ENDOCYTE INC
Form 10-K
March 13, 2015

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

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2014

OR

o **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:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $.001 par value	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

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 o

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 o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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 o	Accelerated filer þ	Non-accelerated filer o	Smaller reporting company o
	(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). o Yes þ No

The aggregate market value of the registrant s common stock, $0.001 par value per share, held by non-affiliates of the registrant, based upon the closing price of the Common Stock on the Nasdaq Global Market on June 30, 2014, was approximately $244.6 million (excludes shares of the registrant s common stock held as of such date by officers, directors and stockholders that the registrant has concluded are or were affiliates of the registrant, exclusion of such shares should not be construed to indicate that the holder of any such shares possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.)

Number of shares of the registrant s Common Stock, $0.001 par value, outstanding on February 27, 2015: 41,887,010

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement to be delivered to stockholders in connection with the 2015 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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This annual report contains certain statements that are forward-looking statements within the meaning of federal securities laws. When used in this report, the words may, will, should, could, would, anticipate, estimate, believe, predict, potential, project, target, forecast, intend and similar expressions are intended to id 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 that we describe in Part I, Item 1A Risk Factors of this report, including, but not limited to, statements regarding the progress and timing of clinical trials, the safety and efficacy of our product candidates, the goals of our development activities, estimates of the potential markets for our product candidates, estimates of the capacity of manufacturing and other facilities to support our product candidates, projected cash needs and our expected future revenues, operations and expenditures. 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.

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PART I

Item 1. *Business*

Overview

We are a biopharmaceutical company developing targeted therapies for the treatment of cancer and inflammatory diseases. We use our proprietary technology to create novel small molecule drug conjugates, or SMDCs, and companion imaging agents. Our SMDCs actively target receptors that are over-expressed on diseased cells, relative to healthy cells. This targeted approach is designed to enable the treatment of patients with highly active drugs at greater doses, delivered more frequently, and over longer periods of time than would be possible with the untargeted drug alone. We are also developing companion imaging agents for each of our SMDCs that are designed to identify the patients whose disease over-expresses the target of the therapy and who are therefore likely to benefit from treatment. This combination of an SMDC with a companion imaging agent is designed to personalize the treatment of patients by delivering effective therapy, selectively to diseased cells, in the patients most likely to benefit.

Vintafolide in Lung Cancer. Our first generation SMDC, vintafolide, targets the folate receptor with the anti-cancer drug payload DAVLBH. The folate receptor is frequently over-expressed in some of the most prevalent and difficult to treat solid tumor indications. We identify the presence of the folate receptor in cancer patients by using etarfolatide, our proprietary companion imaging agent for vintafolide. We are conducting a randomized phase 2b clinical trial called TARGET in folate receptor positive, recurrent non-small cell lung cancer, or NSCLC, patients comparing single agent vintafolide, the combination of vintafolide and docetaxel, and single agent docetaxel. Docetaxel is a commonly used second line chemotherapy approved by the U.S. Food and Drug Administration, or the FDA. The combination therapy met the progression free survival, or PFS, primary endpoint of the trial, demonstrating a 25% reduction in the risk of progression or death (hazard ratio of 0.75 (p=0.0696)) compared to single agent docetaxel. The results were more favorable in a predefined adenocarcinoma subgroup. In this population, there was a 27% reduction in the risk of progression or death. While the overall survival, or OS, results are not final, interim analysis of the adenocarcinoma patients showed a 30% reduction in the risk of death for patients receiving vintafolide in combination with docetaxel compared to docetaxel alone. Final OS results are expected to be announced in the second or third quarter of 2015. The future development of vintafolide in NSCLC will be assessed based on the final OS analysis, and the results of the ongoing phase 1 clinical trial of our second generation folate targeted agent, EC1456, described below.

EC1456 Phase I Trial. EC1456, our second generation SMDC, like vintafolide, also targets the folate receptor. However, the drug payload and linker system in EC1456 have been modified to increase the potency and stability of the conjugate. We are currently screening patients for enrollment in a phase 1 dose escalation trial for the treatment of advanced solid tumors with EC1456. In preclinical models, EC1456 s drug payload, tubulysin, has demonstrated a higher level of potency and less vulnerability to multi-drug resistance mechanisms compared to the drug payload in vintafolide. In some preclinical models in which vintafolide demonstrates no activity or there is a resistance to vintafolide, the folate tubulysin SMDC has demonstrated activity. EC1456 has progressed in the phase 1 trial to a dose that exceeds the dose of vintafolide delivered in trials to date. Once the maximum tolerated dose is determined, we plan to expand the trial to evaluate EC1456 in NSCLC, triple-negative breast cancer, ovarian cancer and endometrial cancer in patients who are FR(100%), which means 100 percent of their target lesions over-expressed the folate receptor.

EC1169 Phase I Trial. EC1169, our first non-folate SMDC, is a tubulysin therapeutic targeting prostate-specific membrane antigen, or PSMA. We have initiated a phase 1 dose escalation trial in recurrent prostate cancer for EC1169. Once a maximum tolerated dose is identified, we plan to expand this trial to enroll up to 50 patients at that dose. We have developed a companion imaging agent, EC0652, to scan patients prior to therapy to identify the presence of PSMA. Patients are scanned with EC0652, but we are not limiting enrollment based on the results of the scan. To date, EC0652 has shown the presence of PSMA in the prostate cancer of all prostate cancer patients scanned.

PROCEED Trial. In the first half of 2011, we initiated enrollment of our PROCEED trial, a phase 3 registration trial in women with platinum-resistant ovarian cancer, or PROC. PROCEED was a randomized, double-blinded trial of vintafolide in combination with pegylated liposomal doxorubicin, or PLD (marketed in

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the U.S. under the brand name DOXIL® and in Europe under the brand name CAELYX®), compared to PLD plus placebo. In May 2014, we stopped the PROCEED trial based on the review of interim data by the Data Safety Monitoring Board, or DSMB, because vintafolide in combination with PLD compared to PLD alone did not meet the pre-specified criteria for improvement in PFS. While the PFS and overall response rates for the vintafolide combination arm of the trial were similar to those of a prior phase 2 trial, PRECEDENT, the PLD control arm performed better in the PROCEED trial than in the PRECEDENT trial and other historical trials. Detailed results of the PROCEED trial will be presented at an upcoming medical conference.

Filings with the European Medicines Agency. As a result of the termination of the PROCEED trial, in May 2014, we withdrew our conditional marketing authorization applications in Europe for vintafolide for the treatment of PROC, and etarfolatide and folic acid for patient selection. During 2014, we terminated contracts and reduced headcount related to pre-launch commercial activities.

Collaboration with Merck. 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. This agreement was terminated by Merck effective September 15, 2014. As a result of the termination of the collaboration with Merck, we are no longer eligible for additional milestone payments from Merck. In addition, all of our obligations under the agreement have been fulfilled, and we are not required to perform any additional services for Merck. Pursuant to the collaboration agreement, we received a non-refundable $120.0 million upfront payment and a $5.0 million milestone payment in 2012 from Merck as well as reimbursement for development expenditures of $44.8 million during the term of the agreement. Under the collaboration agreement, Merck was responsible for funding a portion of the PROCEED trial and all of the TARGET trial. Both trials are substantially complete, pending the completion of treatment of the patients who elected to stay in the PROCEED trial and the receipt of final OS results for the TARGET trial.

We currently have no commercial products and we have not received regulatory approval for, nor have we generated commercial revenue from, any of our product candidates.

Our Technology Platform

Our technology platform has enabled us to develop multiple new SMDCs for a range of disease indications. Each SMDC is comprised of three modules: a targeting ligand, a linker and a drug payload. Our companion imaging agents employ the same modular structure as our SMDCs, replacing the drug payload with an imaging agent.

Targeting Ligand. Our technology is founded on our high-affinity small molecule ligands that bind to over-expressed receptors on target cells, while largely avoiding healthy cells. We are developing a number of targeting ligands to address a broad range of cancers and inflammatory diseases.

Linker System. Our linker system attaches the targeting ligand to the drug payload or imaging agent. It is designed to be stable in the bloodstream, and to release the active drug from the targeting ligand when the SMDC is taken up by the diseased cell. The linker system can be customized for each SMDC and each companion imaging agent to improve its pharmacologic properties.

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Drug Payload. This module is the biologically active component of our SMDCs. The majority of our drug payloads are highly active molecules that are too toxic to be administered in their untargeted forms at therapeutic dose levels. We are using drug payloads in our SMDCs that were shown in our in vitro preclinical studies to be between 10,000 and 100,000 times more potent than traditional cancer cell-killing drugs such as cisplatin.

With our modular approach, we use a variety of different targeting ligands, linker systems and drug payloads to create a pipeline of novel SMDC candidates for clinical development. For example, our PSMA targeting technology uses a targeting ligand that specifically binds to a receptor over-expressed on the surface of prostate cancer cells. We have developed alternative linker systems that modulate the pharmacologic and biodistribution properties of our SMDCs. We can also attach a wide variety of different drug payloads to our targeting ligands to address different disease indications. For example, we have SMDCs in preclinical development that incorporate proven anti-cancer and anti-inflammatory drug classes, such as microtubule destabilizers, DNA alkylators, proteasome inhibitors and mTOR inhibitors.

We own or have rights to over 370 issued patents and patent applications worldwide covering our core technology, SMDCs and companion imaging agents. Our U.S. patent covering our core technology and our lead SMDC, vintafolide, expires in 2026, and our U.S. patents covering etarfolatide expire in 2024. In 2012, the United States Patent and Trademark Office awarded us a patent with claims specifically directed to vintafolide entitled Vitamin Receptor Binding Drug Delivery Conjugates. EC1456 and EC1169 patent applications were filed in 2013, and if granted, should expire no earlier than 2033.

Our Strategy

Our strategy is to develop and commercialize SMDCs to treat patients who suffer from a variety of cancers and inflammatory diseases that are not well addressed by currently available therapies. The critical components of our business strategy are to:

Develop folate-targeted SMDCs in multiple indications. With the prevalence of folate receptor presence in the disease, NSCLC is a promising indication for folate targeted therapy. Following the positive PFS results for the combination of vintafolide and docetaxel in the TARGET trial, we will evaluate the final OS data from this trial before making a decision on future development of vintafolide. These results will be assessed along with the ongoing phase 1 results of the potentially more potent EC1456. We are currently conducting a phase 1 dose escalation trial of EC1456. Once the maximum tolerated dose is determined in the phase 1 dose escalation trial, we plan to expand the trial to evaluate EC1456 as a single agent and in combination with other therapies in patients with FR(100%) NSCLC, triple-negative breast cancer, ovarian cancer and endometrial cancer. We also continue to evaluate other potential indications.

Develop EC1169 for Prostate Cancer. We are currently conducting a phase 1 dose escalation trial of EC1169 in recurrent prostate cancer. We plan to expand our evaluation of this agent once the maximum tolerated dose is determined. We have developed a companion imaging agent, EC0652, to scan patients prior to therapy to identify the presence of PSMA. To date, EC0652 has shown the presence of PSMA in the prostate cancer of all prostate cancer patients scanned.

Build a pipeline of additional therapeutic SMDCs by leveraging our technology platform. We believe that the modular approach of our technology platform will allow us to quickly and efficiently expand our pipeline of SMDC candidates featuring various combinations of our targeting ligands, linker systems and drug payloads. We are currently evaluating vintafolide, EC1456 and EC1169 in ongoing clinical trials. We have multiple additional therapeutic SMDCs in pre-clinical development.

Develop companion imaging agents for each of our therapies. We believe there is a significant opportunity to create targeted therapies where individual patients are selected based upon the use of non-invasive imaging diagnostic tools. Our companion imaging agents may lower the risk of development of our SMDCs by allowing us to select for our clinical trials only those patients whose disease over-expresses the receptor targeted by our SMDCs. This benefit may, following any regulatory approval, extend to clinical practice by giving physicians the information they need to

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prescribe our SMDCs to patients who are most likely to respond to our therapy. We are currently evaluating etarfolatide and EC0652 for the selection of patients for folate-targeted and PSMA-targeted therapies, respectively.

Build commercial capabilities and partner to maximize the value of our SMDCs. We have retained all worldwide commercial rights to our SMDCs. If we obtain the required regulatory approvals to commercialize our oncology SMDCs in the United States, we intend to do so through our own focused sales force that we would build in connection with such commercialization efforts, or by co-promoting these SMDCs in collaboration with one or more larger pharmaceutical companies that have established capabilities in commercializing cancer therapies. Outside of the United States, we will consider partnering with established international pharmaceutical companies to maximize the value of our pipeline. In the large inflammatory disease markets, we expect to out-license our SMDCs in order to mitigate their higher costs of development and commercialization.

Our Small Molecule Drug Conjugate (SMDC) Technology

Traditional cytotoxic cancer chemotherapies kill rapidly dividing cancer and normal cells in an indiscriminate manner, leading to significant toxicity in patients. The need for patients to recover from this toxicity can limit the ability to deliver effectively-dosed cancer therapy. In addition, cancer therapies for a given tumor type are generally selected based on observations of efficacy and toxicity in that patient population and not, in most cases, based on an understanding of the differences between tumors on a molecular level. In response to these limitations, a number of targeted therapies were developed to be more selective, including monoclonal antibody-based therapies. Due to their selectivity against certain cancers, antibody therapies have achieved tremendous therapeutic and financial success in recent years. According to Roche Holdings publicly available information, the three largest cancer drugs in the world, Avastin, Herceptin and Rituxan, are monoclonal antibodies, with collective U.S. sales of $8.7 billion in 2014.

For certain cancers, antibodies alone are not sufficiently effective to achieve meaningful clinical benefit. This limitation has led to the development of a new class of agents called antibody drug conjugates, or ADCs. ADCs are comprised of a monoclonal antibody, which is used to target the specific cancer, attached via a linker system to a cell-killing drug. In clinical trials, ADCs have enabled the targeted delivery of highly active anti-cancer drugs, improving response rates in several cancer indications, with generally less toxicity than standard chemotherapy. However, ADCs also have limitations. First, larger molecules, like ADCs, do not penetrate dense solid tumors as efficiently as small molecules, and as a result, ADC efficacy may be compromised due to limited accessibility to the target cells. Second, the slow clearance of antibodies from a patient s bloodstream may lead to increased toxicity. Third, the longer half-life of ADCs has also limited the development of antibody-based imaging diagnostics due to the poor image quality associated with the high background noise caused by ADCs remaining in a patient s bloodstream. Fourth, ADCs are biologic molecules that are costly and often complex to manufacture.

We believe our SMDC platform represents a novel approach, comparable to ADCs, in its ability to deliver highly active drug payloads in a targeted manner, but also with a number of potential advantages:

Small size to better penetrate solid tumors. We believe a key characteristic of our SMDCs is their ability to penetrate deeply into dense solid tumors. The targeting ligands for our SMDCs are approximately 300 times smaller in molecular weight than a typical antibody incorporated in ADCs. This may result in greater uptake and higher concentrations of these molecules within solid tumors.

Rapid clearance for reduced toxicity. The circulating half-life of ADCs currently in development generally range from several hours to several days. In contrast, our SMDCs are engineered to provide rapid uptake in targeted cells and rapid clearance from the bloodstream with a half-life of approximately 20 minutes. As a result of this shorter half-life, we believe there is reduced risk that our SMDCs will release the unconjugated drug payload into the blood stream.

Companion imaging agents for targeted therapy. A companion imaging agent can be created for each of our SMDCs. Because of the modular nature of our SMDC technology, the drug payload can be replaced with a radioisotope imaging agent, such as technetium-99m, or Tc-99m, that we employ

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in etarfolatide and EC0652, to create a companion imaging agent designed to target the same diseased cells as the SMDC. The companion imaging agent is intended to allow for real-time, full-body assessment of the receptor target without requiring an invasive tissue biopsy. Using full-body imaging, the receptor expression can be measured in every tumor and monitored throughout treatment. In our clinical trials that combined vintafolide with etarfolatide, we have seen correlations between favorable therapeutic outcomes and increased uptake of etarfolatide.

Cost-effective and simple to manufacture. Given the increasing pressure on drug pricing posed by payors, costs of development and manufacturing are increasingly important. Our SMDCs are relatively simple to manufacture and do not have the complexity and expense of biological molecules, like antibodies and ADCs.

In preclinical studies, our SMDC therapies of vintafolide, EC1456 and EC1169 have been observed to eliminate human tumors in mice across multiple receptor positive tumor models, using regimens that caused little to no observable toxicity. In the same models, treatment at the maximum tolerated dose, or MTD, with the free drug, DAVLBH or tubulysin, generated only modest or temporary tumor responses at best, and always in association with substantial toxicity. In addition, SMDC therapies caused no anti-tumor responses in preclinical tumor models that did not express the target receptor, thus confirming the SMDC s specificity to the target receptor.

Our SMDCs have also been evaluated in preclinical models for activity in combination with several approved chemotherapeutic agents. For example, vintafolide has shown significant anti-tumor responses in animals when dosed in combination with approved drugs, such as PLD, cisplatin, topotecan, bevacizumab, docetaxel, carboplatin, erlotinib and paclitaxel protein-bound. The toxicity profile of both SMDCs, particularly their lack of hematologic toxicity, make these SMDCs good potential candidates for combination therapies.

Receptor Targets

We are developing SMDCs to identify a variety of cancer and other disease receptor targets in addition to folate receptor and PSMA receptor. These receptors are over-expressed on diseased cells. An SMDC binds to the receptor and is internalized through a process known as endocytosis.

Cellular Uptake of Folate

The following image depicts the process by which a human cell internalizes folate.

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We select types of receptor targets on which to focus our development efforts through our biology screening system and the use of our companion imaging agents. The folate receptor is not significantly expressed on most normal tissues. Lung, brain, small intestine, kidney and activated macrophages are the normal tissues known to express the folate receptor. In the lung, brain and small intestine, the folate receptor does not face the bloodstream, thus these folate receptors are not accessible to our folate-targeted SMDCs. In the kidney, the folate receptor functions as a salvage receptor that captures folates and transports them back into the blood stream to prevent folate deficiency. Our drug payload does not appear to be released during this transport process and, as a result, we have not observed kidney toxicity with our folate-targeted SMDC therapies. Imaging is used to identify cellular targeting for specificity, thereby validating the receptor target as viable for potential therapy.

Market Opportunity for Folate Receptor Cancers

The graph below shows the percentage of patients with different cancer types that are known to over-express the folate receptor. We estimate, based on worldwide cancer incidences combined with our own imaging studies, that there are over one million newly diagnosed cancer patients per year in the United States, Europe and Japan whose tumors over-express the folate receptor.

Source: *American Cancer Society and Endocyte estimates based upon imaging studies and tissue biopsies.*

Companion Imaging Agents for Patient Selection

We believe the future of medicine includes not only safer and more effective drugs, but also the ability to identify the appropriate therapy for a particular patient. We are committed to this approach, which is commonly referred to as personalized medicine or precision medicine.

Our technology allows us to create companion imaging agents intended for use with each of our SMDCs. Because of the modular nature of our SMDC technology, the drug payload can be replaced with a radioisotope imaging agent, such as Tc-99m, which we employ in etarfolatide, to create a companion imaging agent designed to target the same diseased cells as the SMDC and is easily seen with widely available nuclear imaging equipment. The companion imaging agent allows for real-time, full-body assessment of the receptor target without requiring an invasive tissue biopsy. Using full-body imaging, the receptor expression can be

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measured in every tumor and monitored throughout treatment. Potential key advantages of companion imaging agents over tissue-based samples include:

minimally invasive (not requiring biopsy);
real-time assessment of tumor receptor expression (as opposed to analysis based on archived tissue);
greater sensitivity because etarfolatide binds to all forms of the folate receptor (tissue sample analysis may understate folate receptor expression by not recognizing all forms of the folate receptor);
greater specificity because etarfolatide distinguishes between those receptors accessible to folate in the blood and those not accessible (tissue sample analysis may overstate folate receptor expression); and
full-body evaluation (as opposed to samples of tumor which may or may not be indicative of all areas of disease).

The information provided by our companion imaging agents is used throughout the development of every new SMDC. In both preclinical and clinical trials, a companion imaging agent is used to validate targeting of our SMDC to specific tissues and cells. These companion imaging agents also allow for the screening of large patient populations to select diseases where a high percentage of the patient population have tumors or diseased cells that over-express the molecular target. These companion imaging agents may also enable us to expand the use of our SMDCs to cancer indications where the percentage of patients who over-express a given receptor target of interest may be relatively low. If we obtain regulatory approval, we believe companion imaging agents, such as etarfolatide, will help to identify patients who will most likely benefit from treatment with our SMDCs. As a result, use of our companion imaging agents may broaden the commercial use of our SMDCs.

SMDC Pipeline

We have a pipeline of multiple SMDCs and companion imaging agents that are in varying stages of clinical and preclinical development, all of which use our platform SMDC targeting technology. A summary of our most advanced development pipeline SMDCs and companion imaging agents are as follows:

Vintafolide (EC145)

Vintafolide is designed to deliver a highly cytotoxic drug payload directly to folate receptors that are over-expressed on cancer cells, with low toxicity to healthy cells. Vintafolide consists of a targeting ligand, folate, conjugated via a linker system to an anti-cancer drug payload, DAVLBH. DAVLBH is derived from a proven class of anti-cancer drugs and is a potent destabilizer of microtubules. In preclinical models, this agent demonstrated 73,000 times the potency of the widely used chemotherapy, cisplatin. Since microtubules are

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critical for the separation of chromosomes during cell division, disruption of this microtubule system with DAVLBH promotes cell death. As folate is required for cell division, many rapidly dividing cancer cell types have been found to over-express high-affinity folate receptors. In clinical trials using our companion imaging agent, etarfolatide, we found that ovarian, non-small cell lung, breast, colorectal, kidney, endometrial and other cancers over-express folate receptors. Vintafolide binds to these folate receptors on cancer cells with high-affinity and is internalized through a process known as endocytosis. Once vintafolide is inside the cell, the linker system is cleaved, releasing the active drug payload within the cancer cell.

Phase 2 Single-Arm Clinical Trial

We conducted a phase 2 single-arm trial of vintafolide in 43 patients with NSCLC. Prior to treatment with vintafolide, patients were scanned with etarfolatide to determine whether their tumors over-expressed the folate receptor. Only FR(100%) and FR(10 90%) patients were eligible for the trial. In addition to standard eligibility criteria, patients were required to have a diagnosis of adenocarcinoma of the lung and to have at least a single RECIST-measurable tumor. RECIST refers to the response evaluation criteria in solid tumors, a set of published rules that define when the patients disease shrinks, remains stable, or progresses. There were no limits to the maximum number of prior therapies allowed in this patient population.

At the eight week patient assessment, the disease control rate, or DCR, was 57 percent in the patients who had all of their target tumors identified as over-expressing the folate receptor. This compares to DCRs for approved therapies of 21 to 30 percent reported in trials of less heavily pre-treated patients. In a subset of only FR(100%) patients who had received three or fewer prior therapies, the DCR was 70 percent. DCR has been shown to correlate with OS in NSCLC.

