS data for the TARGET trial.

In March 2014, we received positive opinions from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency on our applications for conditional marketing authorizations in Europe for vintafolide for the treatment of PROC, and etarfolatide and folic acid for patient selection, and we were awaiting formal approval from the European Commission, or EC, on our applications. As a result of the suspension of the PROCEED trial, and pending additional review of the PROCEED trial interim data, the EC is not expected to take further action on the pending applications for conditional marketing authorizations in Europe.

In August 2013, we entered into a license and commercialization agreement with Nihon Medi-Physics Co., Ltd., or NMP, that grants NMP the right to develop and commercialize etarfolatide in Japan for use in connection with vintafolide in Japan. We received a $1.0 million non-refundable upfront payment and are eligible to receive double-digit percentage royalties on sales of etarfolatide in Japan. The upfront payment will be recognized on a straight-line basis over the performance period, which is from the execution of the agreement through the end of 2033, the estimated termination date of the agreement. The agreement with NMP also 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 regulatory approval in Japan for specific and non-specific indications. We evaluated each of these milestone payments and believe that all of the milestones are substantive as there is substantial performance risk that must occur in order for them to be met as they 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. NMP has the right to terminate the collaboration agreement on 90 days notice prior to 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 and/or Merck fail to launch vintafolide 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.

We have never been profitable and have incurred significant net losses since our inception. As of March 31, 2014, we had a retained deficit of $177.1 million. We expect to continue to incur significant and increasing operating expenses for the next several years as we pursue the advancement of our SMDCs and companion imaging diagnostics through the research, development, regulatory and commercialization processes.

As of March 31, 2014, our current cash position was $131.5 million, which includes cash equivalents and investments. In April 2014, we completed a public offering of 5,175,000 shares of our common stock and received net proceeds of approximately $101.8 million. We believe that our current cash balance, including the proceeds from that offering, will be sufficient to fund our current operating plan, including the expenses of the PROCEED trial and the advancement of our pipeline.

Critical Accounting Policies

While our significant accounting policies are described in more detail in our 2013 Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our condensed consolidated financial statements.

Revenue Recognition

We recognize 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,* or ASC 605. Our 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.* 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, 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 our 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 us. If at the inception of an arrangement we determine 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 in the balance sheet and are recognized in a manner consistent with the final deliverable. Subsequent to the inception of an arrangement, we evaluate 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, we recognize 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 our 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.

Milestone payments under collaborative arrangements are triggered either by the results of our research and development efforts, achievement of regulatory goals or by specified sales results by a third-party collaborator. Milestones related to our 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 our performance. Because our involvement is necessary to the achievement of development-based milestones, we 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 our development activities, we 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 our products have been approved and therefore we have not earned any royalty revenue from product sales. In territories we and the collaborator will share profit, the revenue will be recorded in the period earned.

We often are 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 our 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, our estimates regarding the period of performance may change in the future. Any change in our estimates could result in substantial changes to the period over which the revenues are recognized.

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Results of Operations

Comparison of Three Months Ended March 31, 2013 to Three Months Ended March 31, 2014

	Three Months Ended March 31,		$ Increase/ (Decrease)	% Increase/ (Decrease)
	2013	2014		
	(In thousands)			
Statement of operations data:				
Collaboration Revenue	$14,514	$17,269	$ 2,755	19 %
Operating expenses:				
Research and development	12,259	12,987	728	6 %
General and administrative	6,256	7,501	1,245	20 %
Total operating expenses	18,515	20,488	1,973	11 %
Loss from operations	(4,001)	(3,219)	(782)	(20 %)
Interest income	140	85	(55)	(39 %)
Interest expense	(1)	–	(1)	(100 %)
Other income (expense), net	–	(7)	7	100 %
Net loss	$(3,862)	$(3,141)	$ (721)	(19 %)

Revenue

Our revenue of $17.3 million recorded in the three months ended March 31, 2014 related primarily to the collaboration with Merck. Of this revenue, $11.3 million related to the amortization of the $120.0 million upfront license payment, $0.5 million related to a milestone payment and $3.2 million related to reimbursable research and development expenditures incurred prior to the three months ended March 31, 2014. The remaining $2.3 million of revenue related to the amortization of reimbursable research and development expenditures that we incurred during the three months ended March 31, 2014 and the amortization of the $1.0 million non-refundable upfront payment from NMP.

