ENDOCYTE INC
Form 10-Q
November 13, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2012

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

Securities registered pursuant to Section 12(b) of the Act:

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 þ 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 þ 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 ¨	Non-accelerated filer þ	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 þ

Number of shares of the registrant's Common Stock, $0.001 par value, outstanding on November 1, 2012: 35,910,084

ENDOCYTE, INC.

FORM 10-Q

FOR THE THREE MONTHS AND NINE MONTHS ENDED SEPTEMBER 30, 2012

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

ENDOCYTE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2011	September 30, 2012 (unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$61,352,483	$36,728,677
Short-term investments	66,732,242	152,701,213
Receivables	—	5,738,330
Prepaid expenses	1,122,979	1,701,471
Other assets	548,320	510,795
Total current assets	129,756,024	197,380,486
Long-term investments	—	15,277,363
Property and equipment, net	1,107,851	2,531,863
Other noncurrent assets	811,229	631,757
Total assets	$131,675,104	$215,821,469
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$2,125,500	$2,080,682
Accrued wages and benefits	1,032,334	1,555,086
Accrued clinical trial expenses	665,477	1,960,596
Accrued interest payable	105,942	—
Accrued expenses	1,540,749	1,346,070
Deferred revenue	—	48,546,369
Current portion of capital lease	—	12,336
Total current liabilities	5,470,002	55,501,139
Capital lease, net of current portion	—	19,722
Long-term debt, net of current portion	12,833,179	—
Deferred revenue, net of current portion	—	60,682,951

Total liabilities	18,303,181	116,203,812
Stockholders' equity:		
Common stock: $0.001 par value, 100,000,000 shares authorized; 35,784,485 and 35,906,490 shares issued and outstanding at December 31, 2011 and September 30, 2012, respectively	35,785	35,907
Additional paid-in capital	251,942,922	254,558,750
Accumulated other comprehensive loss	(6,264)	66,684
Retained deficit	(138,600,520)	(155,043,684)
Total stockholders' equity	113,371,923	99,617,657
Total liabilities and stockholders' equity	$131,675,104	$215,821,469

See accompanying notes.

ENDOCYTE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2012	2011	2012
	(unaudited)		(unaudited)	
Revenue:				
Collaboration revenue	$—	$12,414,684	$—	$20,227,649
Operating expenses:				
Research and development	8,915,577	9,930,766	21,075,853	25,153,659
General and administrative	2,723,296	3,814,991	7,137,657	10,103,692
Total operating expenses	11,638,873	13,745,757	28,213,510	35,257,351
Loss from operations	(11,638,873)	(1,331,073)	(28,213,510)	(15,029,702)
Other income (expense) net:				
Interest income	35,374	96,459	91,238	137,497
Interest expense	(448,762)	(891)	(1,637,022)	(628,215)
Other expense, net	(17,646)	(3,861)	(18,308)	(922,744)
Net loss	(12,069,907)	(1,239,366)	(29,777,602)	(16,443,164)
Net loss per share — basic and diluted	$(0.36)	$(0.03)	$(1.11)	$(0.46)
Weighted-average number of common shares used in net loss per share calculation — basic and diluted	33,414,303	35,881,112	26,732,173	35,841,116
Items included in other comprehensive loss:				
Unrealized gain (loss) on foreign currency translation	(1,109)	1,544	(1,109)	2,624
Unrealized gain (loss) on available-for-sale securities	(14,815)	114,855	14,961	70,324
Other comprehensive loss	(15,924)	116,399	13,852	72,948
Comprehensive loss	$(12,085,831)	$(1,122,967)	$(29,763,750)	$(16,370,216)

See accompanying notes.

ENDOCYTE, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Retained	
	Shares	Amount	Capital	Income (Loss)	Deficit	Total
Balances, December 31, 2011	35,784,485	$35,785	$251,942,922	$ (6,264)	$(138,600,520)	$113,371,923
Exercise of stock options	122,005	122	367,474	—	—	367,596
Stock-based compensation	—	—	2,248,354	—	—	2,248,354
Net loss	—	—	—	—	(16,443,164)	(16,443,164)
Unrealized gain on foreign currency translation	—	—	—	2,624	—	2,624
Unrealized gain on securities	—	—	—	70,324	—	70,324
Balances September 30, 2012 (unaudited)	35,906,490	$35,907	$254,558,750	$ 66,684	$(155,043,684)	$99,617,657

See accompanying notes.

ENDOCYTE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,	
	2011	2012
	(unaudited)	
Operating activities		
Net loss	$(29,777,602)	$(16,443,164)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	200,326	244,004
Stock-based compensation expense	1,345,609	2,248,354
Accretion of bond discount	190,326	564,690
Non cash interest expense	601,817	73,915
Loss on disposal of property and equiment	3,422	—
Loss on debt extinguishment	—	992,281
Change in operating assets and liabilities:		
Receivables		(5,738,330)
Prepaid expenses and other assets	1,081,921	(313,968)
Accounts payable	1,302,055	(489,281)
Accrued interest, wages, benefits and other liabilities	1,136,425	1,549,308
Deferred revenue	—	109,229,320
Net cash provided by (used in) operating activities	(23,915,701)	91,917,129
Investing activities		
Purchases of property and equipment	(198,810)	(1,626,280)
Purchases of investments	(193,560,556)	(243,336,342)
Proceeds from sale of investments	121,156,529	141,595,642
Net cash used in investing activities	(72,602,837)	(103,366,980)
Financing activities		
Proceeds from issuance of subordinated convertible notes, net of issuance costs	3,590,837	—
Repayment of long-term borrowings	(2,708,011)	(13,544,175)
Proceeds from initial public offering, net of issuance costs	78,167,843	—
Proceeds from second public offering, net of issuance costs	66,734,890	—
Proceeds from the exercise of stock options	502,299	367,596
Net cash provided by (used in) financing activities	146,287,858	(13,176,579)
Effect of Exchange Rate	(1,108)	2,624
Net increase in cash and cash equivalents	49,768,212	(24,623,806)
Cash and cash equivalents at beginning of period	16,872,783	61,352,483
Cash and cash equivalents at end of period	$66,640,995	$36,728,677

See accompanying notes.

ENDOCYTE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Organization

Endocyte, Inc. (the "Company") was incorporated on December 6, 1995. 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 diagnostics.

The Company has a wholly-owned subsidiary, Endocyte Europe B.V., a limited liability company in The Netherlands, formed to assist with the administration of the filing of applications with the European Medicines Agency ("EMA") and pre-commercial planning activities.