We also evaluated OS in FR(100%) patients (n=14) compared to FR (10 90%) patients (n=14). Median OS improved from 3.4 months for FR (10 90%) patients to 10.9 months for FR(100%) patients. The hazard ratio was 0.539, meaning FR(100%) patients were 46.1 percent less likely to die when compared to FR(10 90%) patients when receiving vintafolide (p=0.209).

Trial to Access the benefit of folate-Receptor tarGEted Treatment of second line NSCLC: Phase 2b Clinical Trial of Vintafolide for Second Line NSCLC

Based on results of our single-arm, single agent phase 2 clinical trial of vintafolide in patients with second line NSCLC, in 2012 we began enrollment in TARGET, a randomized phase 2b trial, which is now substantially complete. The trial enrolled and treated 199 patients with adenocarcinoma and squamous cell carcinoma of the lung who have failed one prior line of therapy and enrollment was completed in July 2013. Patients were selected based on etarfolatide scan results and only FR(100%) patients are included. The trial design is intended to evaluate the safety and efficacy of vintafolide in second line NSCLC as a single agent and in combination with docetaxel, a commonly used second line chemotherapy approved by the FDA. The study has three arms: docetaxel alone; vintafolide alone; and vintafolide plus docetaxel. The primary outcome measure is PFS with secondary measures of OS tumor response and duration of response. In October 2013, we announced the outcomes of the planned DSMB review of the interim futility analysis for the TARGET trial. The DSMB recommended the continuation of the vintafolide plus docetaxel arm and docetaxel alone arm of the trial. Based on the DSMB s additional recommendation, investigators and patients were advised that the vintafolide alone arm was not likely to be declared superior to docetaxel in PFS at the end of the study, and patients then on the vintafolide alone arm could continue treatment based on guidance from their investigator. In March 2014, we announced that the study met the primary endpoint of PFS for the combination vintafolide plus docetaxel arm, and demonstrated initial positive trends in secondary endpoints of OS and response rate. We communicated the detailed data, including updated OS results, at the European Society of Medical Oncology

Congress, or ESMO, in September 2014. The data showed that patients in the predefined adenocarcinoma subgroup treated with the vintafolide plus docetaxel combination had a 27 percent reduction in risk of the disease worsening or death (HR=0.73, p=0.0899, one-sided test), and a 30 percent reduction in the risk of death (HR=0.70, p=0.1018), compared to docetaxel monotherapy. Stratified analysis, which adjusts for pre-defined patient characteristics in the trial, reflected a 49 percent reduction in the risk of death in patients with adenocarcinoma (HR=0.51, p=0.0147). These data included approximately 78 percent of the targeted number of events in the OS analysis. OS in all patients, including those with squamous disease, reflected a 12 percent reduction in the risk of death (HR=0.88, p=0.2874) or 25 percent reduction when stratified (HR=0.75, p=0.1066). The primary endpoint of the study, as disclosed previously, showed that PFS

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was reduced by 25 percent for patients who received vintafolide plus docetaxel (HR=0.75, p=0.0696). The future development of vintafolide in NSCLC will be assessed based on the final OS analysis expected in the second or third quarter of 2015, and the results of the ongoing phase 1 clinical trial of EC1456.

EC1456

EC1456 is a second generation folate receptor-targeted SMDC. It is a conjugate of folate and an anti-cancer drug payload of tubulysin, a microtubule destabilizer that, in our in vitro models, showed more potency than DAVLBH. EC1456 is an investigational, proprietary, injectable SMDC consisting of folate (vitamin B9) linked to a potent cytotoxic agent, tubulysin B hydrazide (TubBH). TubBH is a member of the tubulysin class of anti-neoplastic agents that inhibits the polymerization of tubulin into microtubules, a critical component during cell division. The targeting ligand folate, essential for cell division, has been established in vintafolide. EC1456 is the first SMDC with TubBH to enter clinical trials. Tubulysin alone is too toxic to be used in patients rendering it impractical for therapeutic use. In contrast, our folate receptor-targeted tubulysin SMDC, EC1456, is curative in multiple xenograft models under conditions that produce no observable toxicities. EC1456 also employs a new spacer chemistry designed to reduce uptake in the liver which was believed to be the cause of dose limiting toxicities for vintafolide. EC1456 has progressed in a phase 1 trial to a dose that exceeds the dose of vintafolide delivered in trials to date. Once the maximum tolerated dose is determined in the phase 1 dose escalation trial, we plan to expand the trial to evaluate EC1456 in patients with FR(100%) NSCLC. The evaluation will be a single agent and combination trial.

Based on the assessment of the presence and intensity of the folate receptor, the estimate of the FR-positive patient population and responses of human tumor xenografts in animals, we have selected NSCLC, triple-negative breast cancer, ovarian cancer and endometrial cancer as the primary indications for evaluation of EC1456. Once the maximum tolerated dose for EC1456 is determined from the phase 1 dose escalation trial, we plan to expand the trial to evaluate EC1456 as a single agent in all indications selected and in combination with a different agent for some indications selected. Based on the results of that trial, we may pursue a registration trial in single agent or combination therapy.

EC1169 in Prostate Cancer

EC1169 is our first non-folate targeted SMDC and is designed to specifically target PSMA. PSMA is a cell surface protein found on nearly all prostate cancer cells. Similar to the folate receptor, PSMA has been shown to have an internalization signal that allows internalization of the protein on the cell surface into an endosomal compartment. EC1169 is designed to deliver a highly cytotoxic drug payload directly to PSMA receptors that are over-expressed on prostate cancer cells, with low toxicity to healthy cells. EC1169 consists of a targeting ligand, DUPA, conjugated via a linker system to an anti-cancer drug payload, tubulysin. Tubulysin is a potent microtubule destabilizer. Because microtubules are critical for the separation of chromosomes during cell division, disruption of this microtubule system promotes cell death. Once EC1169 is internalized into the cell, the linker system is cleaved, releasing the tubulysin within the prostate cancer cell. In the development of EC1169, we are employing a companion imaging agent, EC0652, to help us better understand if we might be able to select patients that may respond better to treatment with EC1169.

In March 2014, the FDA accepted the investigational new drug application, or IND, that we filed for EC1169. EC1169 is currently being evaluated in a phase 1 dose escalation trial in recurrent prostate cancer patients. Once a maximum tolerated dose is identified, we plan to expand this trial to enroll up to 50 patients at that dose.

EC1788 in Cancer

EC1788 is a folate receptor-targeted SMDC in preclinical development with a very potent DNA alkylator drug. Other DNA alkylators, such as platinum agents, have shown significant activity in a variety of cancers but have dose limiting toxicities. We are in the process of optimizing the chemistry of EC1788 and testing in preclinical models. Targeted, more potent DNA alkylators have shown promising results in preclinical studies and may represent another potential drug payload that could be used to treat cancer patients, depending on the results of future studies.

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EC1669 in Inflammation

EC1669 is a folate receptor-targeted SMDC in preclinical development for treatment in inflammatory diseases. During the clinical development of etarfolatide, it was discovered that patients with active inflammatory conditions, such as arthritic knees, displayed areas of etarfolatide uptake in non-cancerous regions of the body. Based on this observation, we began to test preclinical models of rheumatoid arthritis and discovered that activated, but not resting, macrophages present within the inflamed joints over-expressed the folate receptor. Activated macrophages are a type of white blood cell involved in a variety of inflammatory diseases, and they are responsible for the release of pro-inflammatory molecules, such as tumor necrosis factor alpha, or TNF-alpha, as well as other cytokines, into the body. Commercially available drugs such as etanercept and adalimumab, both designed to neutralize TNF-alpha biological activity, have proven to be effective for the treatment of a variety of inflammatory diseases. In 2014, these products generated $17.2 billion in annual sales according to Amgen Inc. s and AbbVie Inc. s publicly available filings. Although effective in some patients, other patients may fail to respond to these costly biological products because the activated macrophages secrete a variety of pro-inflammatory agents, in addition to TNF-alpha, into the systemic circulation, which results in continuing inflammation, causing a decreased therapeutic effect.

Our strategy for treating chronic inflammatory disorders differs from these available drugs that neutralize specific secreted factors such as TNF-alpha because our technology targets the folate receptor over-expressed on activated macrophages, which we believe are the source of pro-inflammatory agents, like TNF-alpha. We are developing a new class of SMDCs designed to neutralize, or de-activate, the activated macrophage itself. Preclinical data suggest that our SMDC candidates may suppress the secretion of all mediators of inflammation. Our oncology class of SMDCs, such as vintafolide, target folate receptor-expressing activated macrophages; however, these types of cells are not rapidly dividing, and as a result, anti-cancer drug payloads that would otherwise disrupt cellular division processes are inactive against this cell type.

Utilizing an identical strategy to that which we applied in the development of our oncology programs, SMDCs designed for treating inflammation may be constructed with more potent forms of known, active drugs, and then used along with companion imaging agents to provide personalized therapy. Using our folate receptor-targeted etarfolatide companion imaging agent in both preclinical and clinical trials, we have identified a number of diseases involving activated macrophages that over-express the folate receptor, including rheumatoid arthritis, osteoarthritis, inflammatory bowel disease and psoriasis.

In our preclinical models of rheumatoid arthritis, SMDCs targeted to activated macrophages result in significant reduction in inflammation and prevention of bone destruction that often accompanies these diseases. EC1669 is a SMDC constructed with the targeting ligand, folate, and an inhibitor of cellular metabolism, called aminopterin. We observed in preclinical models that EC1669 was safe and reduced inflammation more than the most commonly prescribed anti-inflammatory agent, methotrexate, and the anti-TNF-alpha agent, etanercept.

EC1669 s drug payload is aminopterin, a potent anti-inflammatory drug. In preclinical models, EC1669 has shown promising anti-inflammatory activity, including reduction in joint swelling and bone loss. As a first step in development, EC1669 is being tested in a naturally occurring arthritic animal model to guide future development decisions.

EC0371 (Polycystic Kidney Disease)

EC0371 is a folate receptor-targeted SMDC in preclinical development for treatment of polycystic kidney disease, or PKD. This is an opportunity to provide a new treatment to a disease with a very high unmet need.

PKD affects approximately 650,000 people in the U.S., and over 12 million people worldwide suffer from PKD. There are no effective treatments for this disease. We have identified a receptor target and are performing pre-clinical testing in a variety of SMDCs with different drug payloads. We may have sufficient information to make a decision on whether to pursue this opportunity by the end of 2015.

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Companion Imaging Agents

Etarfolatide: Lead Companion Imaging Agent for Folate-Targeted Therapies

Etarfolatide is the companion imaging agent for all of our SMDCs that target the folate receptor. Etarfolatide is a conjugate of the targeting ligand folate and the radioisotope imaging agent Tc-99m. Following intravenous administration, etarfolatide rapidly binds to tumors that over-express the folate receptor, allowing the treating physician to distinguish between patients who are FR(100%) (patients in which 100 percent of their target lesions over-expressed the folate receptor as determined by an etarfolatide scan), FR(10 90%) (patients in which at least one of the target lesions, but not all, over-expressed the folate receptor) or FR(0%) (patients in which none of their target lesions over-expressed the folate receptor). Etarfolatide enables high quality diagnostic scans one to two hours following its administration as a result of the quick clearance from the blood of etarfolatide not taken up by cells which over-express the folate receptor.

Etarfolatide Development Plan

In the U.S., etarfolatide is being developed under the FDA s published guidance regarding usage of imaging agents for therapeutic management of patients. Consistent with this guidance, our development strategy for etarfolatide will be to show that the presence of etarfolatide uptake in tumors is predictive of improved therapeutic outcomes resulting from treatment with our SMDC s.

With an estimated incidence of over one million newly diagnosed cancer patients per year in the United States, Europe and Japan who have tumors that over-express the folate receptor, etarfolatide could, if approved, represent a substantial commercial opportunity for us as a screening diagnostic. Companion imaging agents are an important part of our development and commercial plan, which may allow us not only to provide a targeted therapy, but also a truly personalized and more effective therapy. This could benefit patients, doctors and payors by allowing doctors to select only patients who are likely to benefit from our therapies.

We conducted an additional inter-reader analysis to further determine the reliability of etarfolatide. Five independent radiologists/nuclear medicine physicians read images from the PROCEED study and the evaluation resulted in a 76.7 percent agreement rate (0.69 Kappa) among all five readers in selecting patients with all target lesions positive for the folate-receptor, FR(100%), and a 73.3 percent five reader agreement (0.71 Kappa) in selecting patients with at least one tumor positive for the folate-receptor, FR(10 100%). This provides evidence supporting the reliability of the etarfolatide scan process to consistently classify patients.

EC0652

In January 2013, we announced the achievement of key objectives in a phase 0 study of EC0652, a diagnostic imaging agent targeting PSMA, a protein expressed on cancer cells originating from the prostate as well as on tumor neovasculature. The prostate cancer imaging agent EC0652, also termed DUPA- ^{99m} Tc, is a conjugate of a high affinity PSMA-targeting ligand, 2-[3-(1, 3-dicarboxy propyl)-ureido] pentanedioic acid (DUPA) to technetium 99m (^{99m} Tc). The discovery process utilized a unique structure-based drug design approach to synthesize the ideal targeting ligand for binding to PSMA. The corresponding SMDC, EC1169, utilizes the same targeting ligand. Based on the observed safety of the agent and its specificity for binding to diseased cells, we are advancing the development of both the diagnostic imaging agent, EC0652, and the corresponding therapeutic agent, EC1169, a proprietary PSMA-targeted SMDC linked with tubulysin. In March 2014, the FDA accepted the IND we filed for EC1169, and in July 2014, the FDA accepted the IND we filed for EC0652. We have initiated a phase 1 trial in recurrent prostate

cancer for EC1169, and we are imaging patients with EC0652.

Competition

The biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our SMDCs. A number of multinational pharmaceutical companies and large biotechnology companies are pursuing the development of or are currently marketing pharmaceuticals that target NSCLC, prostate cancer, ovarian cancer and endometrial cancer, or other oncology pathways on which we are focusing. It is possible that the number of companies seeking to develop products and therapies for the treatment of unmet medical needs in oncology will increase.

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Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drugs, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining approval for drugs and achieving widespread market acceptance. Our competitors drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

Recent successes with targeted therapies in solid tumors, such as those found in colon, breast and lung cancers, have led to a marked increase in research and development in targeted treatments for cancer, including cancer of the ovary. We are aware of multiple competitors, many advanced clinical trials and clinical data is under review by regulatory authorities for potential commercial approval for triple-negative breast cancer and ovarian cancer,

We are also aware of a number of companies that have ongoing programs to develop both small molecules and biologics to treat patients with NSCLC. Eli Lilly and Company recently announced FDA approval of Cyramza and Boehringer Ingelheim Pharmaceuticals Inc. recently announced European Medicines Agency, or EMA, approval of Nintedanib, both in combination with docetaxel in second line NSCLC. Bristol-Myers Squibb Company, Merck & Co, Inc., AstraZeneca PLC and Roche Holdings are all aggressively developing anti-programmed death-1 receptor (PD-1) agents. PD-1 is an inhibitory costimulatory molecule found on activated T cells and has been shown to play a role in the regulation of individual s immune response to recognize cancer and fight cancer. Bristol-Myers Squibb Company recently stopped a pivotal phase 3 study of their PD-1 inhibitor nivolumab early because an assessment conducted by the independent Data Monitoring Committee, or DMC, concluded that the drug demonstrated superior OS, the study s primary endpoint, in patients receiving nivolumab compared to the control arm. Anti-PD-1 agents may meaningfully change the manner in which patients are treated and in turn affect our ability to effectively develop our SMDC therapeutics.

Other targeted therapies are in phase 3 development for NSCLC including Pfizer Inc. s dacomitinib, Roche Holding s onartuzumab, and AstraZeneca PLC s selumetinib. Many more targeted agents are in phase 2 development by biotechnology and pharmaceutical firms including AbbVie, Inc., Ariad Pharmaceuticals, Inc., Astex Pharmaceuticals, Inc., Bristol-Myers Squibb Company, Clovis Oncology, Inc., Exelixis, Inc., GlaxoSmithKline PLC, Novartis AG, Puma Biotechnology, Inc., Roche Holdings, Synta Pharmaceuticals Corp., Tesaro, Inc., and Verastem, Inc.

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 SMDCs and companion imaging agents;
the cost of treatment in relation to alternative therapies;
the speed at which we develop our SMDCs and companion imaging agents;
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 SMDCs and companion imaging agents;
our ability to commercialize and market any of our products that may receive regulatory approval;

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our ability to have our partners manufacture and sell commercial quantities of any approved SMDCs and companion imaging agents to the market;

acceptance of SMDCs and companion imaging agents 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 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. Technological advances or products developed by our competitors may render our SMDCs or companion imaging agents obsolete or less competitive.

Manufacturing

To date, our SMDCs and companion imaging agents have been manufactured in small and medium size quantities for preclinical studies, clinical trials and validation activities by third-party manufacturers and we intend to continue to do so in the future. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our SMDC candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. To meet our projected needs for pre-clinical development and clinical trials, third parties with whom we currently work have sufficient capacity, but they may need to increase their scale of production or we may need to secure alternate suppliers. We have identified several manufacturers that have the capacity to manufacture etarfolatide in the quantities that our development and future commercialization efforts, if any, may require. We have utilized two such suppliers to date. We expect to continue to depend on third-party contract manufacturers for the foreseeable future.

Our SMDCs and companion imaging agents 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.

As a result of the potency of our compounds, we do not expect the quantities that may be required at full commercial scale to present a challenge to our third-party manufacturing partners.

Sales and Marketing

Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology, undertaking preclinical testing and clinical studies of our SMDCs and companion imaging agents and engaging in research and development under collaboration agreements. We have not yet demonstrated an ability to obtain regulatory approval, formulate and manufacture commercial-scale products, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, it is difficult to predict our future success and the viability of any commercial programs that we may choose to take forward.

We entered into a license and commercialization agreement with Nihon Medi-Physic Co., LTD., or NMP that grants NMP the right to develop and commercialize etarfolatide in Japan for use in connection with vintafolide in Japan. To date, the products have not been approved in Japan and no revenue has been recognized related to the regulatory milestones or royalties.

We have retained all worldwide commercial rights to our SMDCs. If approved, we intend to commercialize our oncology SMDCs in the United States through our own focused sales force that we would build in connection with such commercialization efforts, or by co-promoting these SMDCs in collaboration with one or more larger pharmaceutical companies that have established capabilities in commercializing cancer therapies. Outside of the United States, we will consider partnering with established international pharmaceutical companies to maximize the value of our pipeline. In the large inflammatory disease markets,

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we currently expect to out-license our SMDCs in order to mitigate their higher costs of development and commercialization. With the exception of the rights granted to NMP with respect to etarfolatide in Japan, we have retained all worldwide commercial rights to etarfolatide, and we intend to commercialize etarfolatide through our own sales force.

Employees

As of December 31, 2014, we had a total of 81 full-time employees, 65 of whom were engaged in research and development activities. None of our employees is represented by a labor union or subject to a collective bargaining agreement. We have not experienced a work stoppage and consider our relations with our employees to be good.

Government Regulation

Government authorities in the United States (including federal, state and local authorities) and in other countries extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, distribution, post-approval monitoring and reporting, advertising and promotion, and export and import of pharmaceutical products, such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and related regulations. Drugs are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an Institutional Review Board, or IRB, of a clinical hold on trials, the FDA s refusal to approve pending applications or supplements, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The Investigational New Drug Process

An IND is a request for authorization from the FDA to administer an investigational drug to humans. Such authorization must be secured before commencing clinical trials of any new drug candidate in humans.

The central focus of the initial IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal studies or other human studies, as appropriate, as well as manufacturing information, analytical data and any available clinical data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials as outlined in the IND. In such a case, the IND may be placed on clinical hold until any outstanding concerns or questions are resolved.

Clinical trials involve the administration of the investigational drug to patients under the supervision of qualified investigators in accordance with Good Clinical Practices, or GCP. Clinical trials are conducted under protocols

detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical site s IRB before the trials may be initiated. All participants in clinical trials must provide their informed consent in writing prior to their enrollment in the trial.

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The clinical investigation of an investigational drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

Phase 1. Phase 1 involves the initial introduction of an investigational new drug into humans. Phase 1 clinical trials are typically closely monitored and may be conducted in patients with the target disease or condition or healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During phase 1 clinical trials, sufficient information about the investigational drug s pharmacokinetics and pharmacologic effects may be obtained to permit the design of well-controlled and scientifically valid phase 2 clinical trials. The total number of participants included in phase 1 clinical trials varies, but generally ranges from 20 to 80.

Phase 2. Phase 2 includes the controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug for a particular indication in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase 2 clinical trials are typically well controlled, closely monitored and conducted in a limited patient population, usually involving no more than several hundred participants.

Phase 3. Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for product approval by the FDA. Phase 3 clinical trials usually involve several hundred to several thousand participants.

The decision to terminate development of an investigational drug may be made by either a health authority body such as the FDA, or by us for various reasons. Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a DSMB or committee. This group provides a recommendation of whether or not a trial may move forward at pre-specified check points based on access that only the group maintains to available data from the trial. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. We may decide to suspend or terminate development based on evolving business objectives and/or the competitive climate.

In addition, there are requirements and industry guidelines that require the posting of ongoing clinical trials on public registries and the disclosure of designated clinical trial results and related payments to healthcare professionals.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug information is submitted to the FDA in the form of a NDA except under limited circumstances, requesting approval to market the product for one or more indications.

The NDA Approval Process

In order to obtain approval to market a drug in the United States, a NDA must be submitted to the FDA that provides data establishing the safety and effectiveness of the investigational drug for the proposed indication to the FDA s satisfaction. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product s chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators.

The FDA will initially review the NDA for completeness before it accepts the NDA for filing. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete to permit substantive review. After the

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NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with Current Good Manufacturing Practices, or cGMP, to assure and preserve the product s identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Based on phase 3 clinical trial results submitted in an NDA, upon the request of an applicant a priority review designation may be granted to a product by the FDA, which sets the target date for FDA action on the application at six months. Priority review is given where preliminary estimates indicate that a product, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists, or a significant improvement compared to marketed products is possible. If criteria are not met for priority review, the standard FDA review period is ten months. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process for a drug requires substantial time, effort and financial resources and this process may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to develop our SMDCs or companion imaging agents and secure necessary governmental approvals, which could delay or preclude us from marketing our products. Even if the FDA approves an SMDC or companion imaging agent, it may limit the approved indications for use or place other conditions on approval that could restrict commercial application, such as a requirement that we implement special risk management measures through a Risk Evaluation and Mitigation Strategy. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Regulation

After regulatory approval of a drug product is obtained, we are required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA, the FDA may require post-marketing testing, including phase 4 clinical trials, and surveillance to further assess and monitor the product s safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the OS benefit of the drug. The FDA has indicated to us that if we receive approval of a drug based on PFS data, we will be required to continue to follow patients in the registration trial to determine the OS benefit of the drug. In addition, as a holder of an approved NDA, we would be required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and

efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to assure and preserve the long-term stability of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record-keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and

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any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our SMDCs. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product s approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA s policies may change, which could delay or prevent regulatory approval of our products under development.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we are subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to each country s national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country s requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application with EMA. This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures, and our SMDCs and companion imaging agents fall under the centralized authorization procedure.