The amortization of both the upfront license payment and the ongoing reimbursable research and development expenditures related to the Merck collaboration have been recognized as revenue ratably over the performance period. NMP revenue related to the upfront payment will be recorded ratably over the contract period. Our revenue of $14.5 million in the three months ended March 31, 2013 related to the collaboration with Merck.

In the second quarter of 2014, we may accelerate the recognition of the balance of deferred revenue of $45.7 million associated with the Merck collaboration. This deferred revenue is a combination of a portion of the upfront payment from Merck, a $5.0 million milestone payment received and reimbursable services provided by us for the development of vintafolide which, through the end of the first quarter of 2014, was being recognized over the performance period. The potential acceleration would be the result of the expected completion of certain obligations associated with the Merck collaboration agreement, the transfer of knowledge and know-how to Merck and as a result of the completion of the enrollment of the 250th FR(100%) patient in the PROCEED trial. If the remaining deferred revenue balance is recognized in the second quarter of 2014, any future reimbursable research and development services will be recognized as revenue in the period in which the services are performed.

Research and Development

The increase in research and development expense for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 was primarily attributable to a $0.8 million increase in expenses relating to the PROCEED trial, a $1.3 million increase in compensation expenses due to increases in headcount and stock based compensation, as well as a $1.0 million increase in development of the pipeline and general research and development expenses. These increases were partially offset by a $1.0 million decrease in expenses relating to the TARGET trial and a $1.2 million decrease in manufacturing expenses for vintafolide which has been transitioned to Merck. Included in research and development expense for the three months ended March 31, 2014 were $3.2 million of expenses that are reimbursable from Merck under the collaboration agreement for vintafolide. In the event that we decide to terminate the PROCEED trial, we would record a charge in the period of termination for the remaining expenses of the trial, including prepaid research and development expenses and site close-out expenses.

Included in research and development expense were stock-based compensation charges of $0.6 million and $1.2 million for the three months ended March 31, 2013 and 2014, respectively.

Research and development expense included expense of $0.2 million and $0.3 million for the three months ended March 31, 2013 and 2014, respectively, for company-funded research at Purdue University, the primary employer of our Chief Science Officer.

General and Administrative

The increase in general and administrative expense in the three months ended March 31, 2014 compared to the three months ended March 31, 2013 was primarily attributable to stock-based compensation and expenses related to European Union, or EU, launch preparations, including an increase in compensation expenses. As previously discussed, pending additional review of the PROCEED interim data, we do not expect the EC to take further action on our conditional marketing applications in Europe for vintafolide, etarfolatide and folic acid, and therefore we will not be incurring any additional launch preparation expenses in the EU during that review. Included in general and administrative expense for the three months ended March 31, 2014 were $0.1 million of expenses that are reimbursable from Merck under the collaboration agreement for vintafolide relating to patent and trademark costs.

Included in general and administrative expense were stock-based compensation charges of $0.5 million and $1.0 million for the three months ended March 31, 2013 and 2014, respectively.

Interest Income

The decrease in interest income in the three months ended March 31, 2014 compared to the three months ended March 31, 2013 resulted from a decrease in the average short- and long-term investment balances during the three months ended March 31, 2014 as compared to the three months ended March 31, 2013.

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 March 31, 2014, we had cash, cash equivalents and investments of $131.5 million.

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

	Three Months Ended March 31,	
	2013	2014
	(In thousands)	
Net cash used in operating activities	$(15,203)	$(16,585)
Net cash provided by (used in) investing activities	17,116	(3,698)
Net cash provided by financing activities	122	292
Effect of exchange rate	1	1
Net increase (decrease) in cash and cash equivalents	$2,036	$(19,992)

Operating Activities

The cash used in operating activities for the three months ended March 31, 2013 and the three months ended March 31, 2014 primarily resulted from our net loss adjusted for non-cash items and changes in operating assets and liabilities, including a decrease in deferred revenue related to the upfront payment from Merck, a milestone payment, and the reimbursable research and development expenditures that through the end of the first quarter have been recognized ratably over the performance period.

Investing Activities

The cash provided by and used in investing activities for each of the three month periods was due primarily to the net result of maturities and purchases of investments, which were partially offset by capital expenditures for equipment of $0.1 million during each of the 2013 and 2014 periods.