Public Offerings

On February 9, 2011, the Company completed its initial public offering of 14,375,000 shares of common stock, including 1,875,000 shares of common stock pursuant to the exercise of the over-allotment option by the underwriters. Proceeds, net of underwriting discounts, commissions and other transaction costs were approximately $78.2 million. Upon the closing of the offering, all outstanding subordinated convertible notes were converted into shares of common stock, all outstanding shares of preferred stock were converted to common stock and all outstanding warrants to purchase preferred stock were converted to warrants to purchase common stock and reclassified from a liability to equity. On August 2, 2011, the Company completed a public offering of 5,839,810 shares of common stock, including 871,489 shares of common stock pursuant to the exercise of the over-allotment option by the underwriters. Proceeds, net of underwriting discounts, commissions and other transaction costs were approximately $66.7 million.

2. Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of Endocyte, Inc. and Endocyte Europe B.V., and all intercompany amounts have been eliminated. The condensed consolidated financial statements are prepared in conformity with United States ("U.S.") generally accepted accounting principles ("GAAP") for interim financial information and with the instructions 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 and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2012 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, 2011. The Company issues its financial statements by filing them with the Securities and Exchange Commission ("SEC") and evaluates subsequent events up to the time of filing.

Reclassifications

Certain amounts in the 2011 consolidated financial statements have been reclassified to be consistent with the 2012 presentation.

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 with the EMA and pre-commercial planning activities. 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, including 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 designation 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.

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"). Our license and collaboration agreements may contain multiple elements, including grants of licenses to intellectual property rights and agreement to provide research and development services. The deliverables under such arrangements are evaluated under ASC Subtopic 605-25, *Multiple-Element Arrangements.* Effective January 1, 2011, we adopted an accounting standard update that amends the guidance on accounting for arrangements with multiple deliverables. Pursuant to the new standard, 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 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. When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting. This evaluation requires subjective determinations and requires management to make judgments about the selling price of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

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 the Company determines that the license does not have stand-alone value separate from the research and development services, the license and the services are combined as one unit of account and upfront payments are recorded as deferred revenue in the balance sheet and are recognized as revenue over the estimated performance period that is consistent with the term of the research and development obligations contained in the collaboration agreement. 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 issued.

In those circumstances where research and development services 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. 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 the Company’s research and development efforts 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 substantial (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. 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 when sales first achieve a defined level. Under the Company’s collaboration agreement with Merck Sharp & Dohme Research GmbH, a subsidiary of Merck & Co, Inc. (“Merck”) for vintafolide, one of the Company’s SMDCs, Merck will take the lead in commercialization activities in certain territories and the Company has retained the right (which the Company can opt out of) to co-promote vintafolide in the U.S. with Merck. 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 diagnostics 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 September 30, 2012, the Company had approximately $1,700,000 of capitalized research and development costs included in prepaid expense and 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 to employees 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 restricted stock units (“RSUs”) for which stock-based compensation expense will be recognized once the performance conditions are achieved. The Company used the calculated value 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, restricted stock, warrants 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 and nine months ended September 30, 2011 and 2012.

Historical net loss per share

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2012	2011	2012
Numerator:				
Net loss	$(12,069,907)	$(1,239,366)	$(29,777,602)	$(16,443,164)
Denominator:				
Weighted-average common shares outstanding	33,414,303	35,881,112	26,732,173	35,841,116
Basic and diluted net loss per share	$(0.36)	$(0.03)	$(1.11)	$(0.46)

Common stock equivalents

As of September 30, 2011 and 2012, the following number of potential common stock equivalents were outstanding:

	As of September 30,	
	2011	2012
Outstanding common stock options	2,633,247	3,876,968
Outstanding RSUs	270,988	273,988
Outstanding warrants	133,968	133,968
Total	3,083,203	4,284,924

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 Standard s

In May 2011, the FASB issued ASU 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in GAAP and IFRS,* or ASU 2011-04. ASU 2011-04 amends ASC Topic 820, *Fair Value Measurements and Disclosure* ("ASC 820"), to ensure that fair value has the same meaning in GAAP and International Financial Reporting Standards ("IFRS"), and improves the comparability of the fair value measurement and disclosure requirements in GAAP and IFRS. ASU 2011-04 applies to all entities that measure assets, liabilities or instruments classified in shareholders' equity at fair value, or provide fair value disclosures for items not recorded at fair value. ASU 2011-04 results in common fair value measurement and disclosure requirements in GAAP and IFRS. Consequently, ASU 2011-04 changes the wording used to describe many of the requirements in GAAP for measuring fair value and for disclosing information about fair value measurements. For many of the requirements, ASU 2011-04 will not result in a change in the application of the requirements in ASC 820. Some of the requirements in ASU 2011-04 clarify the FASB's intent about the application of existing fair value measurement requirements. Other requirements change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. ASU 2011-04 is effective for public companies for interim and annual periods beginning after December 15, 2011 and should be applied prospectively. This update became effective for the Company on January 1, 2012. The adoption of this guidance did not have an impact on the Company's condensed consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income* an update to ASC Topic 220, *Comprehensive Income* . This update requires that all nonowner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This update is to be applied retrospectively and is effective for financial statements issued for fiscal years, and interim periods within those years, beginning after December 15, 2011, and interim and annual periods thereafter. This update became effective for the Company on January 1, 2012. The adoption of this guidance did not have a material impact on the Company's condensed consolidated financial statements.

4. Investments

Effective January 1, 2008, the Company adopted and applies the provisions of 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 not 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 tables summarize the fair value of cash and cash equivalents and investments as of December 31, 2011:

Description	Cost	Level 1	Fair Value (Carrying Value)
Cash			
Cash	$7,186,896	$7,186,896	$ 7,186,896
Cash equivalents			
Money market funds	$54,165,587	$54,165,587	$ 54,165,587
Cash and cash equivalents	$61,352,483	$61,352,483	$ 61,352,483
Short-term investments			
U. S. treasury obligations	$23,013,799	$23,016,965	$ 23,016,965
U.S. government agency obligations	43,718,989	43,715,277	43,715,277
Total Short-term investments	$66,732,788	$66,732,242	$ 66,732,242

The following tables summarize the fair value of cash and cash equivalents and investments as of September 30, 2012:

Description	Cost	Level 1	Level 2	Fair Value (Carrying Value)
Cash				
Cash	$4,698,344	$4,698,344	$—	$ 4,698,344
Cash equivalents				
Money market funds	32,030,333	32,030,333	—	32,030,333
Cash and cash equivalents	$36,728,677	$36,728,677	$—	$ 36,728,677
Short–term investments (due within 1 year)				
U.S. government agency obligations	$102,186,851	$102,205,459	$—	$ 102,205,459
Corporate obligations	50,447,853	—	50,495,754	50,495,754
Total Short–term investments	$152,634,704	$102,205,459	$50,495,754	$ 152,701,213

Long–term investments (due after 1 year through 2 years)				
U.S. government treasury obligations	10,062,326	10,064,513	—	10,064,513
U.S. government agency obligations	3,702,626	3,702,032	—	3,702,032
Corporate obligations	$1,509,142	$—	$1,510,818	$ 1,510,818
Total Long–term investments	$15,274,094	$13,766,545	$1,510,818	$ 15,277,363

All securities held at September 30, 2012, were classified as available-for-sale as defined by ASC 320.