The European Commission may grant conditional marketing authorization for a product that addresses an unmet medical need while additional development work is being completed. Conditional marketing authorization is subject to annual review, and such authorization may be limited or even withdrawn if subsequent development work is not satisfactory.

The European Commission implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Union. This procedure results in a single marketing

authorization issued by the European Commission that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering; contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions; and officially designated orphan medicines.

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA s Committee for

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Medicinal Products for Human Use, or CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria: the seriousness of the disease to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Compliance

During all phases of development (pre- and post-marketing), failure to comply with the applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the following actions by the FDA or other regulatory authorities: imposition of a clinical hold on trials; refusal to approve pending applications; withdrawal of an approval; warning letters; product recalls; product seizures; total or partial suspension of production or distribution; product detention or refusal to permit the import or export of products; injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our SMDCs may not be considered medically necessary or cost-effective. A payor s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In 2003, the United States government enacted legislation providing a partial prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we would be required to sell products to Medicare recipients through

prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. The most recent legislation enacted was the Patient Protection and Affordable Care Act and its amendment, the Health Care and Education Reconciliation Act. This and future legislation could limit payments for pharmaceuticals such as the drug candidates that we are developing.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a

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reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular SMDC to currently available therapies. Other member countries allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, the Veterans Health Care Act of 1992 and the Patient Protection and Affordable Care Act, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the Veterans Health Care Act, or VHCA, drug companies are required to offer certain drugs at a reduced price to a number of federal agencies including U.S. Department of Veterans Affairs and U.S. Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Legislative changes purport to require that discounted prices be offered for certain U.S. Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities or register their sales representatives, as well as prohibiting pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and prohibiting certain other sales and marketing practices. All of our activities are potentially subject to federal and state

consumer protection and unfair competition laws.

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Patents and Proprietary Rights

Because of the length of time and expense associated with bringing new products to market, biopharmaceutical companies have traditionally placed considerable importance on obtaining and maintaining patent protection for significant new technologies, products and processes.

Our success depends in part on our ability to protect the proprietary nature of our SMDC candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. As a matter of policy, we seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

We have applied, and are applying, for patents directed to our three main areas of focus: anti-tumor therapeutics and diagnostics, anti-inflammation therapeutics and diagnostics and immunotherapy therapeutics and diagnostics, both in the United States and, when appropriate, in other countries. We own or have rights to over 370 issued patents and applications worldwide covering our core technology, SMDCs and companion imaging agents.

Currently, we own 18 issued U.S. patents in whole. Several of these of these patents relate to vintafolide or etarfolatide compositions of matter. For example, patent number 7,601,332, or the 332 patent, entitled Vitamin Receptor Binding Drug Delivery Conjugates , patent number 8,105,568 or the 568 patent, with the same title, patent number 7,128,893, or the 893 patent, entitled Vitamin-Targeted Imaging Agents, patent number 7,862,798, or the 798 patent, also entitled Vitamin-Targeted Imaging Agents and patent number 8,313,728 with the same title, or the 728 patent, relate to these compounds. The 332 patent was issued on October 13, 2009 in the United States and is scheduled to expire in 2026. The 332 patent includes claims covering vintafolide, among other compounds. The 568 patent is a continuation to the 332 patent and claims the vintafolide structure specifically. In 2012, the United States Patent and Trademark Office, or the USPTO, awarded us the 568 patent. Additionally, we have filed continuation patent applications to the 568 patent and prosecution is ongoing. With respect to vintafolide coverage, we have patents issued in the United States, Canada, Japan, many European nations including Germany, Spain, France, the United Kingdom, and Italy, as well as Australia, China, India, New Zealand, Taiwan and South Africa. Applications are pending in the United States, Japan, Europe, Taiwan, Israel, Hong Kong, Argentina and Venezuela. We also have issued patents and pending applications directed to compositions of matter, pharmaceutical compositions, and methods for linking vitamins to drugs through our linker system. We also have filed several patent applications related to vintafolide specifically, such as, for example, using etarfolatide to predict patients response to vintafolide and methods of treatment with the combination of vintafolide with docetaxel.

The 893 patent and 798 patent were issued on October 31, 2006 and on January 4, 2011, respectively, in the United States and are both scheduled to expire in 2024. The 893 patent and 798 patent include claims covering etarfolatide, among other compounds. Additional patents have issued which are continuations. The 798 patent was one such continuation application issued as a patent as was the 728 patent. Patent claims covering etarfolatide have issued outside of the United States. For example, we have obtained etarfolatide coverage in many European jurisdictions.

We have filed additional patent applications worldwide to protect our innovations such as multidrug ligand conjugates including EC0225, spacer conjugates including EC0489, tubulysin conjugates including EC1456 and conjugates directed to the PSMA, including EC0652. EC0652 is owned by the Purdue Research Foundation, a non-profit organization, which manages the intellectual property of Purdue University, and is exclusively licensed to us.

Based on research we fund at Purdue University, we have entered into three exclusive, worldwide in-licenses for a number of patents and patent applications owned by the Purdue Research Foundation related to select folate-targeted technology, select technology related to PSMA, and select technology related to other ligands. The folate-technology license was originally entered into on July 17, 1998 with an effective date as of December 21, 1995, and was restated on October 21, 1998. The PSMA license was entered into on March 1,

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2010. The license to other technologies was entered into in 2014 with an effective date of July 1, 2013. Under these three licenses, over 80 patents and published applications are licensed to us.

We may terminate the Purdue Research Foundation licenses without cause with 60 days notice for the folate and PSMA license and three months notice for the license directed to other ligands. Purdue Research Foundation may terminate any of the licenses for material default by us which is not cured within 90 days notice, or upon 60 days notice, for the folate and PSMA licenses, in the event we fail to meet public demand for approved products covered by the licensed patents after a six month cure period following commercial introduction. The Purdue Research Foundation may terminate the license to other ligands if we fail to make a payment within 60 days of notice under the specific terms of the license. The folate and PSMA licenses also contain provisions allowing Purdue Research Foundation to terminate upon our bankruptcy. We have annual minimum royalty obligations to Purdue Research Foundation, as well as royalty obligations based on sales of products that are designed, developed or tested using the licensed technology, and milestone obligations based upon the achievement of specific scientific, clinical and regulatory milestones. See Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations ***Contractual Obligations and Commitments*** for a description of our payment obligations under the license agreements with the Purdue Research Foundation.

Most of our portfolio consists of intellectual property we exclusively license from Purdue Research Foundation or which we own ourselves. Generally, the intellectual property licensed from Purdue Research Foundation is early stage and relates to methods that were invented in the laboratory of Professor Philip Low. Internally, we typically develop these methods further and refine them to determine the commercial applicability. Additionally, these early-stage patents often provide us protection from competitors while we evaluate commercial possibilities of a specific program. For example, some of the very early patents we licensed from Purdue Research Foundation covered methods of delivering folate attached to targeting ligand across a cell membrane. We were able to use the patent protection afforded by such early patents to develop folate conjugates, including the invention and clinical development, and in the future, the commercialization of our linker system incorporated in vintafolide.

Due to the use of federal funds in the development of some folate-related technology, the U.S. government has the irrevocable, royalty-free, paid-up right to practice and have practiced certain patents throughout the world, should it choose to exercise such rights.

Our development strategy also employs lifecycle management positions. For example, we explore the potential for filing patent applications claiming methods of treatment combining our molecules with other treatments. Such strategies may provide additional patent protection even after the expiration of composition of matter patent protection for our intellectual property. As a result, our general guiding strategy is to obtain patent coverage for innovations that show a clinical benefit to patients and an economic opportunity for us.

Pursuant to a license agreement with Bristol-Myers Squibb, or BMS, we co-own several patent applications directed to epothilone with BMS. BMS notified us of their intent to terminate our license agreement in June 2010 and in July 2010 also notified us of their intent to abandon certain of the patent applications subject to the license related to folate conjugates with epothilone.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent.

The patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent.

The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar

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provisions are available in Europe and other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. In the future, if our pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products.

While we pursue patent protection and enforcement of our SMDC candidates and aspects of our technologies when appropriate, we also rely on trade secrets, know-how and continuing technological advancement to develop and maintain our competitive position. To protect this competitive position, we regularly enter into confidentiality and proprietary information agreements with third parties, including employees, independent contractors, suppliers and collaborators. Our employment policy requires each new employee to enter into an agreement containing provisions generally prohibiting the disclosure of confidential information to anyone outside of us and providing that any invention conceived by an employee within the scope of his or her employment duties is our exclusive property. We have a similar policy with respect to independent contractors, generally requiring independent contractors to enter into an agreement containing provisions generally prohibiting the disclosure of confidential information to anyone outside of us and providing that any invention conceived by an independent contractor within the scope of his or her services is our exclusive property with the exception of contracts with universities and colleges that may be unable to make such assignments. Furthermore, our know-how that is accessed by third parties through collaborations and research and development contracts and through our relationships with scientific consultants is generally protected through confidentiality agreements with the appropriate parties. We cannot, however, assure you that these protective arrangements will be honored by third parties, including employees, independent contractors, suppliers and collaborators, or that these arrangements will effectively protect our rights relating to unpatented proprietary information, trade secrets and know-how. In addition, we cannot assure you that other parties will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our proprietary information and technologies.

Additionally, there can be no assurance that our patents will provide significant protection, competitive advantage or commercial benefit. The validity and enforceability of patents issued to biopharmaceutical companies has proven highly uncertain. For example, legal considerations surrounding the validity of patents in the fields of biopharmaceuticals are in transition, and we cannot assure you that the historical legal standards surrounding questions of validity will continue to be applied or that current defenses relating to issued patents in these fields will be sufficient in the future. In addition, we cannot assure you as to the degree and range of protections any of our patents, if issued, may afford us or whether patents will be issued. For example, patents which may issue to us may be subjected to further governmental review that may ultimately result in the reduction of their scope of protection, and pending patent applications may have their requested breadth of protection significantly limited before being issued, if issued at all. Further, since publication of discoveries in scientific or patent literature often lags behind actual discoveries, we cannot assure you that we were the first creator of inventions covered by our pending patent applications, or that we were the first to file patent applications for these inventions.

Many biopharmaceutical companies and university and research institutions have filed patent applications or have received patents in our areas of product development. Many of these entities applications, patents and other intellectual property rights could prevent us from obtaining patents or could call into question the validity of any of our patents, if issued, or could otherwise adversely affect the ability to develop, manufacture or commercialize SMDC candidates. In addition, certain parts of our technology originated from third-party sources. These third-party sources include academic, government and other research laboratories, as well as the public domain. If use of technology incorporated into or used to produce our SMDCs is challenged, or if a conflicting patent issued to others is upheld in the courts or if a conflicting patent application filed by others is issued as a patent and is upheld, we may be unable to market one or more of our SMDCs, or we may be required to obtain a license to market those SMDCs. To contend with these possibilities, we may have to enter into license agreements in the future with third parties for technologies that may be useful or necessary for the manufacture or commercialization of some of our SMDCs. In addition, we are

routinely in discussions with academic and commercial entities that hold patents on technology or processes that we may find necessary in order to engage in some of our activities. However, we cannot assure you that these licenses, or any others that we may be required to obtain to market our SMDCs, will be available on commercially reasonable terms, if at all, or that we will be able to develop alternative technologies if we cannot obtain required licenses.

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To protect our rights to any of our issued patents and proprietary information, we may need to litigate against infringing third parties, or avail ourselves of the courts or participate in hearings to determine the scope and validity of those patents or other proprietary rights. These types of proceedings are often costly and could be very time-consuming to us, and we cannot assure you that the deciding authorities will rule in our favor. An unfavorable decision could allow third parties to use our technology without being required to pay us licensing fees or may compel us to license needed technologies to avoid infringing third-party patent and proprietary rights, or even could result in the invalidation or a limitation in the scope of our patents or forfeiture of the rights associated with our patents or pending patent applications. Although we believe that we would have valid defenses to allegations that our current SMDCs, production methods and other activities infringe the valid and enforceable intellectual property rights of any third parties, we cannot be certain that a third party will not challenge our position in the future. Even if some of these activities were found to infringe a third party s patent rights, we may be found to be exempt from infringement under 35 U.S.C. §271(e) to the extent that these are found to be pre-commercialization activities related to our seeking regulatory approval for a SMDC. However, the scope of protection under 35 U.S.C. §271(e) is uncertain and we cannot assure you that any defense under 35 U.S.C. §271(e) would be successful. Further, the defense under 35 U.S.C. §271(e) is only available for pre-commercialization activities, and could not be used as a defense for sale and marketing of any of our SMDCs. There has been, and we believe that there will continue to be, significant litigation in the biopharmaceutical and pharmaceutical industries regarding patent and other intellectual property rights.

Corporate Information

We were incorporated in the State of Indiana in 1995 and we were reincorporated in the State of Delaware in 2001. Our principal executive offices are located at 3000 Kent Avenue, Suite A1-100, West Lafayette, Indiana 47906, and our telephone number is (765) 463-7175.

Available Information

Our Internet address is *www.endocyte.com.* We routinely post important information for investors on our website in the Investors & News section. We use this website as a means of disclosing material information in compliance with our disclosure obligations under Regulation FD. Accordingly, investors should monitor the Investors & News section of our website, in addition to following our press releases, Securities and Exchange Commission, or SEC, filings, public conference calls, presentations and webcasts. Investors can easily find or navigate to pertinent information about us, free of charge, on our website, including:

our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with or furnish it to the SEC;
announcements of investor conferences and events at which our executives talk about our products and competitive strategies. Archives of some of these events are also available;
press releases on quarterly earnings, product announcements, legal developments and other material news that we may post from time to time;
corporate governance information, including our Corporate Governance Principles, Code of Ethics and Business Conduct, information concerning our Board of Directors and its committees, including the charters of the Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee, and other governance-related policies;
stockholder services information, including ways to contact our transfer agent; and
opportunities to sign up for email alerts and RSS feeds to have information provided in real time.

The information available on our website is not incorporated by reference in, or a part of, this or any other report we file with or furnish to the SEC.

The name Endocyte and our logo are our trademarks. All other trademarks and trade names appearing in this annual report are the property of their respective owners.

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Executive Officers of the Registrant

The following table sets forth certain information concerning our executive officers as of March 1, 2015:

Name	Age	Position
P. Ron Ellis	53	President and Chief Executive Officer
Michael A. Sherman	48	Chief Operating Officer and Chief Financial Officer
Philip S. Low, Ph.D.	67	Chief Science Officer
Michael A. Brinkley	51	Vice President of Quality
Scot L. Harper, Ph.D.	58	Vice President of Clinical Operations
Christopher P. Leamon, Ph.D.	48	Vice President of Research
Binh Nguyen, M.D., Ph.D.	56	Vice President of Medical Affairs
Katherine K. Parker	50	Vice President of Human Resources
Beth A. Taylor	49	Corporate Controller

P. Ron Ellis is one of our founders and has served as our President and Chief Executive Officer since January 1996 and as a member of our Board of Directors since December 1995. From May 1987 to December 1995, Mr. Ellis served in various positions at Hill-Rom Company, but most recently as Vice President of Strategy and Corporate Development of the specialty care division. Mr. Ellis holds a B.S. in computer science, an M.B.A. from Brigham Young University and a certification in regulatory affairs from Purdue University.

Michael A. Sherman has served as our Chief Operating Officer since June 2014 and as our Chief Financial Officer since October 2006. From December 1994 to October 2006, Mr. Sherman served in various executive roles, but most recently as Vice President of Finance and Strategic Planning from May 2004 to October 2006, of Guidant Corporation, a cardiovascular device manufacturer acquired by Boston Scientific Corporation, a medical device company, in April 2006. Mr. Sherman serves on the Board of Directors of Mead Johnson Nutrition Company, a pediatric nutrition company. He also serves on the Indianapolis Children s Museum Board of Trustees. Mr. Sherman holds a B.A. in economics from DePauw University and an M.B.A. from the Amos Tuck School, Dartmouth College.

Philip S. Low, Ph.D. is one of our founders and has served as our Chief Science Officer since April 1998 and as a member of our Board of Directors since December 1995. Dr. Low has served on the faculty at Purdue University since August 1976, where he is currently the Director of the Purdue Center for Drug Discovery and the Ralph C. Corley Distinguished Professor of Chemistry. Dr. Low holds a B.S. in chemistry from Brigham Young University and a Ph.D. in biochemistry from the University of California, San Diego.

Michael A. Brinkley has served as our Vice President of Quality since June 2013. From January 2012 to June 2013, Mr. Brinkley served as our Director of Quality. Prior to joining us, Mr. Brinkley was Director of Quality for JHP Pharmaceuticals from April 2010 to January 2012 and Vice President of Quality & Compliance for Boehringer-Ingelheim Chemicals, Inc. from January 2007 to February 2010. His background also includes experience in the pharmaceutical industry in analytical chemistry, microbiology, and quality assurance. Mr. Brinkley holds a B.S. in Microbiology from North Carolina State University and an MBA from University of North Carolina, Chapel Hill.

Scot L. Harper, PhD. has served as our Vice President of Clinical Operations since May 2013. Prior to joining us, he was Global Portfolio Director, Oncology at Parexel International from January 2012 to May 2013. From July 2004 to January 2012, he was Vice President of Clinical Operations at Novartis and he was Senior Director of Clinical Operations at Eli Lilly and Company from August 2000 to July 2004. He also served as Oncology Medical Director for Lilly s US affiliate. Dr. Harper received his doctorate in medical physiology from Indiana University School of

Medicine and an MBA from the University of South Alabama, where he served on the faculty of the College of Medicine. He received his undergraduate degree from DePauw University.

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Christopher P. Leamon, Ph.D. has served as our Vice President of Research since April 2000. From February 1999 to April 2000, Dr. Leamon served as our Director of Biology and Biochemistry. Prior to joining us, Dr. Leamon was employed in the pharmaceutical industry where he conducted discovery research in the field of peptide, oligonucleotide, liposome and DNA drug delivery for GlaxoWellcome, a healthcare company and Isis Pharmaceuticals, a biomedical pharmaceutical company. Dr. Leamon holds a B.S. in chemistry from Baldwin Wallace College and a Ph.D. in biochemistry from Purdue University.

Binh Nguyen, M.D., Ph.D. has served as our Vice President of Medical Affairs since June 2011. Dr. Nguyen has notified us of his resignation from our Company, effective March 23, 2015. From August 2005 to June 2011, he served as Chief Medical Officer at Tigris Pharmaceuticals, Inc. and prior to August 2005, he worked at Eli Lilly & Company for 10 years, most recently as Executive Director, Global Oncology Platform Team, for which he was responsible for the global development of Gemzar®, Alimta®, and Enzastaurin. Dr. Nguyen received his Ph.D. in organic chemistry from Georgetown University and his M.D. from the University of Maryland. He completed fellowships at the National Cancer Institute and worked at the FDA s Division of Oncology as a medical reviewer.

Katherine K. Parker has served as our Vice President of Human Resources since January 2015. From December 2013 to January 2015, she served as our Senior Director of Human Resources. Prior to December 2013, Ms. Parker served as Principal for Auxilius International, LLC from August 2010 to December 2013. She also has served as President/Owner of Auxilius Heavy Industries, LLC, a wind turbine maintenance, cleaning and repair company, from August 9, 2013 to the present. Prior to her entrepreneurial endeavors, Ms. Parker worked at Hyundai Motor America for 21 years, most recently as Vice President of Human Resources and Administrative Services from April 2005 to April 2009. Ms. Parker holds a B.A. in history from the University of California, Los Angeles and an M.B.A. from California State University, Dominguez Hills.

Beth A. Taylor has served as our Corporate Controller since January 2011. She served as Corporate Controller of Author Solutions, Inc. from December 2009 to December 2010, as Vice President of Accounting, Financial Reporting and Control at Harlan Laboratories, Inc. from July 2007 to May 2009 and in various roles at Republic Airways Holdings, Inc. from May 1999 through June 2007, including Vice President and Corporate Controller from August 2004 through June 2007. Ms. Taylor holds a B.S. in Accounting from Indiana University.

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Item 1A. *Risk Factors*

Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed below and elsewhere in this report. Additional risks and uncertainties not presently known to us or that are currently not believed to be significant to our business may also affect our actual results and could harm our business, financial condition and results of operations. If any of the risks or uncertainties described below or any additional risks and uncertainties actually occur, our business, results of operations and financial condition could be materially and adversely affected.

Risks Related to Our Business and Industry

Until our most recent fiscal year, we had incurred significant losses in each year since our inception and we anticipate that we will continue to incur significant losses for the foreseeable future. We may never again achieve or sustain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. In 2014, we were profitable, but prior to 2014, we had incurred significant losses in each year since our inception in December 1995. We have not generated any revenue from product sales to date. As of December 31, 2014, we had a retained deficit of $168.5 million. Even though we had net income for the year ended December 31, 2014, we expect to continue to incur significant operating expenses for the next several years as we pursue the advancement of our SMDCs and companion imaging diagnostics through the research, development, regulatory and commercialization processes. As such, we are subject to all of the risks incident to the creation of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. If our product candidates fail in clinical trials, or do not gain regulatory approval, or fail to achieve market acceptance, we may never again be profitable. Even if we achieve profitability again in the future, we may not be able to sustain profitability in subsequent periods.

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

As of December 31, 2014, we have not derived any revenue from the sales of our products. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology, undertaking preclinical studies and clinical trials of our product candidates and engaging in research and development under collaboration agreements. Although we had filed applications with the European Medicines Agency, or the EMA, for conditional marketing authorization of vintafolide and companion imaging components, imaging agent etarfolatide and intravenous folic acid, for the treatment of adult patients with folate receptor-positive, platinum-resistant ovarian cancer, or PROC, in combination with pegylated liposomal doxorubicin, or PLD, we withdrew those applications in May 2014 based on the review of interim data from our randomized phase 3 clinical trial that we refer to as PROCEED, following the Data Safety Monitoring Board s, or DSMB, recommendation that the study be stopped because vintafolide in combination with PLD compared to PLD alone did not meet the pre-specified criteria for improvement in progression free survival, or PFS. We have not yet demonstrated an ability to obtain regulatory approval, formulate and manufacture commercial-scale products, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, it is difficult to predict our future success and the

viability of any commercial programs that we may choose to take forward. While we have in the past derived revenues from payments under collaboration agreements, all of such agreements have been terminated.

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

We entered into a collaboration agreement with Merck for the development of vintafolide, which agreement was terminated by Merck, effective September 15, 2014. Vintafolide was being evaluated in PROC in the PROCEED trial, but in 2014, we and Merck terminated the PROCEED trial following the DSMB s recommendation that the trial be stopped for futility. Since we no longer have a collaboration agreement with respect to vintafolide, if there are any future development and commercialization activities related to

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vintafolide, we will be responsible for all of those activities and the associated costs and expenses. Our randomized phase 2b clinical trial, which we refer to as TARGET, of vintafolide for the treatment of second line non-small cell lung cancer, or NSCLC, is now substantially complete. The TARGET trial and future trials may not be sufficiently successful to merit future development, and vintafolide may never receive regulatory approval or be successfully commercialized. We may fail to obtain necessary marketing approvals for vintafolide from the U.S. Food and Drug Administration, or the FDA, or other regulatory authorities if our remaining 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 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.