Financing Activities

The cash provided by financing activities during the three month periods ended March 31, 2013 and March 31, 2014 consisted of proceeds from the exercise of stock options.

Operating Capital Requirements

We anticipate we will continue to incur significant losses for the next several years as we bear the majority of the expenses of the PROCEED trial for vintafolide and etarfolatide in PROC and as we develop our pipeline.

As of March 31, 2014, our current cash position was $131.5 million, which includes cash equivalents and investments. In April 2014, we completed a public offering of 5,175,000 shares of our common stock and received net proceeds of approximately $101.8 million. We believe that our current cash balance, including the proceeds from that offering, will be sufficient to fund our current operating plan, including the expenses of the PROCEED trial and the advancement of our pipeline.

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 SMDCs and companion imaging diagnostics we pursue;
- the scope, progress, results and costs of researching and developing our SMDCs and companion imaging diagnostics and conducting preclinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our SMDCs and companion imaging diagnostics;
- the cost of commercialization activities if any of our SMDCs and companion imaging diagnostics are approved for sale, including marketing sales and distribution costs;
- the cost of manufacturing any SMDCs and companion imaging diagnostics we successfully commercialize;

- the continuation and success of our collaboration with Merck for vintafolide, including receiving milestone payments under the collaboration, and our ability to establish and maintain other strategic partnerships, licensing or other arrangements and the financial terms of such agreements;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and

- the timing, receipt and amount of sales of, or royalties on, our SMDCs and companion imaging diagnostics, if any.

If our available cash, cash equivalents and investments are insufficient to satisfy our liquidity requirements, or if we develop additional opportunities to pursue, we may seek to sell additional equity or debt securities or obtain new loans or credit facilities. The sale of additional equity securities 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 three month period ended March 31, 2014 to the items that we disclosed as our contractual obligations and commitments in our Form 10-K for the year ended December 31, 2013.

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 March 31, 2014 we had cash, cash equivalents and investments of $131.5 million. The investments consisted of U.S. government money market funds, U.S. Treasuries, U.S. Government agency obligations, U.S. corporate 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, particularly because our investments are in marketable securities. Our 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 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. The carrying value of our investments is 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.

We contract with contract research organizations and investigational sites globally. We may be subject to fluctuations in foreign currency rates in connection with these agreements. A ten percent fluctuation in foreign currency rates would not have a material impact on our financial statements. We currently do not hedge our foreign currency exchange rate risk, but as our operations in foreign countries expand, we may consider the use of hedges.

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

Conclusion Regarding Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our 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 quarter ended March 31, 2014, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

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

Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed below and elsewhere in this report. 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 and results of operations. If any of the risks or uncertainties described below or any additional risks and uncertainties actually occur, our business, results of operations and financial condition could be materially and adversely affected.

Risks Related to Our Business and Industry

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We may never 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 are not profitable and have incurred losses in each year since our inception in December 1995. We have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss for the three months ended March 31, 2014 was $3.1 million. As of March 31, 2014, we had a retained deficit of $177.1 million. We expect to continue to incur significant expenses for the foreseeable future as we continue our development of, and seek regulatory approvals for, our small molecule drug conjugates, or SMDCs, and companion imaging agents, and begin to commercialize any approved products. As such, we are subject to all 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 become profitable. Even if we achieve profitability 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.

As of March 31, 2014, we have not derived any revenue from the sales of our products. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology, undertaking

preclinical studies and clinical trials of our product candidates, engaging in research and development under collaboration agreements and filing applications with the European Medicines Agency, or the EMA, for conditional marketing authorization of our lead SMDC, vintafolide (EC145), and its companion imaging agent, etarfolatide (EC20), and folic acid. The European Commission, or EC, is not expected to take further action on the pending applications for conditional marketing authorizations in Europe pending further review of the PROCEED trial interim data. 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.

We cannot give any assurance that we will successfully complete the clinical development of vintafolide, or that it will receive regulatory approval or be successfully commercialized.