Total unrealized gross gains were $18,731 and $71,936 for the nine months ended September 30, 2011 and 2012, respectively. Total unrealized gross losses were $3,770 and $2,158 for the nine months ended September 30, 2011 and 2012, respectively. The Company does not consider any of the unrealized losses to be other-than-temporary impairments.

5. Long-Term Debt

Long-term debt consisted of the following:

	As of December 31, 2011	As of September 30, 2012
Notes payable to Mid-Cap and SVB including final payment, with fixed interest rate of 9.75%, monthly payments through December 1, 2015	12,929,489	—
Less unamortized discount	(96,310)	—
	$ 12,833,179	$ —

In August 2010, the Company obtained a $15.0 million credit facility from Mid Cap Financial (“Mid-Cap”) and Silicon Valley Bank (“SVB”) and borrowed $10.0 million at the time the facility was created. In December 2010, the Company accessed the remaining tranche of $5.0 million. In June 2012, the Company terminated the facility, paid the entire outstanding balance and recorded a loss on debt extinguishment of $992,000, which included a 5% prepayment fee of $615,000 and the write off of unamortized deferred financing fees and discounts of $377,000.

6. Merck Collaboration Agreement

In April 2012, the Company entered into a worldwide collaboration agreement with 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 is eligible for milestone payments of up to $880.0 million based on the successful achievement of development, regulatory and commercialization goals for vintafolide in a total of six different cancer indications. In addition, following regulatory approval and launch of vintafolide, the Company will split U.S. earnings under the collaboration arrangement on a 50/50 basis with Merck and will 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 will be responsible for the majority of funding and completion of the ongoing Phase 3 PROCEED clinical trial of vintafolide for the treatment of patients with platinum resistant ovarian cancer. The Company will be responsible for the execution of the Phase 2b TARGET trial of vintafolide for the treatment of second line non-small cell lung cancer. Merck will be 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 will remain 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. The performance period that the revenue will be recognized over continues from the date of execution of the agreement through the end of 2014, when the Company expects to be completed with the various trials that are specified in the collaboration agreement and the Company’s performance obligations will be completed.

The Company will recognize the non-refundable $120.0 million upfront payment and funding from the research and development services on a straight-line basis over the performance period. The Company recognized approximately $12.4 million and $20.2 million of collaboration revenue during the three and nine month periods ended September 30, 2012, and has deferred revenue of approximately $109.2 million at September 30, 2012. As future research and development services are performed and become billable, the Company will utilize a cumulative catch-up approach for purposes of recognizing the consideration on a straight-line basis. 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 and nine month periods ended September 30, 2012, license revenue was approximately $9.8 million and $16.0 million, respectively, and research and development services were approximately $2.6 million and $4.2 million, respectively, 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 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 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. The non-substantive milestone is $5.0 million and once earned will be combined with the other consideration received in the arrangement, being the license and research and development reimbursements, and under the cumulative catch-up approach will be recognized on a straight-line basis during the performance period. 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.

7. Stockholders' Equity

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, RSU, performance units and performance shares. Awards under the 2010 Plan may be made to employees, directors and certain consultants as determined by the compensation committee of the board of directors. There were 3,795,563 and 5,195,563 shares of common stock authorized and reserved at December 31, 2011 and September 30, 2012 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 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, and employee exercise behavior. Since the Company does not yet have sufficient history as a publicly traded company to evaluate volatility, the Company has used an average of several peer companies' volatilities to determine a reasonable estimate of volatility. For purposes of identifying similar entities, 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 elected to use 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 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 is based on historical experience and the Company’s estimate of future dividend yields.

The weighted-average value of the individual options granted during the three and nine months ended September 30, 2011 and 2012 were determined using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2012	2011	2012
Weighted-average volatility	85.0 %	90.0 %	83.0 %	89.1 %
Risk-free interest rate	1.62 %	0.91 %	2.29 %	1.10 %
Weighted-average expected life (in years)	6.3	6.2	6.2	6.2
Dividend yield	0.00 %	0.00 %	0.00 %	0.00 %

The Company’s stock option activity and related information during the nine months ended September 30, 2012 are summarized as follows:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2012	2,592,009	$ 5.12		
Granted during period	1,138,595	3.55		
Exercised during period	(52,659)	2.17		
Expired during period	(2,611)	3.82		
Forfeited during period	(35,684)	5.92		
Outstanding at March 31, 2012	3,639,650	$ 4.67	8.02	$5,079,777
Exercisable at March 31, 2012	1,355,713	$ 2.77	5.86	$3,052,553
Outstanding at April 1, 2012	3,639,650	$ 4.67		
Granted during period	98,000	6.46		
Exercised during period	(31,005)	3.01		
Expired during period	—			
Forfeited during period	(21,445)	7.96		

Outstanding at June 30, 2012	3,685,200	$ 4.71	7.84	$14,122,262
Exercisable at June 30, 2012	1,624,300	$ 3.85	6.15	$7,518,395
Outstanding at July 1, 2012	3,685,200	$ 4.71		
Granted during period	241,000	8.61		
Exercised during period	(38,341)	4.24		
Expired during period	(10,891)	11.30		
Forfeited during period	—			
Outstanding at September 30, 2012	3,876,968	$ 4.94	7.74	$19,876,667
Exercisable at September 30, 2012	1,636,660	$ 3.82	5.93	$10,228,239

As of September 30, 2012, the total remaining unrecognized compensation cost related to stock options was $7.4 million which is being amortized over the remaining requisite service period. The expense is expected to be recognized over a weighted average period of 1.9 years.