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

The clinical trials of our product candidates are, and the manufacturing and marketing of any approved products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States, Europe and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical testing and clinical trials that the product candidate is safe and effective for use in each indication for which we intend to market such product candidate. This process takes many years and requires the expenditure of substantial financial and human resources and may include post-marketing trials and surveillance. To date, we have not completed any randomized phase 3 clinical trials. We have completed two phase 2 single-arm and one phase 2 randomized clinical trials with vintafolide for the treatment of patients with PROC and NSCLC. In May 2014, we terminated the PROCEED trial based on the DSMB s recommendation following the interim futility analysis indicating that vintafolide did not demonstrate efficacy on the pre-specified outcome of PFS. We are continuing to evaluate vintafolide for the treatment of NSCLC in the TARGET trial, and are awaiting final overall survival data from the TARGET trial to assess the future development of vintafolide. In addition, we have other product candidates in the discovery and preclinical testing stages.

Positive results from preclinical studies and early clinical trials should not be relied upon as evidence that later-stage or large-scale clinical trials will succeed. Like us, a number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, even after promising results in earlier trials. We will be required to demonstrate with substantial evidence through adequate and well-controlled clinical trials that our product candidates are safe and effective for use in the target population before the regulatory authorities will approve our product candidates for commercial sale.

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

We cannot give any assurance that we will successfully complete the clinicaldevelopment of our SMDCs, or that the

prospects for our product candidates.

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

Our product candidates are in various stages of development and are prone to the risks of failure inherent in biopharmaceutical development. In many cases, even if we ultimately obtain regulatory approval to market

The results of clinical trials may not be predictive of future results, and thosetrials may not satisfy the requirements

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a product candidate, we will need to complete significant additional clinical trials before we can demonstrate that the product candidate is safe and effective to the satisfaction of the regulatory authorities involved. Clinical trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process. Further, even if a product candidate receives the required regulatory approvals, we cannot assure you that it will be successful commercially. In addition, we have a number of product candidates in our development pipeline, and while we invest in the technology and indications that we believe are most promising, financial and resource constraints may require us to forego or delay opportunities that may ultimately have greater commercial potential than those programs we are currently actively developing.

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

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

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

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

In the United States and in other countries, there have been and we expect there will continue to be a number of legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. International, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical

products and services. The U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the Patient Protection and Affordable Care Act and its amendment, the Health Care and Education Reconciliation Act. Such government-adopted reform measures may adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. In addition, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. The continuing efforts of U.S. and other governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set satisfactory prices for our products, to generate revenues, and to achieve and maintain profitability.

The coverage and reimbursement status of newly approvedbiopharmaceuticals is uncertain, and failure to obtain ac

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

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

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

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

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

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

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities or us. For example, we terminated the PROCEED trial in 2014 after the interim futility analysis indicated that vintafolide did not demonstrate efficacy on the pre-specified outcome of PFS. Failure or significant delay in completing clinical trials for our product candidates could materially harm our financial results and the commercial prospects for our product candidates.

Our development activities could be delayed or stopped for a number of reasons, many of which are outside our co

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

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

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

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

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

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

We may seek approval to market certain of our product candidates in both the United States and in non-U.S. jurisdictions. Prior to commercialization, each product candidate will be subject to an extensive and lengthy governmental regulatory approval process in the United States and in other countries. In order to market our products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We may not receive the approvals necessary to commercialize our product candidates in any market and we may withdraw applications for approval before acted upon by the regulatory authority. For example, in 2014, we withdrew our applications with the EMA for conditional marketing authorization of vintafolide and companion imaging components for the treatment of adult patients with folate receptor-positive PROC, in combination with PLD, based on the review of interim data from the PROCEED trial following the DSMB s recommendation that the study be stopped because vintafolide in combination with PLD compared to PLD alone did not meet the pre-specified criteria for improvement in PFS.

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

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

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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, our directors and certain officers have been named as defendants in securities class action, shareholder derivative and other lawsuits that could result in substantial costs and divert management s attention.

We, our directors and certain officers have been named as defendants in securities class action, shareholder derivative and other lawsuits. See Part I, Item 1A Legal Proceedings for additional information regarding these lawsuits. Any negative outcome from these lawsuits could result in payments of monetary damages or fines, or adversely affect our product candidates, and accordingly our business, financial condition, or results of operations could be materially and adversely affected.

There can be no assurance that a favorable final outcome will be obtained in these cases, and defending any lawsuit is costly and can impose a significant burden on management and employees. We also have certain obligations to indemnify, and advance expenses to, our directors and officers in connection with various actions, suits and proceedings. Any litigation may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of monetary damages or fines not covered by insurance, or we may decide to settle lawsuits on unfavorable terms, which could adversely affect our business, financial condition, or results of operations.

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 costs associated with establishing a sales force and commercialization capabilities;
the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
the costs and timing of seeking and obtaining approval from regulatory authorities;
our ability to maintain, defend and expand the scope of our intellectual property portfolio;
our need and ability to hire additional management and scientific and medical personnel;
the effect of competing technological and market developments; and
the economic and other terms and timing of collaboration, licensing or other arrangements into which we may enter.

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

In addition, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. Also, we may seek additional capital due to favorable market conditions or

other strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

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

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

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

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

Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large biopharmaceutical companies, in particular, have extensive experience in clinical testing and in obtaining regulatory approvals for drugs. Additional mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated by our competition. Competition may increase further as a result of advances in the commercial applicability of technologies currently being developed and a greater availability of capital investment in those fields. These companies may also have significantly greater research and marketing capabilities than we do. Some of the companies developing products which may compete with our product candidates include AbbVie, Inc., Ariad Pharmaceuticals, Inc., Astex Pharmaceuticals, Inc., AstraZeneca PLC, Bristol-Myers Squibb Company, Boehringer Ingelheim Pharmaceuticals Inc., Clovis Oncology, Inc., Eli Lilly and Company, Exelixis, Inc., GlaxoSmithKline PLC, Merck & Co, Inc., Novartis AG, Puma Biotechnology, Inc., Roche Holdings, Synta Pharmaceuticals Corp., Tesaro, Inc., and Verastem, Inc. 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 are more effective, safer or less expensive than our product candidates or reach the market sooner

than our product candidates, we may not achieve commercial success.

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

- our ability to design and successfully execute appropriate clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the results of our clinical trials and the efficacy and safety of our product candidates;
- the speed at which we develop our product candidates;

If our competitors develop and market products that are more effective, saferor less expensive than our product car

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achieving and maintaining compliance with regulatory requirements applicable to our business;
the timing and scope of regulatory approvals, including labeling;
adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
our ability to protect intellectual property rights related to our product candidates;
our ability to commercialize and market any of our product candidates that may receive regulatory approval;
our ability to have any partners manufacture and sell commercial quantities of any approved product candidates to the market;
acceptance of our product candidates by physicians, other healthcare providers and patients; and
the cost of treatment in relation to alternative therapies.

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

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

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

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede the achievement of our research and development objectives, our ability to raise additional capital and our ability to implement our business strategy.

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

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

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

regulatory approval process, and then have to reduce our capabilities or terminate those relationships if the trials or approval processes are terminated. For example, we had begun to expand our commercial capabilities in European markets while the conditional

If we evolve from a company primarily involved in clinical development to a company also involved in commercializa

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marketing applications with the EMA were pending, and then had to eliminate those capabilities following our withdrawal of the applications in May 2014.

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 any of our product candidates receive regulatory approval, we intend to build a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue is likely to be lower than if we directly marketed or sold our products and will depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

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

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

occurring in our trials or otherwise, or if we or they find deficiencies in the clinical trial process or conduct of the investigation.

The FDA and foreign regulatory agencies could also require additional clinical trials before or after granting marketing approval for any products, which would result in increased costs and significant delays in the development and commercialization of such products and could result in the withdrawal of such products from the market after obtaining marketing approval. Our failure to adequately demonstrate the safety and efficacy of a product candidate in clinical development could delay or prevent obtaining marketing approval of the product candidate and, after obtaining marketing approval, data from post-approval 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 conduct clinical trials for our product candidatesand plan to rely on third parties to conduc

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

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

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

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

We are subject to risks associated with the availability of key raw materials, such as technetium-99m.

Our etarfolatide companion imaging agent requires the use of the radioisotope technetium-99m, or Tc-99m, and there have been historical periods in which supply was not able to satisfy demand. Tc-99m for nuclear medicine purposes is usually extracted from Tc-99m generators, which contain molybdenum-99, or Mo-99, as the usual parent nuclide for Tc-99m. The majority of Mo-99 produced for Tc-99m medical use comes from fission of highly enriched uranium from only five reactors around the world located in Canada, Belgium, South Africa, the Netherlands and France. Although Tc-99m is used in various nuclear medicine diagnostics utilized by healthcare providers, Tc-99m has a very

short half-life (6 hours). As a result, healthcare providers extract Tc-99m from generators which use Mo-99. Mo-99 itself has a short half-life (2.75 days) and is sent to the nuclear medicine pharmacy directly from one of the five reactors. Accordingly, Tc-99m diagnostics are made on-site at the clinic, and neither Tc-99m nor Mo-99 can be inventoried. Sources of Tc-99m may be insufficient for our clinical trial site needs due to its limited supply globally. For example, global shortages of Tc-99m emerged in the past few years because aging nuclear reactors in the Netherlands and Canada that provided about two-thirds of the world s supply of Mo-99 were shut down repeatedly for extended maintenance periods and two replacement Canadian reactors constructed in the 1990s were closed before beginning operation for safety reasons.

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We use, and plan to continue to use, etarfolatide or other companion imaging agents that employ Tc-99m in our clinical trials. If our clinical trial sites are not able to obtain sufficient quantities of Tc-99m for use in etarfolatide, we may not be able to gather sufficient data on etarfolatide and as a result, the approval of etarfolatide may be delayed. In addition, to the extent the approval of our product candidates depends on the screening and monitoring of the patient population with a companion imaging agent such as etarfolatide in our clinical trials, we would experience a corresponding delay in approval and commercialization of these SMDCs if we are not able to obtain sufficient Tc-99m.

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

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

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

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

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

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

In the event of an accident, state or federal authorities may curtail our use of these materials, and we could be liable for any civil damages, which may exceed our financial resources and may seriously harm our business. We currently maintain insurance covering hazardous waste clean-up costs in an amount we believe to be sufficient for typical risks regarding our handling of these materials, however, this amount of coverage may not be sufficient to cover extraordinary or unanticipated events. Additionally, an accident could damage, or force us to temporarily shut down, our operations.

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Risks Related to Intellectual Property

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

Cyber attacks or security breaches could compromise confidential, business critical information, cause a disruption in our operations, harm our reputation or increase our stock trading risk. We have attractive information assets, including intellectual property, trade secrets and other sensitive, business critical information, including personally identifiable information of our employees. While we have several levels of security and data protection in place that is continuously reviewed, maintained and upgraded, a significant cyber attack could compromise our networks and data centers, and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, potential liabilities under laws that protect the privacy of personal information, delays and impediments to our discovery and development efforts, damage to our reputation and a negative impact on our financial results.

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

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

We apply for patents covering both our technologies and product candidates, as we deem appropriate. However, we may fail to apply for patents on important technologies or product candidates in a timely fashion, or at all. 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;

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any patents issued to us or our licensors and collaboration partners will provide us with any competitive advantages, or will be challenged by third parties;

we will develop additional proprietary technologies that are patentable;

the U.S. government will exercise any of its statutory rights to our intellectual property that was developed with government funding; or

our business may infringe the patents or other proprietary rights of others.

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

We also rely on trade secrets to protect some of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our or any of our collaboration partners employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors and we may not have adequate remedies in respect of that disclosure. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, non-U.S. courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

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

With respect to patent applications relating to our product candidates that incorporate patents licensed from Purdue Research Foundation, the right and obligation to prosecute and maintain the patents and patent applications covered by these license agreements are retained by Purdue Research Foundation. Generally, we do not have the right to prosecute and maintain such patents in our territories, unless Purdue Research Foundation elects not to file, prosecute or maintain any or all of such patents, however, our most recent master license agreement for future potential technology provides us lead prosecution responsibility. We would need to determine, with our other potential partners, who would be responsible for the prosecution of patents relating to any joint inventions. If any of our licensing partners 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, potential penalty 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

If we breach any of the agreements under which we license commercializationrights to our product candidates or te

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terminate the license in whole or in part or to terminate the exclusive nature of the license. Generally, the loss of any current or future licenses or the exclusivity rights provided therein could materially harm our financial condition and operating results.

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

The patents for our product candidates have varying expiration dates and, if these patents expire, we may be subject to increased competition and we may not be able to recover our development costs or market any of our approved products profitably. For example, one of our U.S. patents claims compounds encompassing vintafolide and is due to expire in 2026, and two of our other U.S. patents claim compounds encompassing etarfolatide and are due to expire in 2024. In some of the larger potential market territories, such as the United States and Europe, patent term extension or restoration may be available to compensate for time taken during aspects of the product s development and regulatory review. However, we cannot be certain that such an extension will be granted, or if granted, what the applicable time period or the scope of patent protection afforded during any extension period will be. In addition, even though some regulatory authorities may provide some other exclusivity for a product under their own laws and regulations, we may not be able to qualify the product or obtain the exclusive time period. If we are unable to obtain patent term extension/restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our U.S. and non-U.S. patents.

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

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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

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

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

If we are sued for infringing intellectual property rights of third parties,litigation will be costly and time-consuming an

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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

We may become involved in lawsuits to enforce our patents or other intellectual property rights, which could be exp

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the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

Risks Related to Ownership of Our Common Stock

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

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

results from, supplemental analyses of and any delays in, our current or planned clinical trials;
announcements of approval or non-approval by any regulatory authorities of any of our product candidates, or delays in any regulatory authority review processes;
other regulatory actions affecting us or our industry;
litigation or public concern about the safety of our product candidates;
failure or discontinuation of any of our research or clinical trial programs;
withdrawal of regulatory approval applications;
delays in the commercialization of our product candidates;
our ability to effectively partner with collaborators to develop or sell our products;
market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors and issuance of new or changed securities analysts reports or recommendations;
actual and anticipated fluctuations in our quarterly operating results;
developments or disputes concerning our intellectual property or other proprietary rights;
introduction of technological innovations or new products by us or our competitors;
issues in 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.

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In addition, the stock markets in general, and the markets for biopharmaceutical, pharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action and other litigation against the issuer. For example, we, our directors and certain officers have been named as defendants in securities class action, shareholder derivative and other lawsuits alleging violations of certain securities and other laws. See Part I, Item 3 Legal Proceedings and We, our directors and certain officers have been named as defendants in securities class action, shareholder derivative and other lawsuits that could result in substantial costs and divert management s attention. These lawsuits and other similar litigation, if instituted against us, could result in substantial costs and diversion of management s attention and resources, which could materially and adversely affect our business and financial condition.

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 December 31, 2014, we had 41,784,692 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, another exemption from registration or an effective registration statement under the Securities Act.

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

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

Our directors, executive officers and each of the two stockholders who own greater than five percent of our outstanding common stock and their affiliates, in the aggregate, beneficially owned approximately 36.1 percent of the outstanding shares of our common stock as of December 31, 2014. As a result, these stockholders, if acting together, could influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might affect the market price of our common stock.

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

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

establishing a classified board so that not all members of our Board of Directors are elected at one time;

authorizing blank check preferred stock that our Board of Directors could issue to increase the number of outstanding shares to discourage a takeover attempt;

eliminating the ability of stockholders to call a special stockholder meeting;

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eliminating the ability of stockholders to act by written consent;
being subject to provisions of Section 203 of the Delaware General Corporate Law regulating corporate takeovers;
providing that our Board of Directors is expressly authorized to make, alter or repeal our bylaws; and
establishing advance notice requirements for nominations for elections to our Board of Directors or for proposing other matters that can be acted upon by stockholders at stockholder meetings.

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

We are subject to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, which requires management to assess and report annually on the effectiveness of internal control over financial reporting and identify any material weaknesses in internal control over financial reporting, and our independent registered public accounting firm to issue an attestation report as to management s assessment of the effectiveness of internal control over financial reporting.

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

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

Under Section 382 of the U.S. Internal Revenue Code, or Code, a corporation that experiences a more-than 50 percent ownership change over a three-year testing period is subject to limitations on its ability to utilize its pre-change net operating losses to offset future taxable income. We experienced such an ownership change in August 2011. As a result, the future use of our net operating losses, after giving effect to net unrealized built-in gains, is currently limited to approximately $133.2 million for 2014, $39.0 million for 2015, $29.7 million for 2016 and $16.8 million for 2017. Any available but unused amounts will become available for use in all successive years. At December 31, 2014, we recorded a full valuation allowance against our net operating loss carryforwards of approximately $75.8 million, as we believe it is more likely than not that the net operating loss carryforwards will not be fully realized.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

Our offices are located in two primary leased facilities, a 25,400 square foot facility in West Lafayette, Indiana in the Purdue University Research Park and a 7,600 square foot corporate office space in Indianapolis, Indiana. The West Lafayette facility includes both administrative and research laboratory space. The lease for this facility expires December 31, 2015, and we do not foresee risk in obtaining an extension to this lease agreement for similar terms or having a disruption to our operations. The Indianapolis offices are used exclusively for corporate and administrative functions. The lease for this facility expires in February 2018. We believe the existing facilities are sufficient to meet our current and near-term needs.

Item 3. *Legal Proceedings*

On June 24, 2014, a complaint in a securities class action lawsuit was filed against us and one of our officers and directors in the United States District Court for the Southern District of Indiana under the following caption: *Tony Nguyen, on Behalf of Himself and All Others Similarly Situated v. Endocyte, Inc. and P. Ron Ellis* (the Nguyen Litigation). On July 13, 2014, a nearly identical complaint in a securities class action lawsuit was filed against us and one of our officers and directors in the United States District Court for the Southern District of Indiana under the following caption: *Vivian Oh Revocable Trust, Individually and on*

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Behalf of All Others Similarly *Situated v. Endocyte, Inc. and P. Ron Ellis* (the Oh Litigation). On September 22, 2014, the court named a lead plaintiff (Lead Plaintiff) and consolidated the Nguyen Litigation and the Oh Litigation under the following caption: *Gopichand Vallabhaneni v. Endocyte, Inc. and P. Ron Ellis* (the Vallabhaneni Litigation). On November 17, 2014, Lead Plaintiff filed a consolidated amended securities class action complaint (the Amended Complaint) against us, P. Ron Ellis, Beth Taylor, Michael A. Sherman, John C. Aplin, Philip S. Low, Keith A. Brauer, Ann F. Hanham, Marc Kozin, Peter D. Meldrum, Fred A. Middleton, Lesley Russell (the Individual Defendants and collectively with us, the Endocyte Defendants), and Credit Suisse Securities (USA) LLC and Citigroup Global Markets Inc. (the Underwriter Defendants). Lead Plaintiff alleged, among other things, that the Endocyte Defendants made false and misleading statements relating to the efficacy of vintafolide and violated Sections 10(b) and 20(a) of the Exchange Act. The putative class related to these allegations consists of all persons who purchased or otherwise acquired our securities between March 21, 2014 and May 2, 2014. Lead Plaintiff also alleged in the Amended Complaint that the Endocyte Defendants and the Underwriter Defendants violated Sections 11 and 15 of the Securities Act of 1933, as amended (the Securities Act), by, among other things, making or allowing us to make false and misleading statements regarding positive opinions about vintafolide issued by the European Medicines Agency s Committee for Medicinal Products for Human Use in our Registration Statement on Form S-3 filed on March 25, 2014, preliminary prospectus filed on March 26, 2014, and final prospectus filed on March 28, 2014. The putative class related to these allegations consists of all those who purchased or otherwise acquired our securities pursuant to or traceable to our April 2, 2014 public offering.

Lead Plaintiff seeks the designation of the Vallabhaneni Litigation as a class action, an award of unspecified damages, interest, costs, expert fees and attorneys fees, and equitable/injunctive relief or other relief as the court may deem just and proper. Pursuant to a December 9, 2014 order, all Defendants filed a motion to dismiss on March 6, 2015. Discovery in this matter is stayed pursuant to provisions of the Private Securities Litigation Reform Act (PSLRA) pending resolution of that motion to dismiss. We believe that this lawsuit is without merit and have defended, and intend to continue to defend, ourselves vigorously against the allegations made in the Amended Complaint.

On September 23, 2014, a complaint in a shareholder derivative lawsuit was filed against all of our current directors in the United States District Court for the Southern District of Indiana under the following caption: *William Moore, Derivatively on Behalf of Nominal Defendant Endocyte, Inc. v. John C. Aplin, et al.* (the Moore Litigation). We were named as a nominal defendant in the case. The complaint alleged, among other things, that the defendants violated state law, including through breaches of fiduciary duties, gross mismanagement, waste of corporate assets and unjust enrichment, in regard to false and misleading statements and material omissions made concerning the efficacy of vintafolide, causing substantial monetary losses to us and other damages, including irreparable damages to our reputation and goodwill. The complaint sought: unspecified damages from each of the defendants, jointly and severally, together with interest thereon; an order directing that actions be taken to reform and improve our corporate governance and internal procedures to comply with applicable laws and to protect our shareholders from a repeat of the alleged damaging events; an award of unspecified exemplary damages; restitution; costs and disbursements, including reasonable attorneys and experts fees, costs and expenses; and such other and further equitable relief as the court may deem just and proper.

On October 31, 2014, a complaint in a shareholder derivative lawsuit nearly identical to the Moore Litigation was filed against all of our current directors in the United States District Court for the Southern District of Indiana under the following caption: *Victor Veloso, Derivatively on Behalf of Endocyte, Inc. v. John C. Aplin, et al.* (the Veloso Litigation). We were named as a nominal defendant in the case. The complaint alleged, among other things, that the defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry and good faith by causing us to issue false and misleading statements concerning our financial condition, resulting in significant damages, not only monetarily, but also to our corporate image and goodwill, including costs associated with defending securities lawsuits, severe damage to our share price, resulting in an increased cost of capital, the waste of corporate assets and

reputational harm. The complaint sought: unspecified damages from all of the defendants; an order directing that we take all necessary actions to reform and improve our corporate governance and internal procedures, to comply with existing governance obligations and all applicable laws and to protect us and our investors from a recurrence of the alleged

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damaging events; costs and disbursements, including reasonable attorneys fees, accountants and experts fees, costs and expenses; and such other and further relief as the court deems just and proper.