We entered into a collaboration agreement with Merck Sharp & Dohme Research GmbH, a subsidiary of Merck & Co, Inc., or Merck, for the development of vintafolide. Vintafolide is being evaluated in platinum-resistant ovarian cancer, or PROC, in a randomized phase 3 clinical trial, which we refer to as PROCEED. On April 30, 2014, the Data and Safety Monitoring Board, or DSMB, recommended that the PROCEED trial be stopped after the interim futility analysis indicated that vintafolide did not demonstrate efficacy on the pre-specified outcome of progression free survival, or PFS. As a result, we suspended screening and enrollment for the PROCEED trial in May 2014 pending review of the interim data, while continuing to treat patients already participating in the trial. We are currently conducting a randomized phase 2b clinical trial, which we refer to as TARGET, of vintafolide for the treatment of second line non-small cell lung cancer, or NSCLC, which is now substantially complete. These and future trials may not be successful, and vintafolide may never receive regulatory approval or be successfully commercialized. We may fail to obtain necessary marketing approvals for vintafolide from the EC, the U.S. Food and Drug Administration, or the FDA, or other regulatory authorities if our clinical development programs for vintafolide 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 vintafolide through the necessary development activities. Even if vintafolide receives regulatory approval, we and Merck 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 vintafolide and successfully commercialize it would have a material and adverse impact on our collaboration with Merck.

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 preclinical 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. We have completed two phase 2 single-arm and one phase 2 randomized clinical trials with

vintafolide for the treatment of patients with PROC and NSCLC. In May 2014, we suspended screening and enrollment for the phase 3 clinical trial PROCEED, based on the DSMB's recommendation following the interim futility analysis indicating that vintafolide did not demonstrate efficacy on the pre-specified outcome of PFS. We are currently evaluating vintafolide for the treatment of NSCLC in TARGET, a phase 2b clinical trial. In addition, we have other product candidates in the discovery and preclinical testing stages.

Positive results from preclinical studies and early clinical trials should not be relied upon as evidence that later-stage or large-scale clinical trials will succeed. 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 we can seek regulatory approvals for their commercial sale in the United States.

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 FDA approval. In addition, 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.

Our efforts to obtain conditional marketing authorization for vintafolide, etarfolatide and folic acid from the EC may be unsuccessful.

In November 2012, the EMA accepted our applications for conditional marketing authorization for vintafolide for the treatment of PROC and for etarfolatide and folic acid for patient selection. These applications are based on the results of our randomized phase 2 clinical trial, which we refer to as the PRECEDENT trial, which investigated vintafolide in combination with standard chemotherapy agent pegylated liposomel doxorobicin, or PLD (marketed in the U.S. under the brand name DOXIL® and in Europe under the brand name CAELYX®), for treatment of women with PROC and which also evaluated the utility of etarfolatide for patient selection. Pending further review of the PROCEED trial interim data, the EC is not expected to take further action on the pending applications for conditional marketing authorizations in Europe. We cannot predict with any certainty whether the EC will grant the marketing authorizations that we are seeking in these applications.

Marketing authorizations based on phase 2 randomized studies are unusual and, if granted, are subject to significant conditions, which likely would include requirements to:

- complete the phase 3 study;
- confirm that the patient risk-benefit is positive; and
- complete an annual renewal process.

If the EC were to grant conditional marketing authorization of vintafolide and etarfolatide based on our phase 2 studies, that authorization could be further limited or even withdrawn if our required phase 3 studies, such as the PROCEED trial, fail to demonstrate evidence of persuasive and robust statistically significant clinical benefit or if they result in unexpected safety concerns with the study drugs. We cannot give any assurance that the EC will approve our applications for conditional marketing authorization or that, if approved, that the labeling restrictions and other approval conditions will enable us and Merck to profitably commercialize these drug candidates in the European Union. Conditional approval by the EC would not authorize us and Merck to commercialize vintafolide or etarfolatide in any country outside the European Union and would not be expected to have any beneficial effect on our ability to obtain regulatory approval from the FDA or other regulatory agencies.

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. 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, we have a large number of product candidates in our development pipeline, and 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, such as the approval of regulatory applications for our product candidates and other 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 our current and potential future collaborators and the uncertainties inherent in the regulatory approval process. As a result, there can be no assurance that we or our current and potential future collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or our current and potential future 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.

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The coverage and reimbursement status of newly approved biopharmaceuticals is uncertain, and failure to obtain adequate coverage and adequate reimbursement of vintafolide or other 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 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, as evidenced by the Patient Protection and Affordable Care Act and its amendment, the Health Care and Education Reconciliation Act. 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, including failure to recruit and enroll patients for clinical trials.