Restricted Stock Units

In May 2011, the Company adopted and granted awards under a new performance-based RSU program (the “2011 RSU Program”) under the Company’s 2010 Plan. Each unit represents one share of the Company’s common stock. The RSUs 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 RSUs that will vest upon a first commercial approval, and a maximum number of RSUs that will vest upon a second commercial approval. The RSUs 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 September 30, 2012, the Company had 273,988 RSU 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 September 30, 2012, the performance condition of obtaining regulatory approval has not been achieved, therefore, no vesting has occurred. The awards are being accounted for under ASC 718, and compensation expense is to be recorded if the Company has determined that it is probable that the performance conditions will be achieved. As of September 30, 2012, it was not probable that the performance conditions will be achieved, therefore, no compensation expense was recorded for the quarter ended September 30, 2012. Unrecorded compensation expense for the 2011 RSU Program as of September 30, 2012 was $2.7 million.

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 an ownership change 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, after giving effect to net unrealized built-in gains, will be limited to approximately $55,200,000 for 2012, $39,000,000 per year for the years 2013 through 2015, $29,700,000 for 2016 and $16,800,000 for 2017. Any available but unused amounts will become available for use in all successive years.

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 diagnostics. 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 diagnostics 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 diagnostic is designed to personalize the treatment of patients by delivering effective therapy, selectively to diseased cells, in the patients most likely to benefit.

Our lead SMDC candidate, vintafolide (EC145), targets the folate receptor, which is frequently over-expressed on cancer cells. We have chosen 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. However, we suspended enrollment for several months due to global shortages of pegylated liposomal doxorubicin, or PLD (marketed in the United States, or U.S., under the brand name Doxil and outside the U.S. under the brand name Caelyx). We secured a sufficient supply of PLD to resume PROCEED enrollment in the U.S. and select sites in Europe. In October, Janssen Products, LP announced that full access to PLD supply in the U.S. is sufficient to bridge to the availability of new supply. This new supply solution is under expedited review by the FDA. Janssen Cilag International NV also announced in October the EU regulatory approval of a new supply solution. Sustainable commercial supply will not

be available immediately so we will activate additional sites in Europe as supply allows. In 2012, we have been increasing the amount of time and resources, both financial and personnel, devoted to our vintafolide program in PROC.

We are planning to file marketing authorization applications to the European Medicines Agency, or EMA, for vintafolide for the treatment of PROC and etarfolatide (EC20) and folic acid for patient selection in the fourth quarter of 2012. These filings will be based on the results and supplemental analyses of our PRECEDENT trial. Our filings will be supported by four clinical studies: a Phase 1 study in solid tumors, two single agent, single-arm Phase 2 studies in ovarian cancer and non-small cell lung cancer, or NSCLC, and the PRECEDENT trial, a randomized study in PROC. The results of the PRECEDENT trial demonstrated a statistically significant delay in disease progression or death in the overall population, with the largest improvement observed in the FR(++) patient population, those with all tumors positive for the folate receptor. Women with FR(++) platinum resistant ovarian cancer who received vintafolide-based therapy experienced a 62 percent decrease in their risk of progression [HR 0.381, p= 0.018] compared to women receiving chemotherapy alone. Median progression free survival (PFS; the time without disease progressing) in the vintafolide based treatment arm was 5.5 months compared to 1.5 months of women who received chemotherapy alone. Tumor shrinkage (overall response rate) was observed in 17.3 percent of women receiving the vintafolide-based therapy compared to 6.7 percent in patients treated with chemotherapy alone.

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 in the second quarter of 2012 and are eligible for milestone payments of up to $880.0 million based on the successful achievement of development, regulatory and commercialization goals for vintafolide in a total of six different cancer indications. In addition, following regulatory approval and launch of vintafolide, we will split U.S. earnings under the collaboration arrangement on a 50/50 basis with Merck and will 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 will be responsible for the majority of funding and completion of the ongoing Phase 3 clinical trial of vintafolide for the treatment of patients with PROC. We will be responsible for the execution of the TARGET trial of vintafolide for the treatment of second line non-small cell lung cancer, or NSCLC. Merck will be 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. We will remain responsible for the development, manufacture and commercialization worldwide of etarfolatide. 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.

In addition to PROC, Merck will be pursuing clinical trials of vintafolide in other indications and we also plan to advance other SMDCs and companion imaging diagnostics through development as preclinical and clinical trial results merit and funding permits. We began enrollment in the TARGET trial, a randomized phase 2b trial of vintafolide and etarfolatide for the treatment of second line NSCLC in the second quarter of 2012.

We have never been profitable and have incurred significant net losses since our inception. As of September 30, 2012, we had a retained deficit of $155.0 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.

We expect that our current cash position of $204.7 million at September 30, 2012, which includes cash equivalents and investments, is sufficient to fund our current operating plan, including completion of PROCEED, the phase 3 clinical trial of vintafolide and etarfolatide, through the availability of final primary PFS data from that study which is anticipated to be in the first half of 2014, assuming the availability of PLD, the filing of applications to the EMA for conditional marketing authorization for vintafolide, etarfolatide and folic acid, and the advancement of our earlier stage pipeline. If we were to receive conditional marketing approval in Europe of vintafolide and etarfolatide prior to the completion of the PROCEED study, this could impact the enrollment timeline as patients to be enrolled in European sites would transition from clinical trials to commercial use. This could delay the availability of final data from the PROCEED trial. We may be able to mitigate this potential delay by adding clinical trial sites in locations where conditional marketing approval has not been granted. If we initiate significant investments in our earlier stage pipeline and commercial capabilities, we may require additional financing through public or private equity or debt financings or other sources, such as other strategic partnerships or licensing arrangements, to fund the additional activities. Such funding may not be available on favorable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies.

Critical Accounting Policies

While our significant accounting policies are described in more detail in our 2011 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 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 the Financial Accounting Standards Board, or

FASB, Accounting Standard Codification, or ASC, Topic 605, *Revenue Recognition* . Our license and collaboration agreements may contain multiple elements, including grants of licenses to intellectual property rights and agreement to provide research and development services. The deliverables under arrangements are evaluated under ASC Subtopic 605-25, *Multiple-Element Arrangements.* Effective January 1, 2011, we adopted an accounting standard update that amends the guidance on accounting for arrangements with multiple deliverables. Pursuant to the new standard, 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 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. When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting. This evaluation requires subjective determinations and requires management to make judgments about the selling price of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

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 we determine that the license does not have stand-alone value separate from the research and development services, the license and the services are combined as one unit of account and upfront payments are recorded as deferred revenue in the balance sheet and are recognized as revenue over the estimated performance period that is consistent with the term of the research and development obligations contained in the collaboration agreement. 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 issued.