On December 31, 2014, the court appointed co-lead counsel and consolidated the Moore Litigation with the Veloso Litigation under the following caption: *In re Endocyte, Inc. Derivative Litigation* (the Endocyte Derivative Litigation). An amended complaint was filed on February 28, 2015 which contains allegations and requests for relief that are substantially the same as the complaints in the Moore Litigation and the Veloso Litigation. Although this lawsuit is brought nominally on behalf of us, we expect to incur defense costs and other expenses in connection with the lawsuit. Discovery and other proceedings in this matter are currently stayed pursuant to agreement of the parties pending resolution of the March 6, 2015 motion to dismiss in the Vallabhaneni Litigation.

On November 6, 2014, a complaint was filed against us, two of our executive officers, Merck and one of Merck s officers in the Superior Court of Tippecanoe County, Indiana under the following caption: *Mohamad Hage and Jamele Hage v. Endocyte, Inc., P. Ron Ellis, Mike A. Sherman, Eric Rubin and Merck & Co., Inc.* (the Hage Litigation). The complaint alleged, among other things, that the defendants: made false and misleading statements about the efficacy of vintafolide and the likelihood that it would be approved for sale; employed devices, schemes and artifices to defraud; made untrue statements of material facts and omitted to state material facts necessary in order to make the statements made about us and our business operations not misleading; and breached fiduciary duties owed to the plaintiffs. The complaint alleged that as a result of the alleged fraudulent misrepresentations, non-disclosures and schemes of the defendants, plaintiffs have suffered pecuniary losses. The plaintiffs seek an award of unspecified actual, compensatory, consequential, incidental and punitive damages, reasonable costs, expert fees and attorneys fees, and such equitable/injunctive or other relief as the court may deem just and proper. We believe that we may have an obligation to indemnify Merck and its named officer in connection with the Hage Litigation, depending on certain factors. On January 9, 2015, the defendants filed a Motion to Stay the Proceeding or in the Alternative to Stay Discovery (the Motion to Stay). A hearing on the Motion to Stay was held on February 19, 2015 and the parties are waiting for the court to rule. We believe that this lawsuit is without merit and have defended, and intend to continue to defend, ourselves vigorously against the allegations made in the complaint.

We also have certain obligations to indemnify, and advance expenses to, our directors and officers in connection with various actions, suits and proceedings.

Item 4. *Mine Safety Disclosures*

Not applicable.

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PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information and Stockholders

Shares of our common stock are traded on the The Nasdaq Global Market (symbol ECYT). The following table sets forth the high and low sale prices per share for our common stock on The Nasdaq Global Market for the periods indicated:

	High	Low
2013		
First Quarter	$ 12.75	$ 8.50
Second Quarter	$ 15.36	$ 11.80
Third Quarter	$ 19.00	$ 13.12
Fourth Quarter	$ 14.71	$ 8.18
2014		
First Quarter	$ 33.70	$ 10.38
Second Quarter	$ 25.19	$ 6.01
Third Quarter	$ 9.35	$ 5.91
Fourth Quarter	$ 6.89	$ 5.31

As of February 27, 2015, there were 99 stockholders of record of our common stock. The number of record holders is based upon the actual number of holders registered on the books of the company at such date and does not include holders of shares in street name or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depositories.

We have never declared or paid any dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, we do not anticipate declaring or paying cash dividends for the foreseeable future. The payment of dividends will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payment of dividends present in our future debt agreements, and other factors that our Board of Directors may deem relevant.

Unregistered Sales of Securities

We did not have any unregistered sales of securities in the fourth quarter of 2014.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities in the fourth quarter of 2014.

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Comparative Stock Performance Graph

The information included under the heading Comparative Stock Performance Graph in this Item 5 of Part II of this Annual Report on Form 10-K shall not be deemed to be soliciting material or subject to Regulation 14A or 14C, shall not be deemed filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act.

Set forth below is a graph comparing the total cumulative returns of ECYT, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes $100 was invested on the first day our common stock began trading on The Nasdaq Global Market, February 4, 2011, in our common stock and each of the indices and that all dividends, if any, are reinvested.

	2/4/11	12/31/11	12/31/12	12/31/13	12/31/14
Endocyte, Inc.	**$ 100.00**	**$ 48.64**	**$ 116.17**	**$ 138.16**	**$ 81.37**
NASDAQ Composite Index	**$ 100.00**	**$ 94.08**	**$ 109.06**	**$ 150.83**	**$ 171.01**
NASDAQ Biotechnology Index	**$ 100.00**	**$ 110.71**	**$ 146.02**	**$ 241.79**	**$ 324.34**

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Item 6. *Selected Financial Data*

We have derived the selected statement of operations data for the years ended December 31, 2012, 2013 and 2014 and selected balance sheet data as of December 31, 2013 and 2014 from our audited financial statements and related notes included in this annual report. We have derived the statement of operations data for the years ended December 31, 2010 and 2011 and the balance sheet data as of December 31, 2010, 2011 and 2012 from our audited financial statements not included in this annual report. Our historical results are not necessarily indicative of the results to be expected for any future period. The following selected financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this annual report.

	Year Ended December 31,				
	2010	2011	2012	2013	2014
	(In thousands, except share and per share amounts)				
Statement of operations data:					
Total revenue	$	$191	$34,682	$64,871	$70,353
Operating expenses:					
Research and development	14,561	28,828	35,671	57,899	41,650
General and administrative	6,039	10,000	15,054	25,314	23,677
Total operating expenses	20,600	38,828	50,275	83,213	65,327
Income (loss) from operations	(20,600)	(38,637)	(16,043)	(18,342)	5,026
Other income (expense), net:					
Interest income	8	129	328	466	579
Interest expense	(1,065)	(1,988)	(629)	(2)	(1)
Other income (expense), net	1,564	(36)	(948)	(154)	(145)
Total other income (expense), net	507	(1,895)	(1,249)	310	433
Income (loss) before income taxes	(20,093)	(40,532)	(17,292)	(18,032)	5,459
Income tax (benefit) expense[1]					
Net income (loss)	$(20,093)	$(40,532)	$(17,292)	$(18,032)	$5,459
Basic net income (loss) per share[2]	$(21.77)	$(1.40)	$(0.48)	$(0.50)	$0.14
Diluted net income (loss) per share[2]	$(21.77)	$(1.40)	$(0.48)	$(0.50)	$0.13
Shares used in computation of:					
Basic income (loss) per share[2][3][4]	923,000	29,003,991	35,858,757	36,036,996	40,242,352
Diluted income (loss) per share[2][3][4]	923,000	29,003,991	35,858,757	36,036,996	41,758,101

(1) For 2014, we had no income tax expense due to net operating losses in prior years, as we had incurred significant net losses since our inception until the current year.

(2) On January 10, 2011, we effected a 1.00 for 1.91 reverse stock split. All historical common stock and per share information has been changed to reflect the stock split.

(3) For 2010, 2011, 2012, and 2013, diluted weighted average common shares outstanding were identical to basic weighted-average common shares outstanding and diluted loss per share was identical to basic loss per share because common share equivalents were excluded from the calculations of diluted weighted-average common shares outstanding for those years, as their effect was anti-dilutive. For 2014, 1,515,749 shares were added to basic weighted-average common shares outstanding to calculate diluted weighted-average shares outstanding because of

their dilutive effect.

(4) Shares for 2010 exclude any preferred shares that converted into common stock in connection with our initial public offering in 2011.

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	As of December 31,				
	2010	2011	2012	2013	2014
	(In thousands)				
Balance sheet data:					
Cash, cash equivalents and investments	$16,873	$128,085	$201,378	$148,853	$206,831
Working capital	12,377	124,286	122,355	59,668	120,153
Total assets	21,214	131,675	214,079	162,858	212,801
Total debt	14,804	12,833			
Subordinated notes[(1)]	9,529				
Total stockholders equity (deficit)	(96,911)	113,372	99,573	88,229	205,004

(1) As of December 31, 2010, our subordinated notes were treated as share-settled debt under Accounting Standards Codification, or ASC, 480-10-25-14 and were recorded at fair value. The subordinated notes accrued interest in kind at an annual rate of 10.0 percent. Subsequent to December 31, 2010, we issued an additional $3.7 million of subordinated notes. All of the subordinated notes plus accrued and unpaid interest thereon were automatically converted into 2,335,823 shares of common stock upon the completion of our initial public offering.

Item 7. *Management s Discussion and Analysis of Financial Condition and Results of Operations*

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes included in this annual report.

Overview

We are a biopharmaceutical company developing targeted therapies for the treatment of cancer and inflammatory diseases. We use our proprietary technology to create novel small molecule drug conjugates, or SMDCs, and companion imaging agents. Our SMDCs actively target receptors that are over-expressed on diseased cells, relative to healthy cells. This targeted approach is designed to enable the treatment of patients with highly active drugs at greater doses, delivered more frequently, and over longer periods of time than would be possible with the untargeted drug alone. We are also developing companion imaging agents for each of our SMDCs that are designed to identify the patients whose disease over-expresses the target of the therapy and who are therefore most likely to benefit from treatment. This combination of an SMDC with a companion imaging agent is designed to personalize the treatment of patients by delivering effective therapy, selectively to diseased cells, in the patients most likely to benefit.

Our first generation SMDC, vintafolide, targets the folate receptor, which is frequently over-expressed on cancer cells. We initially chose platinum-resistant ovarian cancer, or PROC, a highly treatment-resistant disease, as our lead indication for development of vintafolide because of the high unmet need in treating this patient population and the high percentage of ovarian cancer patients whose tumors over-express the targeted folate receptor. In the first half of 2011, we initiated enrollment of our PROCEED trial, a phase 3 registration trial in women with PROC. PROCEED was a randomized, double-blinded trial of vintafolide in combination with pegylated liposomal doxorubicin, or PLD (marketed in the U.S. under the brand name DOXIL® and in Europe under the brand name CAELYX®), compared to PLD plus placebo. In May 2014, we stopped the PROCEED trial based on the review of interim data by the Data and Safety Monitoring Board, or DSMB, because vintafolide in combination with PLD compared to PLD alone did not meet the pre-specified criteria for improvement in progression free survival, or PFS. While the PFS and overall response rates for the vintafolide combination arm of the trial were similar to those of a prior phase 2 trial,

PRECEDENT, the PLD control arm performed better in the PROCEED trial than in the PRECEDENT trial and other historical trials. Detailed results of the PROCEED trial will be presented at an upcoming medical conference. In the year ended December 31, 2014, we recorded a charge of $4.1 million for the remaining expenses of the PROCEED trial, including continued patient therapy costs for the patients who chose to stay on treatment, as well as site close-out expenses.

We are also developing vintafolide for use in non-small cell lung cancer, or NSCLC. Based on results of our single-arm, single agent phase 2 clinical trial of vintafolide in patients with second line NSCLC, in 2012

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we began enrollment in TARGET, a randomized phase 2b trial, which is now substantially complete. The trial enrolled and treated 199 patients with adenocarcinoma and squamous cell carcinoma of the lung who had failed one prior line of therapy and enrollment was completed in July 2013. Patients were selected based on etarfolatide scan results and only FR(100%) patients (patients in which 100 percent of their target lesions over-expressed the folate receptor as determined by an etarfolatide scan) were included. The trial design is intended to evaluate the safety and efficacy of vintafolide in second line NSCLC as a single agent and in combination with docetaxel, a commonly used second line chemotherapy approved by the U.S. Food and Drug Administration, or the FDA. The study has three arms: docetaxel alone; vintafolide alone; and vintafolide plus docetaxel. The primary outcome measure is PFS with secondary measures of overall survival, or OS, tumor response and duration of response. In October 2013, we announced the outcomes of the planned DSMB review of the interim futility analysis for the TARGET trial. The DSMB recommended the continuation of the vintafolide plus docetaxel arm and docetaxel alone arm of the trial. Based on the DSMB s additional recommendation, investigators and patients were advised that the vintafolide alone arm was not likely to be declared superior to docetaxel in PFS at the end of the study, and patients then on the vintafolide alone arm could continue treatment based on guidance from their investigator. In March 2014, we announced that the study met the primary endpoint of PFS for the combination vintafolide plus docetaxel arm, and demonstrated initial positive trends in secondary endpoints of OS and response rate. We communicated the detailed data, including updated OS results, at the European Society of Medical Oncology Congress, or ESMO, in September 2014. The data showed that patients in the predefined adenocarcinoma subgroup treated with the vintafolide plus docetaxel combination had a 27 percent reduction in risk of the disease worsening or death (HR=0.73, p=0.0899, one-sided test), and a 30 percent reduction in the risk of death (HR=0.70, p=0.1018), compared to docetaxel monotherapy. Stratified analysis, which adjusts for pre-defined patient characteristics in the trial, reflected a 49 percent reduction in the risk of death in patients with adenocarcinoma (HR=0.51, p=0.0147). These data included approximately 78 percent of the targeted number of events in the overall survival analysis. Overall survival in all patients, including those with squamous disease, reflected a 12 percent reduction in the risk of death (HR=0.88, p=0.2874) or 25 percent reduction when stratified (HR=0.75, p=0.1066). The primary endpoint of the study, as disclosed previously, showed that PFS was reduced by 25 percent for patients who received vintafolide plus docetaxel (HR=0.75, p=0.0696). The future development of vintafolide in NSCLC will be assessed based on the final overall survival analysis expected in the second or third quarter of 2015, and the results of the ongoing phase 1 clinical trial of EC1456.

EC1456, our second generation SMDC, also targets the folate receptor. We are currently screening patients for enrollment in a phase 1 dose escalation trial for the treatment of advanced solid tumors with EC1456. In preclinical models, the drug payload, tubulysin, has demonstrated a higher level of potency and less vulnerability to multi-drug resistance mechanisms compared to the drug payload in vintafolide. In some preclinical models in which vintafolide demonstrates no activity or there is a resistance to vintafolide, the folate tubulysin SMDC has demonstrated activity. EC1456 has progressed in the phase 1 trial to a dose that exceeds the dose of vintafolide delivered in trials to date. Once the maximum tolerated dose is determined, we plan to expand the trial to evaluate EC1456 in NSCLC, triple-negative breast cancer, ovarian cancer and endometrial cancer in more than 100 patients who are FR(100%).

EC1169, our first non-folate SMDC, is a tubulysin therapeutic targeting prostate-specific membrane antigen, or PSMA. We have developed a companion imaging agent, EC0652, to scan patients prior to therapy to identify the presence of PSMA. To date, EC0652 has shown the presence of PSMA in the prostate cancer of all prostate cancer patients scanned. We have initiated a phase 1 dose escalation trial in recurrent prostate cancer for EC1169. Once a maximum tolerated dose is identified, we plan to expand this trial to enroll up to 50 patients at that dose. Patients are scanned with EC0652, but we are not limiting enrollment based on the results of the scan.

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, which

agreement was terminated by Merck effective September 15, 2014. As a result of the termination of the collaboration with Merck, we are no longer eligible for additional milestone payments from Merck. Pursuant to the collaboration agreement, we received a non-refundable $120.0 million

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upfront payment and a $5.0 million milestone payment in 2012 from Merck. Under the collaboration agreement, we were responsible for the majority of funding and completion of the PROCEED trial, which was terminated in 2014. We are responsible for the execution of the TARGET trial of vintafolide for the treatment of second line NSCLC, which is now substantially complete, pending the receipt of final OS results. Merck was responsible for the costs of the TARGET trial through September 15, 2014. Based on receiving the notice of termination of the collaboration agreement in 2014, we concluded that all of our obligations under the agreement have been fulfilled and we are not required to perform any additional services to Merck, and as a result the entire balance of deferred revenue was recognized in 2014. All reimbursable costs incurred in 2014 were recognized as revenue in 2014. We entered into two letter agreements with Merck in 2014. Under the first letter agreement, Merck agreed to pay (i) $2.2 million of expenses related to costs incurred to prepare for the potential increase in the number of FR(100%) patients in the PROCEED trial from 250 to 350, for which Merck agreed to reimburse at 75%, and (ii) $1.1 million related to the remaining PROCEED trial expenses beyond the September 15, 2014 termination date. We recognized $3.3 million of revenue in 2014 relating to that letter agreement. Under the second letter agreement, Merck agreed to pay $0.5 million for the estimate of reimbursable development expenses incurred but not yet invoiced to Merck. Under that letter agreement, we and Merck agreed that there will be no additional amounts payable by either party if the actual expenses differ from the estimated expenses paid by Merck.

As a result of the termination of the PROCEED trial in 2014, we withdrew the conditional marketing authorization applications in Europe for vintafolide for the treatment of PROC, and etarfolatide and folic acid for patient selection. During 2014, we terminated contracts and reduced headcount related to pre-launch commercial activities.

Financial Operations Overview

Until 2014, we had never been profitable and had incurred significant net losses since our inception. For the year ended December 31, 2014, we had net income of $5.5 million, due to the recognition of the remaining revenue under the Merck collaboration and lower operating costs, specifically in research and development. As of December 31, 2014, we had a retained deficit of $168.5 million. We expect to continue to incur significant operating expenses for the next several years as we pursue the advancement of our SMDCs and companion imaging diagnostics through the research, development, regulatory and commercialization processes.

As of December 31, 2014, our cash, cash equivalents and investments were $206.8 million. In April 2014, we completed a public offering of 5,175,000 shares of our common stock and received net proceeds of $101.9 million. We believe that our current cash balance, including the proceeds from that offering, will be sufficient to fund our current operating plan, including the close-out expenses of the PROCEED trial, the completion of the TARGET trial and the advancement of our pipeline.

Revenue

To date, we have generated no revenue from sales of our SMDCs or companion imaging agents. All of our revenue has been derived from license fees, milestone payments and government grants.

In the future, we may generate revenue from a combination of direct sales of our SMDCs and companion imaging agents, license fees, milestone payments and royalties in connection with strategic collaborations. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, achievement of performance-based milestones and other payments received under such collaborations, and the amount and timing of payments that we receive upon the sale of our SMDCs and companion imaging agents, to the extent any are successfully commercialized. If we or any strategic partners fail to complete the development of our SMDCs and

companion imaging agents in a timely manner or fail to obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

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Research and Development Expenses

Research and development expenses consist of expenses incurred in connection with the discovery and development of our SMDCs and companion imaging agents, including:

employee-related expenses, which include salaries and stock-based compensation expense;
expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a portion of our preclinical studies;
the cost of acquiring and manufacturing clinical trial materials;
license fees for and milestone payments related to in-licensed products and technology;
costs associated with non-clinical activities and regulatory approvals; and
research supplies.

We expense research and development costs as incurred. License fees and milestone payments related to in-licensed products and technology and research supplies are expensed if it is determined that they have no alternative future use.

Conducting a significant amount of research and development is central to our business model. Our SMDCs and companion imaging agents in later stages of clinical development generally have higher development costs than those in earlier stages of development, primarily due to the increased size and duration of late stage clinical trials. We plan to increase our research and development expenses for the foreseeable future due to the phase 1 trials for EC1456 and EC1169, the potential expansion of the EC1456 trial in at least four indications, the potential expansion of the EC1169 trial, and to further advance our earlier-stage research and development projects.

Our internal resources, employees and infrastructure are not directly tied to any individual research project and are typically deployed across multiple projects. Through our clinical development programs, we are advancing our SMDCs and companion imaging agents in parallel for multiple therapeutic indications and through our preclinical development programs we are seeking to develop potential SMDCs and companion imaging agents for additional disease indications. The following table sets forth costs incurred on a program-specific basis for identified lead candidate SMDCs and companion imaging agents, excluding personnel-related costs. Discovery research includes such costs for projects where no lead candidate has yet been identified. All employee-related expenses for those employees working in research and development functions are included in research and development payroll.

	Year Ended December 31,		
	2012	2013	2014
	(in thousands)		
Vintafolide (EC145)	$ 19,685	$ 34,604	$ 18,256
Etarfolatide (EC20)	3,160	4,545	1,913
Folate-Tubulysin (EC1456)	1,488	1,213	1,118
PSMA Imaging (EC0652) and Therapeutic (EC1169)		1,150	1,289
Folate-Aminopterin (EC1669)	46	1,394	326
Discovery research	2,243	2,850	3,827
Research and development payroll	9,049	12,143	14,921
Total research and development expenses	$ 35,671	$ 57,899	$ 41,650

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The following table identifies the current status of our major research and development projects and our currently expected near-term milestone timing:

Project	Status	Expected Near-Term Milestones
Vintafolide & Etarfolatide in PROC (PROCEED)	Phase 3	Terminated trial in May 2014
Vintafolide & Etarfolatide in NSCLC (TARGET)	Phase 2b	Final overall survival results expected in second or third quarter of 2015
Folate-targeted tubulysin therapeutic	Phase 1	Enrolling patients; expect to determine maximum tolerated dose and expand the trial in the second half of 2015
PSMA-targeted tubulysin therapeutic	Phase 1	Enrolling patients; expect to determine maximum tolerated dose and expand the trial in the second half of 2015
Folate inflammation therapeutic and companion imaging	Pre-Clinical	Continuation of preclinical evaluations

General and Administrative Expenses

General and administrative expenses consist principally of salaries and stock-based compensation for personnel in executive, finance, business development, commercial, legal and human resources functions. Other general and administrative expenses include employee benefits, facility costs, patent filing and prosecution costs, and professional service fees. All employees in the commercial department were terminated during 2014 after we withdrew our conditional marketing applications in Europe.

Restructuring Costs included in Research and Development and General and Administrative Expenses

We terminated the PROCEED trial in May 2014 after the interim futility analysis indicated that vintafolide did not demonstrate efficacy on the pre-specified outcome of progression-free survival for the treatment of PROC. As a result, we ceased our pre-launch commercial activities and implemented staff reductions in Europe and in the U.S. Included in general and administrative expenses for the year ended December 31, 2014, were expenses for employee termination benefits and contract termination costs of $1.3 million, and included in research and development expenses were $4.1 million of expenses for the PROCEED trial, including continued patient therapy costs for the patients who chose to stay on treatment, as well as site close-out expenses. As of December 31, 2014, all severance had been paid, and the Company had a clinical trial accrual balance related to the PROCEED trial termination of $1.3 million, which is expected to be fully paid by June 2015.

The following table summarizes the restructuring accruals for the year ended December 31, 2014:

	Employee and Contract Termination Accrual	PROCEED Trial Termination Accrual	Total
Balance, January 1, 2014	$	$	$
Charges for the year ended December 31, 2014	1,300,000	4,100,000	5,400,000

Amounts paid in the year ended December 31, 2014	(1,300,000)	(2,800,000)	(4,100,000)
Balance, December 31, 2014	$	$1,300,000	$1,300,000

Other Income and Expense

Other income and expense consist primarily of gains or losses on disposal of equipment, charitable contributions, gains or losses on foreign currency exchange, state franchise tax fees and loss on extinguishment of debt.

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Interest Income and Interest Expense

Interest income consists of interest earned on our cash, cash equivalents and investments. The primary objective of our investment policy is capital preservation. Interest expense consists primarily of interest, amortization of debt discount and amortization of deferred financing costs associated with a credit facility that we terminated in 2012.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

Our significant accounting policies are described in more detail in Note 2 of the notes to our financial statements appearing elsewhere in this annual report. We believe the following accounting policies to be most critical to the judgments and estimates used in preparation of our financial statements and have been reviewed and discussed with our audit committee.