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;
- delay or failure to obtain IRB approval to conduct a clinical trial at a prospective site; and
- obtaining conditional marketing approval in Europe of vintafolide and etarfolatide prior to the completion of the PROCEED study, which could impact the enrollment timeline as patients to be enrolled in European sites would transition from clinical trials to commercial use.

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 our clinical trial for vintafolide in PROC;

- 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.

For example, we experienced slower than expected rates of patient recruitment and enrollment with our PRECEDENT trial due to a number of reasons, including slower than expected clinical trial site activations due to prolonged contract negotiations and delays in scheduling or approval by IRBs, lack of qualified patients at a particular site, competition with other clinical trials for patients, and clinical investigator scheduling and availability due to vacations or absences.

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities or us. For example, we recently suspended screening and enrollment for the PROCEED trial pending review of the interim data, while continuing to treat patients already participating in the trial, after the interim futility analysis indicated that vintafolide did not demonstrate efficacy on the pre-specified outcome of PFS. 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.

Even if we are able to obtain regulatory approval of vintafolide in Europe based on our pending EMA applications and in the United States based on our initial phase 3 clinical trial, marketing will be limited to our intended indication of PROC and not ovarian cancer generally, or any other type of cancer.

Even if we are able to obtain regulatory approval of vintafolide in Europe based on our pending EMA applications and in the United States based on our PROCEED trial, and Merck formulates and manufactures a commercial-scale product, the marketing of vintafolide will be limited to the initial intended indication of PROC and not ovarian cancer generally, or any other type of cancer. Marketing of vintafolide, if approved for our intended indication, will be limited to those women with ovarian cancer who demonstrate a resistance to platinum-based therapies and who are FR(100%). Marketing efforts for vintafolide outside of PROC will require additional regulatory approvals, which we may never pursue or receive.

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

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

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 EC, 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 this product:

- regulatory authorities may withdraw their approval of this product;
- we may be required to recall this product, change the way this product is administered, conduct additional clinical trials or change the labeling of this product;
- this 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 significant revenues from the sale of the product.

We may not obtain government regulatory approval to market our product candidates or negotiate satisfactory pricing for our product candidates which could adversely impact our future profitability.

We intend to 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. 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 impact the marketability and profitability of the product subject to such restrictions. Satisfaction of these regulatory requirements, which includes satisfying the EMA, the FDA and other 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.

We are advancing multiple product candidates through 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 EC's action on our applications for conditional marketing authorization for vintafolide, etarfolatide and folic acid;
- 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 may enter.

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.

In addition, our operating plan may change as a result of many factors currently unknown to us, and we may need 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, our lead SMDC, vintafolide, is being 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 vintafolide include Roche Holdings, Amgen, ImmunoGen, Inc., Boehringer Ingelheim Pharmaceuticals Inc., GlaxoSmithKline PLC, AstraZeneca PLC, TetraLogic Pharmaceuticals Corp, Verastem, Inc., PsiOxus Therapeutics, Ltd., OncoMed Pharmaceuticals, Inc., Otsuka Pharmaceutical Co., Ltd., VBL Therapeutics, Synta Pharmaceuticals Corp, Sanofi, MolMed S.p.A., California Stem Cell Inc., Karyopharm Therapeutics Inc., AbbVie Inc., Eli Lilly and Company, Peregrine Pharmaceuticals, Inc., KAEL Co. Ltd., Kadmon Pharmaceuticals LLC, Regulon Inc., BioNumerik Pharmaceuticals, Inc., NewLink Genetics Corporation, Bristol-Myers Squibb Company, Synta Pharmaceuticals Corp., and Transgene S.A.**.** In addition, many universities and U.S. private and public research institutes are active in cancer

research, the results of which may result in direct competition with vintafolide or other of our product candidates.

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 that are more effective, safer or less expensive than our product candidates, if any, or that reach the market sooner than our product candidates, if any, we may not achieve commercial success.

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

- the success of our collaboration with Merck for vintafolide;
- 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 our 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. 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. As our operations expand, we expect that we will 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.