In those circumstances where research and development services 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. 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 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, successful completion of a phase of development or results from a clinical trial, 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 substantial (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. 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 the first commercial sale of a product or when sales first achieve a defined level. Under our collaboration agreement with Merck, Merck will take the lead in commercialization activities in certain territories and we have retained the right (which we can opt out of) to co-promote vintafolide in the U.S. with Merck. 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.

Results of Operations

Comparison of Three Months Ended September 30, 2011 and 2012

	Three Months Ended September 30,		Increase/ (Decrease)	%
	2011	2012		
	(In thousands)			
Statement of operations data:				
Collaboration Revenue	$—	$12,415	$ 12,415	100%
Operating expenses:				
Research and development	8,915	9,930	1,015	11 %
General and administrative	2,723	3,815	1,092	40 %

Total operating expenses	11,638	13,745	2,107	18 %
Loss from operations	(11,638)	(1,330)	(10,308)	89 %
Interest income	35	96	61	174%
Interest expense	(449)	(1)	(448)	100%
Other expense, net	(18)	(4)	(14)	78 %
Net loss	$(12,070)	$(1,239)	$(10,831)	90 %

Revenue

Revenue of $12.4 million was recorded in the three months ended September 30, 2012 related to the collaboration with Merck. This revenue is related to an amortization of both the $120.0 million upfront license payment, $4.8 million in reimbursable development expenditures incurred in periods prior to the third quarter 2012 and $4.6 million of reimbursable development expenditures incurred in the third quarter 2012. The amortization for both the upfront license fee and ongoing research and development services will be recognized as revenue ratably over a performance period which began on April 27, 2012, and concludes at the end of 2014.

Research and Development

The increase in research and development expense for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was attributable to a $0.5 million increase in product development expenses and a $0.5 million increase in compensation expenses, including stock-based compensation expense, salaries expense and increase in bonus accrual. The increase in product development expenses was primarily due to an increase of $0.8 million in clinical trial expenses for the PROCEED and TARGET trials and $0.4 million in development costs for the earlier stage pipeline, partially offset by a $0.8 million decrease in expenses related to the anticipated regulatory filing with the EMA for vintafolide and etarfolatide, including process and method validations for vintafolide and etarfolatide which were performed in Q3 2011. Included in research and development expenses for the three months ended September 30, 2012 were $4.6 million of expenses that are reimbursable from Merck under the collaboration agreement for vintafolide.

Included in research and development expense were stock-based compensation charges of $293,000 and $458,000 for the three months ended September 30, 2011 and 2012, respectively.

Research and development expenses include expense of $172,000 and $189,000 for the three months ended September 30, 2011 and 2012, 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 expenses in the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was primarily attributable to an increase in legal fees associated with obtaining patent and trademark rights, expenses associated with being a public company, expenses attributable to establishing commercial capability and compensation expenses.

Included in general administrative expenses were stock-based compensation charges of $274,000 and $283,000 for the three months ended September 30, 2011 and 2012, respectively.

Interest Expense

The decrease in interest expense in the three months ended September 30, 2011 compared to the three month ended September 30, 2012 was due to our repayment in full and termination of our $15.0 million credit facility. Our average loan balances under the credit facility was $13.0 million for the three months ended September 30, 2011.

Comparison of Nine Months Ended September 30, 2011 Compared to Nine Months Ended September 30, 2012

	Nine Months Ended September 30,		Increase/ (Decrease)	%
	2011	2012		
	(In thousands)			
Statement of operations data:				

Collaboration Revenue	$—	$20,228	$ 20,228	100	%
Operating expenses:					
Research and development	21,075	25,153	4,078	19	%
General and administrative	7,138	10,104	2,966	42	%
Total operating expenses	28,213	35,257	7,044	25	%
Loss from operations	(28,213)	(15,029)	(13,184)	47	%
Interest income	91	137	46	51	%
Interest expense	(1,637)	(628)	(1,009)	62	%
Other expense, net	(19)	(923)	904	4758	%
Net loss	$(29,778)	$(16,443)	$ (13,335)	45	%

Revenue

Revenue of $20.2 million was recorded in the nine months ended 2012 related to the collaboration with Merck. This revenue is related to an amortization of both the $120.0 million upfront license payment, $1.7 million in reimbursable development expenditures incurred in periods prior to the nine months ended September 30, 2012 and $7.7 million of reimbursable development expenditures incurred in the nine months ended September 30, 2012. The amortization for both the upfront license fee and ongoing research and development services will be recognized as revenue ratably over the performance period.

Research and Development

The increase in research and development expense for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily due to a $2.5 million increase in product development expenses and a $1.6 million increase in compensation expenses. The increase in product development expenses was due to a $1.8 million increase in expenses related to the anticipated regulatory filing with the EMA for vintafolide and etarfolatide, including process and method validations for vintafolide and etarfolatide, and an increase in development costs for the earlier stage pipeline of $0.7 million. The increase in compensation expense included a $1.9 million increase in stock-based compensation expense, increased salary expense and an increase in bonus accrual, partially offset by a $0.3 million decrease due to severance compensation and related stock-based compensation expense recorded in the nine months ended September 30, 2011. Included in research and development expenses for the nine months ended September 30, 2012 are $7.7 million of expenses that were reimbursable from Merck under the collaboration agreement for vintafolide.

Included in research and development expense were stock-based compensation charges of $751,000 and $1,374,000 for the nine months ended September 30, 2011 and 2012, respectively, which for 2011 included a $133,000 charge relating to severance-related stock-based compensation.

Research and development expenses include expenses of $345,000 and $582,000 for the nine months ended September 30, 2011 and 2012, 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 expenses in the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily attributable to an increase in legal fees associated with obtaining patent and trademark rights, expenses associated with being a public company, expenses attributable to establishing commercial capability and compensation expenses.

Included in general administrative expenses were stock-based compensation charges of $595,000 and $874,000 for the nine months ended September 30, 2011 and 2012, respectively.

Interest Expense

The increase in interest expense in the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was due to the decreased borrowings under our credit facility and the interest payable on outstanding subordinated notes which were converted to common shares at the initial public offering. Our average loan balances were $15.6 million and $7.5 million for the nine months ended September 30, 2011 and 2012, respectively.