Revenue Recognition

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

Upfront payments for licensing our intellectual property are evaluated to determine if the licensee can obtain stand-alone value from the license separate from the value of the research and development services and other deliverables in the arrangement to be provided by us. If at the inception of an arrangement we determine that the license does not have stand-alone value separate from the research and development services or other deliverables, the license, services and other deliverables are combined as one unit of account and upfront payments are recorded as deferred revenue on the balance sheet and are recognized in a manner consistent with the final deliverable. Subsequent to the inception of an arrangement, we evaluate the remaining deliverables for separation as items in the arrangement

are delivered. When stand-alone value is identified, the related consideration is recorded as revenue in the period in which the license or other intellectual property rights are delivered.

In those circumstances where research and development services or other deliverables are combined with the license, and multiple services are being performed such that a common output measure to determine a pattern of performance cannot be discerned, we recognize amounts received on a straight line basis over the performance period. Such amounts are recorded as collaboration revenue. Any subsequent reimbursement payments, which are contingent upon our future research and development expenditures, will be recorded as collaboration revenue and will be recognized on a straight-line basis over the performance period using the cumulative catch up method. The costs associated with these activities are reflected as a component of

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research and development expense in the statements of operations in the period incurred. In the event of an early termination of a collaboration agreement, any deferred revenue is recognized in the period in which all of our obligations under the agreement have been fulfilled.

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

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

Accrued Clinical Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We estimate our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Expense accruals related to clinical trial activity typically comprise the majority of these accruals. Examples of estimated expenses related to clinical trial activity include:

fees paid to contract research organizations in connection with clinical trials;
fees paid to investigative sites in connection with clinical trials; and
fees paid to vendors in connection with preclinical development activities.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical

trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under certain contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services are performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of the effort varies from our estimate, we adjust the accrual accordingly. Although our estimates in the past

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have not been materially different from amounts actually incurred, and we do not expect our estimates to be materially different from amounts actually incurred in the future, if our estimate of the status and timing of services performed differs from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. In the event that a clinical trial is terminated early, we record, in the period of termination, an accrual for the estimated remaining costs to complete the trial. Based on our level of clinical trial expenses for the twelve months ended December 31, 2014, a five percent change in our estimate could result in an adjustment to our accrued clinical trial expense in future periods of approximately $120,000.

Stock-Based Compensation

We account for stock options pursuant to the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718 *Compensation Stock Compensation*, which we refer to as ASC 718. This pronouncement requires the recognition of the fair value, or calculated value for nonpublic entities, of stock-based compensation in net income. Stock-based compensation consists of stock options, which are granted at exercise prices at or above the fair market value of our common stock on the dates of grant, time-based restricted stock units, or RSUs, and performance-based RSUs, or PRSUs. We used the calculated value method to measure our stock-based compensation prior to our initial public offering. We recognize compensation cost based on the grant-date value estimated in accordance with the provisions of ASC 718. With respect to the PRSUs granted by us, stock-based compensation expense would be recognized if we determine that it is probable that the performance conditions will be achieved. Based on the performance conditions and the stage of development of our potential products, we have concluded that the performance conditions will not be achieved before the performance deadline and, as a result, we do not expect to recognize any stock-based compensation expense related to the PRSUs.

We have 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, or 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, restricted stock units, 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.

Under the various plans, employees have been granted incentive stock options, while directors and contractors have been granted non-qualified stock 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 our common stock on the date of grant.

Generally, options granted under the 1997 and 2007 plans in connection with an employee s commencement of employment vest over a four-year period with one-half of the shares subject to the grant vesting after two years of employment and remaining options vesting monthly over the remainder of the four-year period. Options granted under the 1997 and 2007 plans for performance or promotions vest monthly over a four-year period. Generally, options granted under the 2010 Plan vest annually over a four year period. Unexercised stock options terminate on the tenth anniversary date after the date of grant. We recognize the stock-based compensation expense related to stock options over the requisite service period of the individual grantees, which generally equals the vesting period. We utilize a Black-Scholes option-pricing model to estimate the value of stock options. The Black-Scholes model allows the use of a range of assumptions related to volatility, risk-free interest rate, employee exercise behavior and dividend yield. Prior to 2013, since we did not have sufficient history as a publicly traded company to evaluate volatility, we used an average of several peer companies volatilities to determine a reasonable estimate of volatility. Beginning in 2013, we utilize a combination of peer volatility and company volatility. For purposes of identifying peer companies, we considered characteristics such as industry, length of trading history, market capitalization and similar product pipelines.

Due to insufficient history as a public company, we 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 assumption is derived from the weighted-average yield of a Treasury security with the

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same term as the expected life of the options, and the dividend yield assumption is based on historical experience and our estimate of future dividend yields.

The value of our stock options was estimated at the grant date using the following assumptions:

	Year Ended December 31,		
	2012	2013	2014
Weighted-average volatility	89.13%	101.00%	102.86%
Risk-free interest rate	1.10 %	1.31 %	1.98 %
Weighted-average expected life (in years)	6.2	6.6	6.6
Dividend yield	0.00 %	0.00 %	0.00 %

In accordance with ASC 718, we recognized stock-based compensation expense of approximately $3,023,000, $6,059,000 and $8,025,000 for the years ended December 31, 2012, 2013 and 2014, respectively. As of December 31, 2014, we had $11.1 million in total unrecognized compensation expense related to stock options, net of related forfeiture estimates, which we expect to recognize over a weighted average period of approximately of 1.6 years.

In May 2011, we adopted and granted awards under a PRSU program, or the 2011 PRSU Program, under the 2010 Plan. Each unit represents an amount equal to one share of our common stock. The PRSUs will be earned, in whole or in part, based on performance and service conditions. The performance condition is based upon whether we receive regulatory approval to sell a therapeutic product, and the awards include a target number of PRSUs that will vest upon a First Commercial Approval, and a maximum number of PRSUs that will vest upon a Second Commercial Approval. Any earned PRSUs will vest fifty percent based on the performance condition of commercial approval and fifty percent one year thereafter to fulfill the service condition, which requires the employee to remain employed by us.

As of December 31, 2014, we had 245,396 PRSU awards outstanding. The unrecorded stock compensation expense is based on number of units granted, less estimated forfeitures based on our historical forfeiture rate of 6.49%, and the closing market price of our common stock at the grant date. As of December 31, 2014, the performance condition of obtaining regulatory approval had not been achieved, therefore, no vesting had occurred. The awards are being accounted for under ASC 718, and compensation expense is to be recorded if we determine that it is probable that the performance conditions will be achieved. As of December 31, 2014, it was not probable that the performance conditions will be achieved, therefore, no compensation expense related to the PRSUs was recorded for the year ended December 31, 2014. Unrecorded compensation expense for the 2011 PRSU program as of December 31, 2014 was $2.7 million. Based on the performance conditions and the stage of development of our potential products, we have concluded that the performance conditions will not be achieved before the performance deadline and, as a result, we do not expect to recognize any stock-based compensation expense related to the PRSUs.

As of December 31, 2014, we had 161,439 RSU awards outstanding which were granted in February 2014 under the 2010 Plan. The RSUs are service-based awards that will vest and be paid in four equal installments annually beginning in February 2015 in the form of one share of our common stock for each RSU. The awards were granted at a weighted average fair value of $11.11 per share, calculated using the closing stock price of a share of our common stock on the grant date, net of forfeitures, over the life of the vesting period. As of December 31, 2014, we had $1.3 million in total remaining unrecognized compensation expense related to RSUs, net of related forfeiture estimates, which we expect to recognize over a weighted average period of approximately 2.0 years.

Effective January 1, 2014, we implemented our 2010 Employee Stock Purchase Plan, or ESPP, pursuant to which our eligible employees can purchase shares of our common stock at a discount. In the year ended December 31, 2014, plan participants purchased 53,250 shares of common stock under the ESPP at an average purchase price of $5.62 per

share. At December 31, 2014, 569,530 shares were available for issuance under the ESPP.

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Results of Operations

Comparison of Years Ended December 31, 2013 and 2014

	Year Ended December 31,		Increase/ (Decrease)	%
	2013	2014		
	(In thousands)			
Statement of operations data:				
Revenue	$ 64,871	$ 70,353	$ 5,482	8 %
Operating expenses:				
Research and development	57,899	41,650	(16,249)	(28)%
General and administrative	25,314	23,677	(1,637)	(6)%
Total operating expenses	83,213	65,327	(17,886)	(21)%
Income (loss) from operations	(18,342)	5,026	23,368	127 %
Interest income	466	579	113	24 %
Interest expense	(2)	(1)	1	50 %
Other income (expense), net	(154)	(145)	9	6 %
Net income (loss)	$ (18,032)	$ 5,459	$ 23,491	130 %

Revenue

The increase in revenue in the year ended December 31, 2014 compared to the year ended December 31, 2013 was due to the recognition of the balance of deferred revenue and reimbursable research and development expenses for 2014 under the Merck collaboration agreement. Our revenue of $70.4 million recorded in the year ended December 31, 2014 related primarily to the collaboration with Merck, which was terminated by Merck during the year. Of this revenue, $46.9 million related to the amortization of the upfront license payment and a milestone payment, $13.7 million related to the amortization of reimbursable research and development and general and administrative expenditures incurred in prior periods, and $9.7 million related to reimbursable research and development and general and administrative expenditures incurred in 2014.

Research and Development

The decrease in research and development expenses for the year ended December 31, 2014 compared to the year ended December 31, 2013 was primarily attributable to a decrease in expenses related to the TARGET trial which is near completion, a decrease in expenses related to the PROCEED trial which was terminated in May 2014, a decrease in manufacturing expenses for vintafolide, and a decrease in manufacturing expenses for etarfolatide related to pre-commercial activity. These decreases were partially offset by an increase in compensation expenses due to increases in headcount and stock-based compensation. Included in research and development expenses were $19.7 million and $9.5 million of expenses that were reimbursable from Merck for the years ended December 31, 2013 and 2014, respectively.

Included in research and development expenses for the year ended December 31, 2014 were $4.1 million of accrued expenses for the terminated PROCEED trial, including continued patient therapy costs for the patients who chose to stay on treatment, as well as site close-out expenses.

Included in research and development expenses were stock-based compensation charges of $3.3 million and $4.7 million for the years ended December 31, 2013 and 2014, respectively.

Research and development expenses included expense of $0.8 million and $1.0 million for the years ended December 31, 2013 and 2014, respectively, for company-funded research at Purdue University.

General and Administrative

The decrease in general and administrative expense in the year ended December 31, 2014 compared to the year ended December 31, 2013 was attributable to a decrease in the administration expenses related to commercial launch preparations. This decrease was partially offset by an increase in stock-based expenses and severance costs associated with a reduction in headcount following the withdrawal of the marketing

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applications in Europe in May 2014. Included in general and administrative expenses were $0.9 million and $0.2 million of expenses that were reimbursable from Merck under the collaboration agreement for vintafolide relating to patent and trademark costs for the years ended December 31, 2013 and 2014, respectively.

Included in general and administrative expenses for the year ended December 31, 2014 were expenses for employee termination benefits and contract termination costs of $1.3 million related to the cessation of pre-launch commercial activities and related staff reductions in Europe and the U.S.

Included in general and administrative expenses were stock-based compensation charges of $2.8 million and $3.3 million for the years ended December 31, 2013 and 2014, respectively.

Interest Income

The increase in interest income in 2014 compared to 2013 resulted from an increase in the average short-term and long-term investment balances during the year ended December 31, 2014 as compared to the year ended December 31, 2013, due to the investment of proceeds from our public offering of common stock that closed in April 2014.

Other Expense, Net

Other expense, net decreased in 2014 compared to 2013 primarily due to a decrease in foreign exchange losses.

Comparison of Years Ended December 31, 2012 and 2013

	Year Ended December 31,		Increase/ (Decrease)	%
	2012	2013		
	(In thousands)			
Statement of operations data:				
Revenue	$ 34,682	$ 64,871	$ 30,189	87 %
Operating expenses:				
Research and development	35,671	57,899	22,228	62 %
General and administrative	15,054	25,314	10,260	68 %
Total operating expenses	50,725	83,213	32,488	64 %
Income (loss) from operations	(16,043)	(18,342)	(2,299)	(17)%
Interest income	328	466	138	42 %
Interest expense	(629)	(2)	627	100 %
Other income (expense), net	(948)	(154)	794	84 %
Net income (loss)	$ (17,292)	$ (18,032)	$ (740)	(4)%

Revenue

Our revenue of $64.9 million recorded in the year ended December 31, 2013 related primarily to the collaboration with Merck. Of this revenue, $45.0 million related to the amortization of the $120.0 million upfront license payment, $1.9 million related to a milestone payment and $5.1 million related to reimbursable research and development expenditures incurred prior to 2013. The remaining $12.9 million of revenue related to the amortization of reimbursable research and development expenditures that we incurred during 2013 and the amortization of the $1.0 million non-refundable upfront payment from NMP.

The amortization of both the upfront license payment and the ongoing reimbursable research and development expenditures related to the Merck collaboration are being recognized as revenue ratably over the performance period. NMP revenue related to the upfront payment will be recorded ratably over the contract period. Our revenue of $34.7 million in the year ended December 31, 2012 related to the collaboration with Merck.

Research and Development

The increase in research and development expenses in 2013 compared to 2012 was attributable to an $18.3 million increase in product development expenses, a $0.8 million increase in general development costs, and a $3.1 million increase in compensation expenses. The increase in product development expenses was due

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to a $16.3 million increase in expenses principally related to the PROCEED and TARGET trials and a $2.2 million increase in development costs for our earlier stage pipeline. The increase in general development costs was primarily due to increases in lab supplies and research grants of $0.4 million and $0.2 million, respectively. The increase in compensation expenses was due to increases in headcount and a $1.5 million increase in stock-based compensation expense as a result of the additional headcount and a higher stock price. Included in research and development expenses for the year ended December 31, 2013 were $19.7 million of expenses that were reimbursable from Merck under the collaboration agreement.

Included in research and development expenses were stock-based compensation charges of $1.8 million and $3.3 million for the years ended December 31, 2012 and 2013, respectively.

Research and development expenses included expense of $0.8 million in each of the years ended 2012 and 2013 for company-funded research at Purdue University.

General and Administrative

The increase in general and administrative expenses in 2013 compared to 2012 was primarily attributable to increased expenses related to establishing commercial capability in Europe, increased legal fees associated with obtaining patent and trademark rights, and increased compensation expenses due to increases in headcount and stock-based compensation expense as a result of the additional headcount and a higher stock price. Included in general and administrative expenses for the year ended December 31, 2013 were $0.9 million of expenses that are reimbursable from Merck under the collaboration agreement for vintafolide relating to patent and trademark costs.

Included in general and administrative expenses were stock-based compensation charges of $1.2 million and $2.8 million for the years ended 2012 and 2013, respectively.

Interest Income

The increase in interest income in 2013 compared to 2012 resulted from an increase in investments in longer term maturities that earn higher rates of return.

Interest Expense

The decrease in interest expense during 2013 compared to 2012 was due to the decreased borrowings under our credit facility which was terminated in the second quarter of 2012. Our average loan balance under the credit facility was $5.9 million for the year ended 2012.

Other Expense, Net

Other expense, net decreased in 2013 compared to 2012 due to a loss on debt extinguishment of $1.0 million that we recognized in 2012 as a result of terminating our credit facility in June 2012. The loss included a 5% prepayment fee on the outstanding balance of approximately $0.6 million and the write off of unamortized deferred financing fees and discounts of approximately $0.4 million. The decrease in other expense, net was partially offset by increased losses on foreign exchange losses and state franchise and excise taxes.

Liquidity and Capital Resources

We have funded our operations principally through sales of equity and debt securities, revenue from strategic collaborations, grants and loans. As of December 31, 2014, we had cash, cash equivalents and investments of $206.8 million.

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

We expect that our cash position at December 31, 2014 is sufficient to fund our current operating plan, including the close out expenses of the PROCEED trial, the completion of the TARGET trial and advancement of our pipeline.

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

	Year Ended December 31,		
	2012	2013	2014
	(in thousands)		
Net cash provided by (used in) operating activities	$ 89,191	$ (51,080)	$ (42,206)
Net cash provided by (used in) investing activities	(103,395)	69,292	(68,560)
Net cash provided by (used in) financing activities	(13,153)	645	103,491
Effect of exchange rate	1	(7)	(38)
Net increase (decrease) in cash and cash equivalents	$ (27,356)	$ 18,850	$ (7,313)

Operating Activities

The cash provided by operating activities in 2012 resulted from deferred revenue related to the $125.0 million from upfront and milestone payments and the reimbursable research and development expenditures that were recognized ratably over the performance period. The use of cash in 2013 primarily resulted from our net loss adjusted for non-cash items and changes in operating assets and liabilities, including a decrease in deferred revenue related to the upfront payment from Merck, a milestone payment, and the reimbursable research and development expenditures that are recognized ratably over the performance period. The cash used in operating activities for the year ended December 31, 2014 primarily resulted from our net income adjusted for non-cash items and changes in operating assets and liabilities, including the decrease in deferred revenue related to the Merck collaboration that was fully recognized in 2014.

Investing Activities

The cash provided by and used in investing activities in all years was due primarily to the net result of purchases, maturities and sales of investments, and cash used for capital expenditures for equipment of $1.9 million in 2012, $0.8 million in 2013 and $1.5 million in 2014.

Financing Activities

In 2012, the cash used in financing activities consisted of the $13.5 million prepayment of our credit facility, which included a 5% prepayment fee of $0.6 million, which was slightly offset by $0.4 million received from the exercise of stock options. The cash provided by financing activities in 2013 consisted of proceeds received from the exercise of stock options. The cash provided by financing activities in 2014 primarily consisted of $101.9 million in net proceeds from the April 2014 public offering and $1.3 million in net proceeds from the exercise of stock options.

Operating Capital Requirements

Even though we had net income in the year ended December 31, 2014 due to the recognition of the remaining revenue under the Merck collaboration and lower operating expenses, particularly in research and development, we anticipate we will continue to incur significant operating losses for the next several years as we pursue the advancement of our SMDCs and companion imaging agents through the research, development, regulatory and, potentially, the commercialization processes.

As of December 31, 2014, our cash, cash equivalents and investments were $206.8 million. In April 2014, we completed a public offering of 5,175,000 shares of our common stock and received net proceeds of $101.9 million.

We believe that our current cash balance, including the proceeds from that offering, will be sufficient to fund our current operating plan, including the close out expenses of the PROCEED trial, the completion of the TARGET trial and the advancement of our pipeline.

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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 costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
the timing, receipt and amount of sales of, or royalties on, our SMDCs and companion imaging diagnostics, if any.

If our available cash, cash equivalents and investments are insufficient to satisfy our liquidity requirements, or if we develop additional opportunities to pursue, we may seek to sell additional equity or debt securities or obtain new loans or credit facilities. The sale of additional equity securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or convertible preferred stock, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2014:

	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
	(In thousands)				
Operating lease obligations	$ 1,071	$ 731	$ 313	$ 27	$
Capital lease obligations	3	3			
Total contractual cash obligations	$ 1,074	$ 734	$ 313	$ 27	$

In addition to the obligations shown in the above table, we have certain obligations under licensing agreements with third parties. In October 2007, we entered into an exclusive worldwide license with R&D Biopharmaceuticals to research, develop, and commercialize products containing conjugates of folate receptor targeting compounds and tubulysin compounds. In February 2011, this licensing agreement was assigned by R&D Biopharmaceuticals to Trientlgasse. Under this license agreement, we may be required to make $5.9 million in additional contingent payments upon the achievement of specific scientific, clinical and regulatory milestones, in addition to royalties upon commercial sales. We paid an upfront fee of $300,000 as research and development and pay $25,000 in annual maintenance fees unless we pay a milestone in a given year. In 2013, we paid $100,000 for dosing the first human patient with folate tubulysin. In 2014, we paid $50,000 for the completion of toxicology studies in compliance with Good Laboratory Practice and $100,000 for dosing the first human patient with PSMA tubulysin.

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Pursuant to our exclusive license agreement with Purdue Research Foundation relating to folate, we are obligated to pay an annual minimum royalty of $12,500 until commercial sales commence, following which time the payment of royalties with market rates will commence. We do not anticipate incurring liabilities for vintafolide royalty payments based on the estimated timing of when we may have commercial sales and the expiration of the applicable patents. Pursuant to our exclusive license agreement with Purdue Research Foundation relating to PSMA, we are obligated to pay minimum annual royalty payments of $15,000 until commercial sales commence, following which time the payment of royalties with market rates will commence, along with a minimum annual royalty payment of $100,000. In addition, a milestone payment of $500,000 is payable upon approval of a new drug application in the U.S. and sales-based royalties are also payable at market rates when commercial sales commence. During 2014, we paid a penalty because we did not meet one of the milestones related to the PSMA license agreement. We are also subject to future penalties if certain diligence milestones are not met. There are no material obligations greater than five years.

In 2014, we entered into a Master License Agreement with Purdue Research Foundation. Under this license, we have the right to exclusively license patents and technology discovered under company funded research at Purdue University. If we decide to move forward with development of one or more of these technologies, we will be obligated to make an acceptance payment, and we will also be obligated to make contingent payments upon the achievement of specific scientific, clinical and regulatory milestones. Certain scientific, clinical and regulatory milestones, in addition to internal resource targets, must be met by us to avoid fees as consideration for waivers of potentially missed milestones. We are obligated to pay annual minimum payments until commercial sales commence, following which time the payment of royalties with market rates will commence, along with an annual royalty payment.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under rules promulgated by the Securities and Exchange Commission.

Tax Loss Carryforwards

As of December 31, 2014, we had net operating loss carryforwards of approximately $179.5 million and $235.4 million for federal and state income taxes, respectively, that may be used to offset future taxable income. We also have research and development and orphan drug tax credit carryforwards of approximately $8.6 million and $6.3 million, respectively, to offset future federal income taxes and approximately $2.2 million in research and development tax credit carryforwards to offset future state income taxes. 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 $133.2 million for 2014, $39.0 million for 2015, $29.7 million for 2016 and $16.8 million for 2017. Any available but unused amounts will become available for use in all successive years. At December 31, 2014, we recorded a full valuation allowance against our net deferred tax assets of approximately $75.8 million, as we believe it is more likely than not that the net deferred tax assets will not be fully realized.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

We are exposed to market risk related to changes in interest rates. As of December 31, 2013 and December 31, 2014 we had cash, cash equivalents and investments of $148.9 million and $206.8 million, 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 short-term marketable securities. Our short-term investments are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10 percent change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our short-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.

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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 10 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.

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Item 8. *Financial Statements and Supplementary Data*

ENDOCYTE, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Endocyte, Inc.

We have audited the accompanying consolidated balance sheets of Endocyte, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive income (loss), stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Endocyte, Inc. at December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Endocyte, Inc. s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 13, 2015, expressed an unqualified opinion thereon.

Indianapolis, Indiana
March 13, 2015

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Endocyte, Inc.