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 limited marketing, sales or distribution capabilities. If vintafolide and etarfolatide receive regulatory approval, we expect to rely in part on Merck's sales and marketing organization, technical expertise and supporting distribution capabilities. Under our collaboration with Merck, we have retained the right (which we can opt out of) to co-promote vintafolide with Merck in the U.S. and Merck has the exclusive right to promote vintafolide in the rest of the world. We remain responsible for commercializing etarfolatide on a worldwide basis. We have entered into a license and commercialization agreement with Nihon Medi-Physic Co., LTD., or NMP, giving NMP the right to develop and commercialize etarfolatide in Japan for use in connection with vintafolide in Japan. We will need sales, marketing and distribution capabilities to commercialize vintafolide, etarfolatide and any other of our product candidates. Any failure or delay in the development of these capabilities would adversely impact the commercialization of these products. In addition, any revenue we receive under the collaboration agreement with Merck will significantly depend upon the efforts of Merck as it relates to the promotion of vintafolide, which may not be successful and are generally not within our control. If we are not successful in commercializing our other 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.

If Merck terminates or fails to perform its obligations under our collaboration agreement, the development and commercialization of vintafolide could be delayed or terminated.

A significant portion of any future revenues from vintafolide will depend upon the success of our collaboration with Merck. Under our collaboration agreement, Merck has substantial development, manufacturing and commercialization responsibilities with respect to vintafolide. Merck has the ability to terminate the collaboration agreement at any time in its sole discretion on 90 days' notice, and we cannot assure you that it will not terminate the agreement as a result of the suspension of the PROCEED trial, interim or final OS data in the TARGET trial or for any other reason. If Merck was to terminate our collaboration agreement, fail to meet its obligations or otherwise decrease its level of efforts, allocation of resources or other commitments, the development and commercialization of vintafolide could be delayed or terminated. In addition, if some or any of the development, regulatory and commercial milestones are not achieved or if certain net sales thresholds are not achieved, we will not fully realize the potential economic benefits of the agreement. Further, the achievement of certain of the milestones under this collaboration will depend on factors that are outside of our control and most are not expected to be achieved for several years, if at all.

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 contract research organizations, 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, the EMA 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 studies could result in the product being withdrawn from the market, either of which would likely 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. Under the collaboration agreement with Merck, Merck has assumed responsibility to manufacture vintafolide as part of its development and commercialization activities. We lack the resources and the capability to manufacture any of our other product candidates on a clinical or commercial scale. 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 other 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. For example, we are currently obtaining clinical trial quantities of etarfolatide and our other product candidates from our contract manufacturers. 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. 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 preclinical 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 studies, 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 technetium-99m, as well as drugs used in our clinical trials, such as PLD.

Our etarfolatide companion imaging agent requires the use of the radioisotope technetium-99m, or Tc-99m, and there have been historical periods in which supply was not able to satisfy demand. Tc-99m for nuclear medicine purposes is usually extracted from Tc-99m generators, which contain molybdenum-99, or Mo-99, as the usual parent nuclide for Tc-99m. The majority of Mo-99 produced for Tc-99m medical use comes from fission of highly enriched uranium from only five reactors around the world located in Canada, Belgium, South Africa, the Netherlands and France. Although Tc-99m is used in various nuclear medicine diagnostics utilized by healthcare providers, Tc-99m has a very short half-life (6 hours). As a result, healthcare providers extract Tc-99m from generators which use Mo-99. Mo-99 itself has a short half-life (2.75 days) and is sent to the nuclear medicine pharmacy directly from one of the five reactors. Accordingly, Tc-99m diagnostics are made on-site at the clinic, and neither Tc-99m nor Mo-99 can be inventoried. Sources of Tc-99m may be insufficient for our clinical trial site needs due to its limited supply globally. For example, global shortages of Tc-99m emerged in the past few years because aging nuclear reactors in the Netherlands and Canada that provided about two-thirds of the world's supply of Mo-99 were shut down repeatedly for extended maintenance periods and two replacement Canadian reactors constructed in the 1990s were closed before beginning operation for safety reasons.

We use, and plan to continue to use, etarfolatide or other companion imaging agents that employ Tc-99m in our clinical trials. If our clinical trial sites 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 and as a result, the approval of etarfolatide may be delayed. 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 SMDCs 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 our collaborators and contractors fail to comply with continuing regulations, we or they may be subject to enforcement action that could adversely affect us.