Other Income, Net

Other income, net increased in the nine months ended September 30, 2012 compared to September 30, 2011 due to loss on debt extinguishment of $1.0 million we recognized as a result of terminating our credit facility. The loss included a 5% prepayment fee on the outstanding balance of $0.6 million and the write off of unamortized deferred financing fees and discounts of $0.4 million.

Liquidity and Capital Resources

We have funded our operations principally through private placements of equity and debt securities, revenue from strategic collaborations, revenue from grants, loans, the two public offerings of common stock we completed in 2011 and the non-refundable $120.0 million upfront payment from Merck that we received in May 2012. As of September 30, 2012, we had cash, cash equivalents and investments of $204.7 million.

In June 2012, we paid the entire outstanding balance, terminated our $15.0 million credit facility, and recorded a loss on debt extinguishment of $1.0 million, which included a 5% prepayment fee of $0.6 and the write off of unamortized deferred financing fees and discounts of $0.4 million.

We expect that our cash position at September 30, 2012 is sufficient to fund our current operating plan, which includes completion of PROCEED, the phase 3 clinical trial of vintafolide and etarfolatide, through the availability of final primary PFS data from that study which is anticipated to be in the first half of 2014, assuming the availability of PLD, the filing of applications to the EMA for conditional marketing authorization for vintafolide, etarfolatide and folic acid, and the advancement of our earlier stage pipeline.

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

	Nine Months Ended September 30,	
	2011	2012
	(In thousands)	
Net cash provided by (used in) operating activities	$(23,916)	$91,917
Net cash used in investing activities	(72,603)	(103,367)
Net cash provided by (used in) financing activities	146,288	(13,177)
Effect of exchange rate	(1)	3
Net increase in cash and cash equivalents	$49,768	$(24,624)

Operating Activities

The use of cash in 2011 primarily resulted from our net loss adjusted for non-cash items and changes in operating assets and liabilities. The increase in cash provided by operating activities for the nine months ended September 30, 2012 resulted from deferred revenue related to the portion of the $120.0 million upfront payment from Merck and the reimbursable research and development expenditures that will be recognized ratably over the performance period.

Investing Activities

The cash used in investing activities for each of the nine month periods was due primarily to the net result of maturities and sales of investments, and by capital expenditures for equipment of $199,000 in 2011 and $1.6 million in 2012.

Financing Activities

The cash used in financing activities in the nine months ended September 30, 2012 primarily consisted of the $13.5 million prepayment of our credit facility, which included a 5% prepayment fee of $0.6 million, which was partially offset by $0.4 million received from the exercise of stock options. The cash provided by financing activities in the nine months ended September 30, 2011 consisted of proceeds of $3.6 million from the issuance of subordinated convertible notes later converted into common stock, $144.9 million net proceeds from our public offerings and $0.5 million received from the exercise of stock options, partially offset by a $2.7 million payment of principal on our credit facility.

Operating Capital Requirements

If we obtain conditional marketing approval of vintafolide and etarfolatide in Europe, we anticipate commercializing our first product in 2013 at the earliest. Therefore, we anticipate we will continue to incur significant expenses for the next several years to complete the PROCEED trial for vintafolide and etarfolatide in PROC, build commercial capabilities in the U.S for vintafolide and internationally for etarfolatide, develop our earlier stage pipeline, and expand our corporate infrastructure.

We believe that our current cash position of $204.7 million at September 30, 2012, including cash equivalents and investments is sufficient to fund our current operating plan, including PROCEED, which we are responsible for the majority of the funding, and the advancement of our earlier stage pipeline. Merck will be responsible for the costs of the TARGET trial.

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 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 and debt 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.

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Contractual Obligations and Commitments

We repaid the outstanding balance of and terminated our credit facility in June 2012. Under the collaboration agreement that we entered into with Merck in April 2012, we will be responsible for the majority of funding and completion of the PROCEED trial, and we will remain responsible for the development, manufacture and commercialization worldwide of etarfolatide. There have been no other significant changes during the nine months ended September 30, 2012 to the items that we disclosed as our contractual obligations and commitments in our Form 10-K for the year ended December 31, 2011.

Off-Balance Sheet Arrangements

None.

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

We are exposed to market risk related to changes in interest rates. As of December 31, 2011 and September 30, 2012 we had cash, cash equivalents and investments of $128.1 million and $204.7, respectively. 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. We carry our investments based on publicly available information. We do not currently have any investment securities for which a market is not readily available or active.

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

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 SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by 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 September 30, 2012, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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. The risks and uncertainties described below are not the only ones we face. 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 nine months ended September 30, 2012 was $16.4 million. As of September 30, 2012, we had a retained deficit of $155.0 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 diagnostics, and begin to commercialize any approved products. As such, we are subject to all the risks incident to the creation of new SMDCs and companion imaging diagnostics, 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 September 30, 2012, 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 preparing filings for regulatory approval of vintafolide and etarfolatide. 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 are highly dependent on the success of our lead SMDC, vintafolide, and we cannot give any assurance that we will successfully complete its clinical development, or that it will receive regulatory approval or be successfully commercialized.

Our lead SMDC, vintafolide, has been evaluated in a randomized phase 2 clinical trial for the treatment of women with platinum-resistant ovarian cancer, or PROC, and is currently being evaluated in a randomized phase 3 clinical trial in the same indication. In addition, we recently completed a phase 2 single-arm clinical trial for second line non-small cell lung cancer, or NSCLC, and are planning an additional randomized phase 2 clinical trial in the same indication. Our future trials may not be successful, and vintafolide may never receive regulatory approval or be successfully commercialized. Although we plan to seek regulatory approvals for vintafolide from the European Medicines Agency, or EMA, the U.S. Food and Drug Administration, or FDA and other regulatory authorities, we may not be successful if our clinical development program for vintafolide fails 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, along with Merck Sharp & Dohme Research GmbH, a subsidiary of Merck & Co, Inc., or Merck, (with whom we have entered into a collaboration agreement for vintafolide), 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 business.

The results of previous clinical trials may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the EMA, 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 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 2011, we began evaluating vintafolide in a phase 3 clinical trial, known as PROCEED, in PROC. We suspended patient enrollment for several months due to global shortages of pegylated liposomal doxorubicin, or PLD (marketed in the U.S. under the brand name Doxil), but we have since resumed enrollment. In addition, we have other product candidates in the discovery, preclinical testing and phase 1 clinical trial 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, including PROCEED, 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.