We have audited Endocyte, Inc. s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Endocyte, Inc. s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Endocyte, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2014 consolidated financial statements of Endocyte, Inc. and our report dated March 13, 2015 expressed an unqualified opinion thereon.

Indianapolis, Indiana
March 13, 2015

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ENDOCYTE, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2013	2014
Assets		
Current assets:		
Cash and cash equivalents	$52,846,940	$45,533,443
Short-term investments	70,434,148	79,536,211
Receivables	6,353,180	706,403
Prepaid expenses	3,200,924	609,771
Other assets	496,338	652,510
Total current assets	133,331,530	127,038,338
Long-term investments	25,571,659	81,761,177
Property and equipment, net	3,839,426	3,970,665
Other noncurrent assets	114,961	31,194
Total assets	$162,857,576	$212,801,374
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$5,435,473	$1,234,759
Accrued wages and benefits	3,065,905	2,567,924
Accrued clinical trial expenses	3,728,015	2,336,645
Accrued expenses	1,668,944	692,526
Deferred revenue	59,746,952	50,000
Current portion of other liabilities	18,168	3,142
Total current liabilities	73,663,457	6,884,996
Other liabilities, net of current portion	33,458	30,316
Deferred revenue, net of current portion	931,940	881,944
Total liabilities	74,628,855	7,797,256
Stockholders equity:		
Common stock: $0.001 par value, 100,000,000 shares authorized; 36,155,509 and 41,784,692 shares issued and outstanding at December 31, 2013 and 2014	36,156	41,785
Additional paid-in capital	262,060,590	373,571,500
Accumulated other comprehensive income	56,691	(143,928)
Retained deficit	(173,924,716)	(168,465,239)
Total stockholders equity	88,228,721	205,004,118
Total liabilities and stockholders equity	$162,857,576	$212,801,374

See accompanying notes.

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ENDOCYTE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

	Year Ended December 31,		
	2012	2013	2014
Revenue:			
Collaboration revenue	$34,682,111	$64,870,919	$70,353,483
Total revenue	34,682,111	64,870,919	70,353,483
Operating expenses:			
Research and development	35,670,418	57,898,971	41,649,389
General and administrative	15,054,369	25,313,731	23,677,366
Total operating expenses	50,724,787	83,212,702	65,326,755
Income (loss) from operations	(16,042,676)	(18,341,783)	5,026,728
Other income (expense), net:			
Interest income	327,745	465,505	578,636
Interest expense	(628,993)	(2,458)	(1,189)
Other income (expense), net	(947,834)	(153,702)	(144,698)
Net income (loss)	(17,291,758)	(18,032,438)	5,459,477
Net income (loss) per share basic	$(0.48)	$(0.50)	$0.14
Net income (loss) per share diluted	$(0.48)	$(0.50)	$0.13
Items included in other comprehensive income (loss):			
Unrealized gain (loss) on foreign currency translation	707	(6,805)	(38,776)
Unrealized gain (loss) on available-for-sale securities	78,306	(9,253)	(161,843)
Other comprehensive income (loss)	79,013	(16,058)	(200,619)
Comprehensive income (loss)	$(17,212,745)	$(18,048,496)	$5,258,858
Weighted-average number of common shares used in net income (loss) per share calculation basic	35,858,757	36,036,996	40,242,352
Weighted-average number of common shares used in net income (loss) per share calculation diluted	35,858,757	36,036,996	41,758,101

See accompanying notes.

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ENDOCYTE, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Deficit	Total
	Shares	Amount				
Balances December 31, 2012	35,919,019	$35,919	$255,356,888	$72,749	$(155,892,278)	$99,573,278
Exercise of stock options	188,699	189	644,745			644,934
Exercise of warrants	47,791	48	(48)			
Stock-based compensation			6,059,005			6,059,005
Net loss					(18,032,438)	(18,032,438)
Unrealized loss on foreign exchange translation				(6,805)		(6,805)
Unrealized loss on securities				(9,253)		(9,253)
Balances December 31, 2013	36,155,509	36,156	262,060,590	56,691	(173,924,716)	88,228,721
Exercise of stock options	399,654	400	1,290,486			1,290,886
Stock-based compensation	1,279	1	8,021,446			8,021,447
Employee stock purchase plan	53,250	53	299,176			299,229
Issuance of common stock in connection with secondary offering	5,175,000	5,175	101,899,802			101,904,977
Net income					5,459,477	5,459,477
Unrealized loss on foreign exchange translation				(38,776)		(38,776)
Unrealized loss on securities				(161,843)		(161,843)
Balances December 31, 2014	41,784,692	41,785	373,571,500	(143,928)	(168,465,239)	205,004,118

See accompanying notes.

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ENDOCYTE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2012	2013	2014
Operating activities			
Net income (loss)	$(17,291,758)	$(18,032,438)	$5,459,477
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation	358,367	674,725	857,055
Stock-based compensation	3,022,693	6,059,005	8,025,261
Loss on disposal of property and equipment	6,354	1,778	6,100
Loss on extinguishment of debt	992,281		
Accretion of bond premium	961,271	1,246,143	1,615,063
Non cash interest expense	73,914		
Change in operating assets and liabilities:			
Receivables	(1,409,738)	(2,508,687)	5,490,605
Prepaid expenses and other assets	(1,287,834)	2,016,928	2,711,331
Accounts payable	524,936	(386,241)	(3,700,175)
Accrued interest, wages, benefits and other liabilities	3,483,896	1,337,021	(2,923,537)
Deferred revenue	99,757,129	(41,488,719)	(59,746,948)
Net cash provided by (used in) operating activities	89,191,511	(51,080,485)	(42,205,768)
Investing activities			
Purchases of property and equipment	(1,862,872)	(827,839)	(1,501,744)
Proceeds from disposal of property and equipment			10,000
Purchases of investments	(265,203,590)	(125,026,602)	(149,370,678)
Proceeds from sales and maturities of investments	163,671,395	195,146,871	82,302,191
Net cash provided by (used in) investing activities	(103,395,067)	69,292,430	(68,560,231)
Financing activities			
Stock repurchase			(3,814)
Principal payments on borrowings	(13,544,175)		
Proceeds from third public offering, net of issuance costs			101,904,977
Proceeds from the exercise of stock options	391,407	644,934	1,290,886
Proceeds from stock purchase under employee stock purchase plan			299,229
Net cash provided by (used in) financing activities	(13,152,768)	644,934	103,491,278
Effect of exchange rate	707	(6,805)	(38,776)
Net increase (decrease) in cash and cash equivalents	(27,355,617)	18,850,074	(7,313,497)
Cash and cash equivalents at beginning of period	61,352,483	33,996,866	52,846,940
Cash and cash equivalents at end of period	$33,996,866	$52,846,940	$45,533,443

See accompanying notes.

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Organization

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

The Company has two wholly-owned subsidiaries, Endocyte Europe B.V. and Endocyte Europe GmbH, which were formed to assist with the administration of applications with the European Commission (EC) and commercial pre-launch activities in Europe. The applications were withdrawn in May 2014 and the commercial pre-launch activities in Europe ceased. The Company is in the process of dissolving Endocyte Europe GmbH, which should be completed in the first half of 2015. There are no current plans to dissolve Endocyte Europe B.V.

Public Offerings

On April 2, 2014, the Company completed a public offering of 5,175,000 shares of its common stock in a public offering. Proceeds, net of underwriting discounts, commissions and other transaction costs, were $101.9 million.

2. Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Endocyte, Inc. and its subsidiaries and all intercompany amounts have been eliminated. The consolidated financial statements are prepared in conformity with U.S. generally accepted accounting principles (GAAP). Subsequent events have been evaluated through the date of issuance, which is the same as the date this Form 10-K is filed with the Securities and Exchange Commission.

Use of Estimates

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

Cash and Cash Equivalents

The Company considers cash and all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents consist primarily of money market instruments that are maintained by an investment manager.

Investments

Investments consist primarily of investments in U.S. Treasuries, U.S. Government agency obligations and corporate debt securities, which could also include commercial paper, that are maintained by an investment manager. U.S. government agency investments relate to investments in Fannie Mae, Freddie Mac and Federal Home Loan Bank. Management determines the appropriate classification of marketable securities at the time of purchase and reevaluates such classification as of each balance sheet date. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in other income. The Company considers and accounts for other-than-temporary impairments according to the Financial Accounting Standards Board (FASB) Accounting Standards Codification

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant Accounting Policies (continued)

(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.

Property and Equipment

Property and equipment are stated at cost and are being depreciated using the straight-line method over estimated useful lives, which range from three to seven years.

Licenses and Patents

Licenses and patent costs are expensed as incurred as the Company does not believe there is an alternate future use for the costs. Licenses are classified as research and development and patents are classified as general and administrative expenses in the consolidated statements of operations.

Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment when events or changes in business conditions indicate that their full carrying value may not be fully recoverable.

Leases

The Company evaluates all leases to determine whether they should be accounted for as operating or capital leases.

Revenue Recognition

The Company recognizes revenues from license and collaboration agreements when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the fee is fixed or determinable, and there is reasonable assurance that the related amounts are collectible in accordance with ASC Topic 605, *Revenue Recognition* (ASC 605). The Company s license and collaboration agreements may contain multiple elements, including grants of licenses to intellectual property rights, agreement to provide research and development services and other deliverables. The deliverables under such arrangements are evaluated under ASC Subtopic 605-25, *Multiple-Element Arrangements* (ASC 605-25). Under ASC 605-25, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has stand-alone value to the customer. The arrangement s consideration that is fixed or determinable, excluding contingent milestone payments, is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the

consideration that is not contingent upon future deliverables.

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

In those circumstances where research and development services or other deliverables are combined with the license, and multiple services are being performed such that a common output measure to determine a pattern of performance cannot be discerned, the Company recognizes amounts received on a straight line basis

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant Accounting Policies (continued)

over the performance period. Such amounts are recorded as collaboration revenue. Any subsequent reimbursement payments, which are contingent upon the Company s future research and development expenditures, will be recorded as collaboration revenue and will be recognized on a straight-line basis over the performance period using the cumulative catch up method. The costs associated with these activities are reflected as a component of research and development expense in the statements of operations in the period incurred. In the event of an early termination of a collaboration agreement, any deferred revenue is recognized in the period in which all obligations of the Company under the agreement have been fulfilled.

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

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

Research and Development Expenses

Research and development expenses represent costs associated with the ongoing development of SMDCs and

companion imaging agents and include salaries, supplies, and expenses for clinical trials. The Company records accruals for clinical trial expenses based on the estimated amount of work completed. The Company monitors patient enrollment levels and related activities to the extent possible through internal reviews, correspondence, and discussions with research organizations. In the event that a clinical trial is terminated early, the Company records, in the period of termination, an accrual for the estimated remaining costs to complete the trial.

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

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant Accounting Policies (continued)

service period based upon the level of services provided. As of December 31, 2014, the Company had approximately $0.3 million of capitalized research and development costs included in prepaid expenses.

Stock-Based Compensation

The Company accounts for its stock options pursuant to ASC Topic 718, *Compensation Stock Compensation* (ASC 718), which requires the recognition of the fair value, or calculated value for nonpublic entities, of stock-based compensation in net income. Stock-based compensation consists of stock options, which are granted at exercise prices at or above the fair market value of the Company s common stock on the dates of grant, service-based restricted stock units (RSUs) and performance-based RSUs (PRSUs). For PRSUs issued by the Company, stock-based compensation expense will be recognized when the Company determines that it is probable that the performance conditions will be achieved. For RSUs issued by the Company, stock-based compensation expense is recognized ratably over the service period. The Company used the calculated value method to measure its stock-based compensation prior to its initial public offering on February 4, 2011. The Company recognizes compensation cost based on the grant-date fair value estimated in accordance with the provisions of ASC 718.

Net Income (Loss) Per Share

The Company calculates basic net income (loss) per share based on the weighted-average number of outstanding common shares. The Company calculates diluted net income (loss) per share based on the weighted-average number of outstanding common shares plus the effect of dilutive securities.

Income Taxes

The Company accounts for income taxes under the liability method in accordance with the provision of ASC Topic 740, *Income Taxes* (ASC 740). ASC 740 requires recognition of deferred taxes to provide for temporary differences between financial reporting and tax basis of assets and liabilities. Deferred taxes are measured using enacted tax rates expected to be in effect in a year in which the basis difference is expected to reverse. The Company continues to record a valuation allowance for the full amount of deferred tax assets, which would otherwise be recorded for tax benefits relating to operating loss and tax credit carryforwards, as realization of such deferred tax assets cannot be determined to be more likely than not.

The Company accounts for uncertain income tax positions recognized in the financial statements in accordance with Accounting Standards Update (ASU) No. 2009-06. This guidance prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return and provides guidance on derecognition of tax benefits, classification on the balance sheet, interest and penalties, accounting in interim periods, disclosure, and transition.

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 performs clinical trials globally and has established a subsidiary in The Netherlands to assist in the administration of filing applications in Europe and a subsidiary in Switzerland for commercial pre-launch activities in Europe. The applications filed in Europe were withdrawn in May 2014 and the pre-launch activities in Europe ceased. The Company is in the process of dissolving Endocyte Europe GmbH, which should be completed in the first half of 2015. All long-lived assets are held in the U.S. The Company views its operations and manages its business in one operating segment.

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

3. New Accounting Pronouncements

Recently Adopted Accounting Standards

In November 2014, the FASB issued ASU No. 2014-16, *Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity*, an update to ASC Topic 815, Derivatives and Hedging. This amendment provides clarification regarding the whole instrument approach in determining the nature of a host contract in a hybrid financial instrument issued in the form of a share. Under this new standard, issuers and investors are required to consider all of a hybrid instrument s stated and implied substantive terms and features. This update will be effective for the Company beginning January 1, 2016, unless it elects early adoption. The Company does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15 (Subtopic 205-40), *Presentation of Financial Statements Going Concern*, which requires management to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern and provide related footnote disclosures. The guidance is effective for annual and interim reporting periods beginning on or after December 15, 2016. Early adoption is permitted for financial statements that have not been previously issued. The standard allows for either a full retrospective or modified retrospective transition method. This update will be effective for the Company beginning January 1, 2017, unless it elects early adoption. The Company is currently evaluating the impact, if any, the adoption of this guidance will have on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606), to clarify the principles used to recognize revenue for all entities. Under the new standard, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In order to do so, an entity would follow the five-step process for in-scope transactions: 1) identify the contract with a customer, 2) identify the separate performance obligations in the contract, 3) determine the transaction price, 4) allocate the transaction price to the separate performance obligations in the contract, and 5) recognize revenue when (or as) the entity satisfies a performance obligation. The provisions of the new standard are effective for the Company for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. An entity can apply the new revenue standard retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings. The Company is currently evaluating the impact, if any, the adoption of this guidance will have on its consolidated financial statements.

In July 2013, the FASB issued ASU No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*, an update to ASC Topic 740, *Income Taxes.* This amendment provides clarification regarding the presentation of an unrecognized tax benefit related to a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. Under this new standard,

the liability related to an unrecognized tax benefit, or a portion thereof, should be presented in the financial statements as a reduction to a deferred tax asset if available under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position. Otherwise, the unrecognized tax benefit should be presented in the financial statements as a separate liability. The assessment is based on the unrecognized tax benefit and deferred tax asset that exist at the reporting date. The provisions of the new standard were effective on a prospective basis beginning in 2014 for annual and interim reporting periods. This update became effective for the Company beginning January 1, 2014. The adoption did not have a material impact on the Company s consolidated financial statements.

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

4. Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (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 income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method and the if-converted method. For purposes of this calculation, stock options, warrants, PRSUs, RSUs and shares to be purchased under the Company s 2010 Employee Stock Purchase Plan (ESPP) are considered to be common stock equivalents and are only included in the calculation of diluted net income (loss) per share when their effect is dilutive.

As of December 31, 2012, 2013 and 2014 the following number of potential common stock equivalents were outstanding:

Common stock equivalents

	Year Ended December 31,		
	2012	2013	2014
Outstanding common stock options	3,879,239	5,246,465	5,096,674
Outstanding warrants	133,968	34,647	34,647
Outstanding PRSUs	273,988	270,649	245,396
Outstanding RSUs			161,439
Shares to be purchased under the ESPP			2,894
Total	4,287,195	5,551,761	5,541,050

These common stock equivalents were excluded from the determination of diluted net loss per share for the years ended December 31, 2012 and December 31, 2013, due to their anti-dilutive effect on earnings.

The following weighted-average outstanding common stock options, warrants, RSUs and shares to be purchased under the ESPP were added to basic weighted-average common shares outstanding for the year ended December 31, 2014 to calculate diluted weighted-average shares outstanding because of their dilutive effect:

	Year Ended December 31, 2014
Outstanding common stock options	1,494,796
Outstanding warrants	5,433
Outstanding RSUs	14,128
Shares to be purchased under the ESPP	1,392
Total	1,515,749

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. Other Comprehensive Income (Loss)

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

	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Accumulated Other Comprehensive Gains (Losses)
Balance at December 31, 2011	$ (5,718)	$ (546)	$ (6,264)
Unrealized gain (loss)	707	78,204	78,911
Net amount reclassified to net loss		102	102
Other comprehensive income (loss)	707	78,306	79,013
Balance at December 31, 2012	(5,011)	77,760	72,749
Unrealized gain (loss)	(6,805)	(4,203)	(11,008)
Net amount reclassified to net loss		(5,050)	(5,050)
Other comprehensive income (loss)	(6,805)	(9,253)	(16,058)
Balance at December 31, 2013	(11,816)	68,507	56,691
Unrealized gain (loss)	(38,776)	(165,285)	(204,061)
Net amount reclassified to net income		3,442	3,442
Other comprehensive income (loss)	(38,776)	(161,843)	(200,619)
Balance at December 31, 2014	$ (50,592)	$ (93,336)	$ (143,928)

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

Reclassifications Out of Accumulated Other Comprehensive Income (Loss)

Details about Accumulated Other Comprehensive Income (Loss) Components	Amount Reclassified from Accumulated Other Comprehensive Income (Loss)			Affected Line Item in the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
	Year Ended December 31, 2012	Year Ended December 31, 2013	Year Ended December 31, 2014	

Unrealized Net Gains (Losses) on Securities	$102	$ (5,050)	$ 3,442	Other income (expense)
Total Reclassifications for the Period	$102	$ (5,050)	$ 3,442	

6. Investments

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

6. Investments (continued)

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

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

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

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

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

The following table summarizes the fair value of cash and cash equivalents and investments as of December 31, 2013:

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

6. Investments (continued)

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

Description	Cost	Level 1	Level 2	Fair Value (Carrying Value)
Cash				
Cash	$6,068,579	$6,068,579	$	$6,068,579
Cash equivalents				
Money market funds	39,464,864	39,464,864		39,464,864
Cash and cash equivalents	$45,533,443	$45,533,443	$	$45,533,443
Short-term investments (due within 1 year)				
U.S. government agency obligations	$38,934,684	$38,928,806	$	$38,928,806
Corporate obligations	40,659,036		40,607,405	40,607,405
Total short-term investments	$79,593,720	$38,928,806	$40,607,405	$79,536,211
Long-term investments (due after 1 year through 2 years)				
U.S. government treasury obligations	$38,626,279	$38,623,495	$	$38,623,495
U.S. government agency obligations	35,223,450	35,203,355		35,203,355
Corporate obligations	7,947,275		7,934,327	7,934,327
Total long-term investments	$81,797,004	$73,826,850	$7,934,327	$81,761,177

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

Total unrealized gross gains were $76,630 and $18,858 for the years ended December 31, 2013 and 2014, respectively. Total unrealized gross losses were $8,122 and $112,194 for the years ended December 31, 2013 and 2014, respectively. The Company does not consider any of the unrealized losses to be other-than-temporary impairments because the Company has the intent and ability to hold investments until they recover in value. Total realized gross gains were $11,342 and $1,429 for the years ended December 31, 2013 and 2014, respectively. There were no total realized gross losses for the years ended December 31, 2013 or 2014.

7. Property and Equipment

Property and equipment consisted of the following:

	Estimated Useful Lives	December 31, 2013	2014

Laboratory equipment	7	$ 4,796,393	$ 5,828,045
Office equipment and software	3 7	972,789	1,225,298
Leasehold improvements	7	348,901	400,018
Assets not in service		503,208	23,836
		6,621,291	7,477,197
Less accumulated depreciation		(2,781,865)	(3,506,532)
		$ 3,839,426	$ 3,970,665

Assets not in service represent new laboratory and computer equipment that was not installed and ready to use at December 31, 2013 and 2014. The total amount of depreciation expense for the years ended December 31, 2012, 2013 and 2014 were $358,367, $674,725 and $857,055, respectively.

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8. Long-Term Debt

In August, 2010 the Company obtained a $15.0 million loan commitment 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. In connection with the loan during 2010, the Company issued warrants to lenders to purchase an aggregate of 64,674 shares of Series C-3 convertible preferred stock. The fair value of the preferred stock warrants issued was $219,322 on the dates of issuance and was based on observable inputs using quoted market values and the income approach as derived by the Black-Scholes model. The terms of these preferred stock warrants are described in Note 9.

Interest paid was $655,834, $0 and $0 for the years ended December 31, 2012, 2013 and 2014, respectively.

9. Warrants

In 2007, the Company issued warrants as consideration in connection with its loan commitment from General Electric Capital Corporation and Oxford Finance Corporation (Oxford) to purchase 69,294 of Series C-3 convertible preferred stock, maturing in 2017. These preferred stock warrants were exercisable upon issuance, and no contingent conversion feature exists. Upon closing of the initial public offering, these warrants were converted to warrants to purchase common stock and were reclassified to stockholders equity.

In August 2010 and December 2010, the Company issued warrants as consideration in connection with its loan commitment from Mid-Cap and SVB to purchase either Series C-3 preferred stock or preferred stock offered in a subsequent offering. The number of preferred stock warrants issued was based on the Series C-3 convertible preferred stock and an $8.12 per share exercise price. The preferred stock warrants would have matured in 2020, were exercisable upon issuance and did not contain contingent conversion features. Upon closing of the initial public offering, these warrants were converted to warrants to purchase common stock and were reclassified to stockholders equity.

During 2013, the Company issued 47,791 shares of common stock in connection with the cashless exercise of warrants to purchase stock. As a result, the warrants issued to Oxford, Mid-Cap and SVB were no longer outstanding as of December 31, 2013.

10. Leases

Future minimum lease payments for noncancellable operating leases as of December 31, 2014, are as follows:

2015	$ 731,555

2016	154,663
2017	158,474
2018	26,677
2019	
Thereafter	
Total minimum lease payments	$ 1,071,369

Rent expense for operating leases was $512,855, $784,531 and $866,768 for the years ended December 31, 2012, 2013 and 2014, respectively.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. Stockholders Equity (Deficit)

Stock-Based Compensation Plans

The Company has had stock-based compensation plans since 1997. The awards made under the plans adopted in 1997 and 2007 consisted of stock options. The 2010 Equity Incentive Plan (the 2010 Plan), which is the only plan under which awards may currently be made, authorizes awards in the form of stock options, stock appreciation rights, restricted stock, PRSUs, performance units and performance shares, and RSUs. Awards under the 2010 Plan may be made to employees, directors and certain consultants as determined by the compensation committee of the board of directors. There were 6,625,563 and 8,071,563 shares of common stock authorized and reserved under these plans at December 31, 2013 and December 31, 2014, respectively.