If our product candidates become approved products, we and our contractors will continue to be subject to pervasive regulation by the EMA, the FDA and other regulatory authorities. We and our 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 of our collaborators or contractors fail to comply with the requirements of the EMA, 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 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

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. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. We cannot be certain that our patent applications will be approved or that any patents issued will adequately protect our intellectual property. For example, our issued patents do not claim composition of matter protection for the drug payloads connected to the linker system and targeting ligand modules of our SMDCs. In addition, we generally do not 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. 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 Purdue Research Foundation 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:

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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 patents and our financial ability to enforce our patents 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 on trade secrets to protect some of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our or any of our collaboration partners' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors and we may not

have adequate remedies in respect of that disclosure. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, non-U.S. courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

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

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 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. 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 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 Purdue Research Foundation, pursuant to a license agreement, which enables us to use and administer vintafolide in the treatment of cancer. Under this license we are subject to commercialization and development, diligence obligations, sublicense revenue sharing requirements, royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach this 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. Generally, the loss of any current or future licenses or the exclusivity rights provided therein could 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. For example, one of our U.S. patents claims compounds encompassing vintafolide and is due to expire in 2026, and two of our other U.S. patents claim compounds encompassing etarfolatide and are due to expire in 2024. 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 our U.S. and non-U.S. 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 we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have 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 for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost 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 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.

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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 competitor'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 our patents or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or other intellectual property rights. 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 patents held by the Purdue Research Foundation, it would have to file such an infringement lawsuit since we do not have the independent right to enforce the Purdue Research Foundation's intellectual property. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our 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 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 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, including vintafolide, 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;

- possible termination of, or other unfavorable developments relating to, our collaboration with Merck for vintafolide;
- 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 manufacturing 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;
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- 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 litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could result in the delays of our clinical trials or commercialization efforts.

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 March 31, 2014, we had 36,302,600 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. Subject to the expiration of the 90-day lock-up agreements entered into by our affiliates in March 2014, shares held by our affiliates may be sold in the public market pursuant to Rule 144, another exemption from registration or an effective registration statement under the Securities Act.

Certain holders of our common stock have contractual registration rights pursuant to which they may require us to register the resale of their shares in a public offering — either a public offering we have initiated for other purposes or a special offering initiated by these holders. These registration rights are subject to a variety of conditions, limitations and exceptions. The market price of our common stock could decline if these holders exercise their registration rights or they are otherwise perceived as intending to sell their shares.

Our existing stockholders have substantial control of our management and affairs, which could limit your ability to influence the outcome of key transactions, including a change of control.

Our directors, executive officers and each of the three stockholders who own greater than five percent of our outstanding common stock and their affiliates, in the aggregate, beneficially owned approximately 44.4 percent of the

outstanding shares of our common stock as of March 31, 2014. As a result, these stockholders, if acting together, could influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might affect the market price of our common stock.

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 Corporate 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 management’s assessment of 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 $133.2 million for 2014, $39.0 million for 2015, $29.7 million for 2016 and $16.8 million for 2017. Any available but unused amounts will become available for use in all successive years. At December 31, 2013, we recorded a full valuation allowance against our net operating loss carryforwards of approximately $76.4 million, as we believe it is more likely than not that the net operating loss carryforwards will not be fully realized.

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

Unregistered Sales of Securities

None.

Item 5. ***Other Information***

During the quarter ended March 31, 2014, the Audit Committee of our Board of Directors did not approve the engagement of Ernst & Young LLP, our independent registered public accounting firm, to perform certain non-audit services and no such services were provided during this period. This disclosure is made pursuant to Section 10A(i)(2) of the Securities Exchange Act of 1934, as added by Section 202 of the Sarbanes-Oxley Act of 2002.

Item 6. ***Exhibits***

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

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: May 12, 2014 By: **/s/ P. Ron Ellis**
P. Ron Ellis
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 12, 2014 By: **/s/ Michael A. Sherman**
Michael A. Sherman
Chief Financial Officer
(Principal Financial Officer)

Date: May 12, 2014 By: **/s/ Beth A. Taylor**
Beth A. Taylor
Corporate Controller
(Principal Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
10.1	Third Amendment of Lease Agreement dated January 31, 2014 between Endocyte, Inc. and Purdue Research Foundation.
10.2	Form of Endocyte, Inc. 2010 Equity Incentive Plan Time-Based Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed February 10, 2014).
31.1	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.
31.2	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.
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101^	The following materials from Endocyte, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at December 31, 2013 and March 31, 2014, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2013 and 2014, (iii) Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the three months ended March 31, 2014, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2013 and 2014 and (v) Notes to Condensed Consolidated Financial Statements.

^ XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Exchange Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.