In our end of phase 2 meeting with the FDA related to vintafolide, the FDA stated that, because of the difficulty in reliably determining cancer progression based on imaging studies in ovarian cancer, its office policy is to require overall survival, or OS, to be the primary endpoint for an ovarian cancer registration trial. However, the FDA stated that we may choose, at our own risk, to conduct a phase 3 trial in which progression free survival, or PFS, is the primary endpoint; provided that for such a trial to be the basis for approval, the PFS results must be very robust statistically and clinically meaningful, and the trial must be powered to demonstrate a statistically significant OS benefit. In a follow-up meeting in March 2012, the FDA reiterated this position and added that the design of the Phase 3 PROCEED trial could lead to an accelerated approval depending on the results. The primary endpoint of the phase 3 PROCEED trial is PFS in the FR(++) patient population. Based on feedback from EU health authorities and the FDA, we are evaluating the inclusion of additional patients for exploratory analysis in order to assess potential benefit in patients with less than all of their target tumors positive for the folate receptor. While those plans are being finalized, patients will be enrolled regardless of the FR status, although the primary endpoint will include only FR(++) patients. Even if our phase 3 trial meets its PFS primary endpoint, a positive trend in OS at the time of filing our new drug application, or NDA, may be required for approval or the FDA may delay consideration of approval until final OS data becomes available, which would result in significant additional costs and delay our ability to market vintafolide for this indication. The FDA also noted that the final OS analysis from our phase 3 trial would be required as a post-marketing commitment should approval be granted based upon PFS. In addition, if the FDA approves vintafolide based upon meeting our PFS primary endpoint, in certain circumstances the approval could be withdrawn if any

required post-marketing trials or analyses do not meet FDA requirements. Furthermore, as is typical for cancer drug approvals, the FDA stated that for the initial approval of vintafolide to be based on a single phase 3 clinical trial, the trial must provide evidence of persuasive and robust statistically significant clinical benefit such that it would be considered unethical to conduct another trial. If we fail to demonstrate a benefit of this magnitude in PROCEED, we would expect that the FDA would require us to conduct a second phase 3 trial in order to receive marketing approval of vintafolide for the treatment of PROC. At a minimum such a requirement would delay our ability to market vintafolide for this indication.

Patients in PROCEED are being imaged with our companion imaging diagnostic, etarfolatide, prior to treatment with vintafolide. Although etarfolatide is part of our phase 3 trial design, there can be no assurance that this trial will provide a sufficient basis for approval of an NDA for etarfolatide. Similarly, we can provide no assurance that vintafolide will be approved without etarfolatide approval.

The FDA and other regulatory authorities may change requirements for the approval of our product candidates even after reviewing and providing non-binding comment 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 and etarfolatide from the European Medicines Agency may be unsuccessful.

We expect to file applications with the EMA in the fourth quarter of 2012 for conditional marketing authorization for vintafolide for the treatment of PROC and for etarfolatide and folic acid for patient selection. These filings will be 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 PLD for treatment of women with PROC and which also evaluated the utility of etarfolatide for patient selection. Our filings will be supported by four clinical studies: a Phase 1 study in solid tumors, two single-agent, single-arm Phase 2 studies in ovarian cancer and non small cell lung cancer, and the PRECEDENT trial, a randomized study in PROC.

We cannot predict with any certainty whether the EMA will grant the marketing authorizations that we intend to seek 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 EMA were to grant conditional marketing authorization of vintafolide, etarfolatide and folic acid based on our phase 2 studies, that authorization could be further limited or even withdrawn if our required phase 3 studies 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 EMA 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 EMA would not authorize us or 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 will have invested in our current development and clinical programs, to the exclusion of others, for several more years 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. We will need to complete significant additional clinical trials before we can demonstrate that our product candidates are safe and effective to the satisfaction of the FDA, the EMA or other non-U.S. regulatory authorities. Clinical trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process. Further, even if our product candidates receive required regulatory approvals, we cannot assure you that they 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.

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, including vintafolide, 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 passing of 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 other applicable foreign government guidelines and are subject to oversight by the FDA, foreign governmental agencies and independent institutional review boards, or IRBs, at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under current Good Manufacturing Practice, or cGMP, and other requirements in foreign countries, and may require large numbers of test patients. Our current and planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable sites to conduct our clinical trials;

- government or regulatory delays and changes in regulatory requirements, policy and guidelines;

- delay or failure to obtain sufficient supplies of the product candidate for, or other drugs used in, our clinical trials as a result of our suppliers' non-compliance with cGMP, or for other reasons;

- delay or failure to reach agreement on acceptable clinical trial agreement terms with prospective sites or investigators; and

- delay or failure to obtain IRB approval to conduct a clinical trial at a prospective site.

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

- slower than expected rates of patient recruitment and enrollment;

- unforeseen safety issues;

- lack of efficacy evidenced during clinical trials, which risk may be heightened given the advanced state of disease and lack of response to prior therapies of patients in 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. We also have experienced a delay in enrollment of the PROCEED trial due to the lack of supply of PLD.

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities or us. For example, a Data Safety Monitoring Board will monitor PROCEED and could recommend closing the trial based on the results of a pre-specified interim futility analysis or any observed unexpected safety concern that may occur during the trial. 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 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 based on our initial phase 3 clinical trial, PROCEED, 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. According to the American Cancer Society, approximately 22,280 new cases of ovarian cancer are projected in the United States in 2012. Of those ovarian cancer cases, approximately 50 percent of patients will eventually develop PROC. 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(+) or FR(++). The intended indication for use may be further limited to only patients who are FR(++). Marketing efforts for vintafolide outside of our approved indication 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 of regulatory approval by the FDA, the EMA or other non-U.S. 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. Although we intend to file applications with the EMA in the fourth quarter of 2012 seeking conditional marketing authorization for vintafolide, etarfolatide and folic acid based on the results of our randomized phase 2 PRECEDENT trial and supplemental analyses of that trial's results, we have not yet filed those applications or sought approval for any of our product candidates in the U.S. or in any other jurisdictions and 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 FDA and foreign 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 outcome of the applications we intend to file with the EMA 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 the EMA, FDA and other 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, such as other strategic partnerships or licensing arrangements, such as the collaboration agreement with Merck that we entered into in April 2012 for vintafolide. 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 other 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 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, Nektar Therapeutics, Sunesis Pharmaceuticals, Eli Lilly, Sanofi, Amgen, Bionumerik, Exelixis, AstraZeneca and Eisai Company. 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:

- 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, particularly in Indiana. 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.

As 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.

As we 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 use our collaboration agreement with Merck to establish a sales and marketing organization with technical expertise and supporting distribution capabilities. Under the collaboration agreement with

Merck, we have retained the right 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 will need internal 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 will depend in whole or in part depending upon the efforts of Merck as it relates to 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 fails to perform its obligations under or terminates our collaboration agreement, the development and commercialization of vintafolide could be delayed or terminated and our business could be substantially harmed.

A significant portion of our future revenues from vintafolide will depend upon the success of our collaboration with Merck. Under the collaboration agreement, Merck has development, manufacturing and commercialization responsibilities with respect to vintafolide. 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 and the development of our pipeline 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 non-U.S. 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 of 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 clinical or commercial production of our product candidates. We believe that we currently have sufficient supplies of all of the key components of vintafolide in sufficient quantities to conduct and complete our PROCEED clinical trial and any other clinical trials related to vintafolide. 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 third-party contract manufacturers 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 FDA 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 our approved product candidates, as is the case with etarfolatide. These manufacturers may not be able to successfully increase the manufacturing capacity for any of our approved product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. Additionally, any third-party manufacturer we retain to manufacture our product candidates on a commercial scale must pass an FDA pre-approval inspection for conformance to the cGMPs 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 cGMPs, 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 quality 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 Doxil.

Our etarfolatide companion imaging diagnostic 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 diagnostics that employ Tc-99m in our clinical trials. For example, etarfolatide is a component of PROCEED and, in the future, 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 during PROCEED 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 diagnostic 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.

We had to suspend enrollment in the PROCEED trial for several months due to global shortages of PLD. We have since secured a sufficient quantity of PLD to resume PROCEED in the U.S. and select sites in Europe. Although the manufacturer of PLD has taken steps to restore sustainable commercial supply of PLD in Europe, it will not be available immediately, so we will activate additional sites in Europe as supply allows. Unexpected issues with the supply of PLD could delay the PROCEED trial.

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 contractors fail to comply with continuing regulations, we or they may be subject to enforcement action that could adversely affect us.

Even if our product candidates become approved products, we and our contractors will continue to be subject to pervasive regulation by the EMA, FDA and other regulatory authorities. We and our 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 contractors fail to comply with the requirements of the EMA, 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: restrictions on the products, the manufacturers or manufacturing processes we use, warning letters, civil or criminal penalties, fines, injunctions, product seizures or detentions, import bans, voluntary or mandatory product recalls and publicity requirements, suspension or withdrawal of regulatory approvals, total or partial suspension of production, and refusal to approve pending applications for marketing approval of new products to approved applications.

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.

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 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, will be limited to approximately $55,200,000 for 2012, $39,000,000 per year for the years 2013 through 2015, $29,700,000 for 2016 and $16,800,000 for 2017. Any available but unused amounts will become available for use in all successive years. At December 31, 2011, we recorded a full valuation allowance against our net operating loss carryforwards of approximately $58.7 million, as we believe it is more likely than not that the net operating loss carryforwards will not be fully realized.

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:

- 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.

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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 of 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.

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, including PRECEDENT and PROCEED;
- announcements of EMA or FDA non-approval of our product candidates, including vintafolide, or delays in any regulatory authority review processes;
- FDA or other U.S. or non-U.S. 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;

- 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;
- 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 September 30, 2012, we had 35,906,490 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. Shares held by our affiliates may be sold in the public market pursuant to Rule 144 or another exemption from registration.

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 own approximately 47.1 percent of the outstanding shares of our common stock. 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 Corporation Law regulating corporate takeovers;
- providing that our Board of Directors is expressly authorized to make, alter or repeal our bylaws; and
- establishing advance notice requirements for nominations for elections to our Board of Directors or for proposing other matters that can be acted upon by stockholders at stockholder meetings.

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

We are subject to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. Section 404 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. Beginning with the year ending December 31, 2012, our independent registered public accounting firm must 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

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

Unregistered Sales of Securities

None.

Use of Proceeds from Registered Securities

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-166904) that was declared effective by the SEC on February 4, 2011. We registered an aggregate of 14,375,000 shares of our common stock at an aggregate offering price of approximately $86.3 million. On February 9, 2011, we completed the sale of all 14,375,000 shares of our common stock at a price to the public of $6.00 per share, including the sale of 1,875,000 shares of common stock in connection with the underwriters' exercise of their overallotment option, for aggregate gross proceeds of $86.3 million. The offering commenced on February 4, 2011 and terminated upon the sale of all of the registered securities in the offering. RBC Capital Markets, LLC and Leerink Swann LLC acted as joint book-running managers for the offering. Wedbush Securities, Inc. and Robert W. Baird & Co. acted as co-managers. There were no selling stockholders in the offering.

We paid $5.5 million in underwriting discounts and commissions to the underwriters in connection with the offering and incurred additional costs of approximately $2.6 million in connection with the offering, which when added to the underwriting discounts and commissions paid, amounts to total expenses of approximately $8.1 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and offering expenses, were approximately $78.2 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of September 30, 2012, we have used approximately $66.8 million of the net proceeds from the initial public offering to fund the phase 3 clinical trial of vintafolide and etarfolatide, preparing the applications for conditional marketing authorization from the EMA, preparing for the randomized phase 2 trial of vintafolide and etarfolatide in NSCLC and for working capital expenditures and other general corporate purposes. We have invested the unused proceeds from the offering in short-term interest-bearing, investment grade securities. There has been no material change in our planned use of proceeds from the initial offering from that described in the final prospectus filed with the SEC pursuant to Rule 424(b) on February 9, 2011.

Item 5. Other Information

During the quarter ended September 30, 2012, 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: November 13, 2012 By: **/s/ P. Ron Ellis**
P. Ron Ellis
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2012 By: **/s/ Michael A. Sherman**
Michael A. Sherman
Chief Financial Officer
(Principal Financial Officer)

Date: November 13, 2012 By: **/s/ Beth A. Taylor**
Beth A. Taylor
Corporate Controller
(Principal Accounting Officer)

EXHIBIT INDEX

Exhibit Number	**Description**
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 September 30, 2012, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at December 31, 2011 and September 30, 2012, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2011 and 2012, (iii) Consolidated Statements of Stockholders' Equity for the nine months ended September 30, 2012, (iv) Condensed Consolidated Statements of Cash Flows for the three and nine months ended September 30, 2011 and 2012 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.