Stock Options

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

Generally, options granted under the 1997 and 2007 plans in connection with an employee s commencement of employment vest over a four-year period with one-half of the shares subject to the grant vesting after two years of employment and remaining options vesting monthly over the remainder of the four-year period. Options granted under the 1997 and 2007 plans for performance or promotions vest monthly over a four-year period. Generally, options granted under the 2010 Plan vest annually over a four-year period. Unexercised stock options terminate on the tenth anniversary date after the date of grant. The Company recognizes stock-based compensation expense over the requisite service period of the individual grantees, which generally equals the vesting period. The Company utilizes a Black-Scholes option-pricing model to estimate the value of stock options. The Black-Scholes model allows the use of a range of assumptions related to volatility, risk-free interest rate, employee exercise behavior and dividend yield. Prior to 2013, since the Company did not have sufficient history as a publicly traded company to evaluate volatility, the Company used an average of several peer companies volatilities to determine a reasonable estimate of volatility. Beginning in 2013, the Company utilizes a combination of peer volatility and company volatility. For purposes of identifying peer companies, the Company considered characteristics such as industry, length of trading history, market capitalization and similar product pipelines.

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

The weighted-average value of the individual options granted during 2012, 2013 and 2014 were determined using the following assumptions:

	Year Ended December 31,		
	2012	2013	2014
Weighted-average volatility	89.13 %	101.00 %	102.86 %
Risk-free interest rate	1.10 %	1.31 %	1.98 %
Weighted-average expected life (in years)	6.2	6.6	6.6
Dividend yield	0.00 %	0.00 %	0.00 %

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. Stockholders Equity (Deficit) (continued)

The resulting value of options granted was $13,725,956 and $9,188,595 for the years ended December 31, 2013 and 2014, respectively, which will be amortized into income over the remaining requisite service period. The Company recognized stock-based compensation cost, net of forfeitures, in the amount of $3,022,693, $6,059,005 and $8,025,261 for the years ended December 31, 2012, 2013 and 2014, respectively. The Company s stock option activity and related information are summarized as follows:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2012	2,592,009	$ 5.12		
Granted during year	1,492,395	4.61		
Exercised during year	(134,534)	2.91		
Expired during year	(13,502)	9.86		
Forfeited during year	(57,129)	6.68		
Outstanding at December 31, 2012	3,879,239	$ 4.96	7.50	$16,198,044
Exercisable at December 31, 2012	1,676,016	3.83	5.72	8,882,339
Outstanding at January 1, 2013	3,879,239	4.96		
Granted during year	1,566,062	10.79		
Exercised during year	(188,699)	3.42		
Expired during year				
Forfeited during year	(10,137)	6.04		
Outstanding at December 31, 2013	5,246,465	$ 6.76	7.39	$22,002,357
Exercisable at December 31, 2013	2,269,438	4.59	5.73	13,968,005
Outstanding at January 1, 2014	5,246,465	6.76		
Granted during year	1,065,386	10.54		
Exercised during year	(399,654)	3.23		
Expired during year	(244,121)	9.17		
Forfeited during year	(571,402)	10.49		
Outstanding at December 31, 2014	5,096,674	$ 7.29	6.87	$6,329,518
Exercisable at December 31, 2014	2,695,278	5.89	5.68	4,986,059

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. Stockholders Equity (Deficit) (continued)

The following is a rollforward of the Company s nonvested stock options from January 1, 2012 to December 31, 2014.

	Options	Weighted-Average Grant Date Value
Nonvested stock options at January 1, 2012	1,252,668	$ 5.34
Granted during year	1,492,395	3.42
Vested during year	(484,711)	4.51
Expired during year		
Forfeited during year	(57,129)	4.61
Nonvested at December 31, 2012	2,203,223	$ 4.24
Nonvested stock options at January 1, 2013	2,203,223	$ 4.24
Granted during year	1,566,062	8.76
Vested during year	(782,121)	4.22
Expired during year		
Forfeited during year	(10,137)	4.58
Nonvested at December 31, 2013	2,977,027	$ 6.62
Nonvested stock options at January 1, 2014	2,977,027	$ 6.62
Granted during year	1,065,386	8.62
Vested during year	(1,069,615)	6.61
Expired during year		
Forfeited during year	(571,402)	8.36
Nonvested at December 31, 2014	2,401,396	$ 7.07

The total grant date value of stock options vested during 2012, 2013 and 2014 was $2,216,038, $3,303,701 and $7,072,923 respectively. As of December 31, 2013 and December 31, 2014, the total remaining unrecognized compensation cost, net of forfeitures, related to stock options granted was $13,900,183 and $11,092,519, respectively, which is expected to be recognized over weighted average periods of approximately 1.8 and 1.6 years, respectively. The intrinsic value of options exercised was $1,884,651 and $2,934,244 for the years ended December 31, 2013 and December 31, 2014, respectively.

Restricted Stock Units

In May 2011, the Company adopted and granted awards under a performance-based RSU program (the 2011 PRSU Program) under the 2010 Plan. Each unit represents an amount equal to one share of the Company s common stock. The PRSUs will be earned, in whole or in part, based on performance and service conditions. The performance condition is based upon whether the Company receives regulatory approval to sell a therapeutic product, and the awards include a target number of PRSUs that will vest upon a First Commercial Approval, and a maximum number

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

As of December 31, 2014, the Company had 245,396 PRSU awards outstanding. The unrecorded stock compensation expense is based on number of units granted, less estimated forfeitures based on the Company s historical forfeiture rate of 6.49%, and the closing market price of the Company s common stock at the grant date. As of December 31, 2014, the performance condition of obtaining regulatory approval had not been achieved, therefore, no vesting had occurred. The awards are being accounted for under ASC 718, and compensation expense is to be recorded if the Company determines that it is probable that the performance conditions will be achieved. As of December 31, 2014, it was not probable that the performance conditions will be achieved, therefore, no compensation expense related to the PRSUs was recorded for the

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. Stockholders Equity (Deficit) (continued)

year ended December 31, 2014. Unrecorded compensation expense for the 2011 PRSU program as of December 31, 2014 was $2.7 million. Based on the performance conditions and the stage of development of our potential products, we have concluded that the performance conditions will not be achieved before the performance deadline and, as a result, we do not expect to recognize any stock-based compensation expense related to the PRSUs.

As of December 31, 2014, the Company had 161,439 RSU awards outstanding under the 2010 Plan which were granted in February 2014. The RSUs are service-based awards that will vest and be paid in four equal installments annually beginning in February 2015 in the form of one share of the Company s common stock for each RSU. The awards were granted at a weighted average fair value of $11.11 per share, calculated using the closing stock price of a share of our common stock on the grant date, net of forfeitures, over the life of the vesting period. As of December 31, 2014, the total remaining unrecognized compensation cost, net of forfeitures, related to RSUs was $1.3 million, which is expected to be recognized over a weighted average period of approximately 2.0 years.

Employee Stock Purchase Plan

Effective January 1, 2014, the Company implemented the ESPP. At January 1, 2014, 622,780 common shares were available for issuance under the ESPP. Shares may be issued under the ESPP twice a year. In the year ended December 31, 2014, plan participants purchased 53,250 shares of common stock under the ESPP at an average purchase price of $5.62 per share. At December 31, 2014, 569,530 shares were available for issuance under the ESPP.

12. Income Taxes

A reconciliation of the expected income tax benefit (expense) computed using the federal statutory income tax rate to the Company s effective income tax rate is as follows for the years ended December 31, 2012, 2013, and 2014:

	December 31,		
	2012	2013	2014
Income tax computed at federal statutory tax rate	34.0 %	34.0 %	34.0 %
State taxes, net of federal benefit	3.9 %	4.2 %	6.3 %
State taxes rate change, net of federal benefit			30.4 %
International operations	(0.2)%	(2.1)%	6.6 %
Research and development credits	2.4 %	13.8 %	(22.6)%
Orphan drug credits		6.6 %	(57.4)%
Equity compensation	(2.2)%	(2.5)%	16.6 %
Other	(0.2)%	(1.3)%	(2.1)%
Change in valuation allowance	(37.7)%	(52.7)%	(11.8)%
Total	0.0 %	0.0 %	0.0 %

At December 31, 2014, the Company had net operating loss carryforwards totaling approximately $179,478,000 and $235,422,000 for federal and state income taxes, respectively, that may be used to offset future taxable income. If not used, the carryforwards will begin expiring in the year 2021. The Company has determined that it experienced a change in ownership as defined under Section 382 of the U.S. Internal Revenue Code (the Code), as a result of the public offering 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 $133,200,000 for 2014, $39,000,000 for 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.

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12. Income Taxes (continued)

Net deferred tax assets and liabilities are comprised of the following:

	December 31, 2013	2014
Deferred tax assets		
Net operating loss carryforwards	$ 65,678,000	$ 71,074,000
Research and development credit carryforwards	9,592,000	10,836,000
Orphan Drug Credit	1,495,000	6,286,000
Stock options	2,377,000	4,103,000
Other	120,000	202,000
Deferred tax assets	79,262,000	92,501,000
Deferred tax liabilities		
Deferred revenue	(2,594,000)	(16,408,000)
Property and equipment	(241,000)	(316,000)
Deferred tax liabilities	$ (2,835,000)	$ (16,724,000)
Net deferred tax asset before valuation allowance	$ 76,427,000	$ 75,777,000
Less valuation allowance	(76,427,000)	(75,777,000)
Net deferred tax assets	$	$

13. Collaborations

In October 2007, the Company entered into an exclusive worldwide license with R&D Biopharmaceuticals to research, develop, and commercialize products containing conjugates of folate receptor targeting compounds and tubulysin compounds. In February 2011, this licensing agreement was assigned by R&D Biopharmaceuticals to Trientlgasse. The Company paid an upfront fee of $300,000 as research and development and pays $25,000 in annual maintenance fees unless a milestone is paid in a given year. In 2013, the Company paid $100,000 for dosing the first human patient with folate tubulysin. In 2014, the Company paid $50,000 for the completion of toxicology studies in compliance with Good Laboratory Practice and $100,000 for dosing the first human patient with PSMA tubulysin. The Company could pay $5,900,000 in additional contingent payments upon the achievement of specific scientific, clinical, and regulatory milestones, in addition to royalties upon commercial sales. All payments have been expensed as research and development as incurred, as there is no alternate future use for this technology.

In December 1995, as amended in October 1998, the Company entered into an exclusive license agreement with Purdue Research Foundation, which licenses the right under certain patents to the Company. The Company is obligated to pay an annual minimum royalty of $12,500 until commercial sales commence, following which time the payment of single digit royalty rates will commence. All payments have been expensed as incurred. The Company does not anticipate incurring any liabilities for vintafolide royalty payments based on the estimate timing of when commercial sales may commence and the expiration of the applicable patents.

In December 2009, the Company entered into a financial term sheet to be incorporated into a written license agreement with Purdue Research Foundation for a patent related to prostate cancer. The agreement was signed and became effective on March 1, 2010. Pursuant to the exclusive license agreement, the Company is subject to minimum annual royalty payments of $15,000, payable until first commercial sale, following which time the minimum annual royalty payments increase to $100,000 and sales-based royalties are also payable at market rates when commercial sales commence. In addition, a milestone payment of $500,000 is payable upon approval of a new drug application in the U.S. In 2014, the Company paid a penalty as a milestone was not met. The Company is subject to future penalties if certain diligence milestones are not met.

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13. Collaborations (continued)

In 2014, the Company entered into a Master License Agreement with Purdue Research Foundation. Under this license, the Company has the right to exclusively license patents and technology discovered under company funded research at Purdue University. If the Company decides to move forward with development of one or more of these technologies, the Company will be obligated to make an acceptance payment and the Company will also be obligated to make contingent payments upon the achievement of specific scientific, clinical and regulatory milestones. Certain scientific, clinical and regulatory milestones, in addition to internal resource targets must be met by the Company to avoid fees as consideration for waivers of potentially missed milestones. The Company is obligated to pay annual minimum payments until commercial sales commence, following which time the payments of royalties with market rates will commence, along with an annual royalty payment per annum.

Merck Collaboration Agreement

In April 2012, the Company entered into a worldwide collaboration agreement with Merck Sharp & Dohme Research GmbH, a subsidiary of Merck & Co, Inc. (Merck), regarding the development and commercialization of vintafolide, which agreement was terminated by Merck effective September 15, 2014. As a result of the termination of the collaboration with Merck, the Company is no longer eligible for additional milestone payments from Merck. In addition, all obligations of the Company under the agreement have been fulfilled and the Company is not required to perform any additional services to Merck. Pursuant to the collaboration agreement, the Company received a $120.0 million non-refundable upfront payment and a $5.0 million milestone payment in 2012. Under the collaboration agreement, the Company was responsible for the majority of funding and completion of the Phase 3 PROCEED clinical trial of vintafolide for the treatment of patients with platinum-resistant ovarian cancer (PROC), which was terminated in May 2014. The Company is responsible for the execution of the Phase 2b TARGET trial of vintafolide for the treatment of second line non-small cell lung cancer, which is now substantially complete, pending the receipt of final overall survival results. Merck was responsible for the costs of the TARGET trial through September 15, 2014.

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 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, would 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 research and development services to be provided by the Company were essential to the overall arrangement

as the Company has significant knowledge and technical know-how that was important to realizing the value of the licenses granted. Subsequent to the inception of the Merck arrangement, the Company evaluated the remaining deliverables for separation as items in the arrangement were delivered.

The Company recognized the non-refundable $120.0 million upfront payment, the $5.0 million milestone payment and funding from the research and development services on a straight-line basis over the estimated performance period, which started at the date of execution of the agreement. Based on the termination of the PROCEED trial and receiving the notice of termination of the collaboration agreement in 2014, the Company concluded that all of its obligations under the agreement have been fulfilled and the Company is not required to perform any additional services to Merck, and as a result, the entire balance of deferred revenue related to

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13. Collaborations (continued)

the collaboration agreement was recognized in 2014. The Company recognized approximately $64.9 million and $70.3 million of revenue related to the Merck collaboration during 2013 and 2014, respectively, and had deferred revenue related to the collaboration of approximately $59.7 million at December 31, 2013. There was no deferred revenue related to the collaboration at December 31, 2014. Though accounted for as a single unit of account for presentation purposes, the Company made an allocation of revenue recognized as collaboration revenue between the license and the services. This allocation was based upon the relative selling price of each deliverable. For the years ended December 31, 2013 and 2014, license revenue was approximately $51.5 million and $52.7 million, respectively, while research and development services revenue was approximately $13.4 million and $17.6 million, respectively, of the collaboration revenue.

In 2014, Merck and the Company entered into a letter agreement whereby Merck agreed to pay (i) $2.2 million of expenses related to costs incurred to prepare for the potential increase in the number of FR(100%) patients (patients in which 100 percent of their target lesions over-expressed the folate receptor as determined by an etarfolatide scan) in the PROCEED trial from 250 to 350, for which Merck agreed to reimburse at 75%, and (ii) $1.1 million related to the remaining PROCEED trial expenses beyond the September 15, 2014 termination date. The Company has no obligations nor is it required to perform any additional services under that letter agreement. Revenue for these additional payments was recognized in 2014.

In 2014, Merck and the Company entered into a second letter agreement whereby Merck agreed to pay $0.5 million related to the estimate of reimbursable development expenses incurred but not yet invoiced to Merck. Under that letter agreement, Merck and the Company agreed that there will be no additional amounts payable by either party if the actual expenses differ from the estimated expenses paid by Merck.

NMP License and Commercialization Agreement

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

For revenue recognition purposes, the Company viewed the agreement with NMP as a multiple element arrangement. Multiple element arrangements are analyzed to determine whether the various performance obligations, or elements, can be separated or whether they must be accounted for as a single unit of accounting. The Company has identified the deliverables related to the collaboration with NMP, which include the license granted to NMP, as well as the obligation to provide preclinical and clinical supply of etarfolatide, to provide rights to NMP if a product is developed that replaces etarfolatide, obligation for the Company to provide clinical data to NMP during the contract period and coordination of development and commercialization efforts between the Company for vintafolide and NMP for etarfolatide in Japan. The Company s deliverables will be accounted for as a single unit of account, therefore the

non-refundable upfront payment is being recognized on a straight-line basis over the performance period. This determination was made because the successful development of etarfolatide in Japan requires the ongoing participation by the Company, including the development of the related therapeutic drug, vintafolide. The performance period over which the revenue will be recognized continues from the date of execution of the agreement through the end of 2033, the estimated termination date of the contract which is when the Company s performance obligations will be completed. Any significant changes in the timing of the performance period could result in a change in the revenue recognition period. The Company had deferred revenue related to the agreement of approximately $0.9 million at December 31, 2014. Subsequent to the inception of the NMP arrangement, the Company evaluates the remaining deliverables for separation as items in the arrangement are delivered.

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Collaborations (continued)

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

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

14. Related-Party Transactions

The Company funds research at Purdue University, the employer of one of its founders and current Chief Science Officer. Amounts included in research and development expenses were $788,737, $824,559 and $1,000,000 for the years ended December 31, 2012, 2013 and 2014, respectively.

In September 2011, the Company entered into exclusive worldwide licenses with On Target Laboratories, L.L.C. (On Target) to develop and commercialize products relating to the compound comprising the Company s Folate and DUPA ligands and other certain Licensed Patents. On Target s Chief Executive Officer is the brother of the Company s Chief Science Officer. The Company believes that the terms of the agreement are no less favorable than terms that would have been available in an arm s length transaction. On Target is solely responsible for conducting research and development, seeking regulatory approval and commercialization of products. The Company received nonrefundable upfront license fees totaling $191,000 from On Target in December 2011. The Company has determined that the deliverables under this agreement do not meet the criteria required for separate accounting units for the purposes of revenue recognition, and as a result, the Company recognized revenue from non-refundable, upfront fees when the performance condition of delivering the licenses and certain consultation services had been achieved and there was reasonable assurance of collectability. If On Target fails to meet minimum spend requirements on research and development, the Company has the right to terminate the agreement. The Company will be entitled to receive minimum royalty payments annually based on net sales, but there is no guarantee that a commercial product will be developed and approved for commercial sales. The Company will also be entitled to reimbursement of expenses relating to patent expenses and payments to the inventors and Purdue University if certain milestones are met. During 2011, the Company received a $50,000 reimbursement from On Target for payments made to inventors for issued

patents. The Company received $20,000 in annual maintenance license fees during each of 2013 and 2014, and received $27,394 and $50,614 for reimbursable research and development expenses, for 2013 and 2014, respectively.

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

15. Retirement Plans

The Company maintains a 401(k) retirement savings plan to provide retirement benefits for substantially all of its employees. Participants in the plan may elect to contribute a portion of their annual compensation to the plan, limited to the maximum allowed by the Code. Prior to January 1, 2014 the Company did not match 401(k) contributions. Effective January 1, 2014, the Company implemented a matching contribution for the 401k contributions. For the year ended December 31, 2014, the Company had approximately $0.3 million of expense related to the 401(k) employer match.

16. Commitments and Contingencies

On June 24, 2014, a complaint in a securities class action lawsuit was filed against the Company and one of its officers and directors in the United States District Court for the Southern District of Indiana under the following caption: *Tony Nguyen, on Behalf of Himself and All Others Similarly Situated v. Endocyte, Inc. and P. Ron Ellis* (the Nguyen Litigation). On July 13, 2014, a nearly identical complaint in a securities class action lawsuit was filed against the Company and one of its officers and directors in the United States District Court for the Southern District of Indiana under the following caption: *Vivian Oh Revocable Trust, Individually and on Behalf of All Others* Similarly *Situated v. Endocyte, Inc. and P. Ron Ellis* (the Oh Litigation). On September 22, 2014, the court named a lead plaintiff (Lead Plaintiff) and consolidated the Nguyen Litigation and the Oh Litigation under the following caption: *Gopichand Vallabhaneni v. Endocyte, Inc. and P. Ron Ellis* (the Vallabhaneni Litigation). On November 17, 2014, Lead Plaintiff filed a consolidated amended securities class action complaint (the Amended Complaint) against the Company, P. Ron Ellis, Beth Taylor, Michael A. Sherman, John C. Aplin, Philip S. Low, Keith A. Brauer, Ann F. Hanham, Marc Kozin, Peter D. Meldrum, Fred A. Middleton, Lesley Russell (the Individual Defendants and collectively with the Company, the Endocyte Defendants), and Credit Suisse Securities (USA) LLC and Citigroup Global Markets Inc. (the Underwriter Defendants). Lead Plaintiff alleged, among other things, that the Endocyte Defendants made false and misleading statements relating to the efficacy of vintafolide and violated Sections 10(b) and 20(a) of the Exchange Act. The putative class related to these allegations consists of all persons who purchased or otherwise acquired the Company s securities between March 21, 2014 and May 2, 2014. Lead Plaintiff also alleged in the Amended Complaint that the Endocyte Defendants and the Underwriter Defendants violated Sections 11 and 15 of the Securities Act of 1933, as amended (the Securities Act), by, among other things, making or allowing the Company to make false and misleading statements regarding positive opinions about vintafolide issued by the European Medicines Agency s Committee for Medicinal Products for Human Use in the Company s Registration Statement on Form S-3 filed on March 25, 2014, preliminary prospectus filed on March 26, 2014, and final prospectus filed on March 28, 2014. The putative class related to these allegations consists of all those who purchased or otherwise acquired the Company s securities pursuant to or traceable to the Company s April 2, 2014 public offering.

Lead Plaintiff seeks the designation of the Vallabhaneni Litigation as a class action, an award of unspecified damages, interest, costs, expert fees and attorneys fees, and equitable/injunctive relief or other relief as the court may deem just and proper. Pursuant to a December 9, 2014 order, all Defendants filed a motion to dismiss on March 6, 2015. Discovery in this matter is stayed pursuant to provisions of the Private Securities Litigation Reform Act (PSLRA)

pending resolution of that motion to dismiss. The Company believes that this lawsuit is without merit and has defended, and intends to continue to defend, itself vigorously against the allegations made in the Amended Complaint.

On September 23, 2014, a complaint in a shareholder derivative lawsuit was filed against all of the Company s current directors in the United States District Court for the Southern District of Indiana under the following caption: *William Moore, Derivatively on Behalf of Nominal Defendant Endocyte, Inc. v. John C. Aplin, et al.* (the Moore Litigation). The Company was named as a nominal defendant in the case. The complaint alleged, among other things, that the defendants violated state law, including through breaches of fiduciary duties, gross mismanagement, waste of corporate assets and unjust enrichment, in regard to false and misleading statements and material omissions made concerning the efficacy of vintafolide, causing substantial

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

16. Commitments and Contingencies (continued)

monetary losses to the Company and other damages, including irreparable damages to the Company s reputation and goodwill. The complaint sought: unspecified damages from each of the defendants, jointly and severally, together with interest thereon; an order directing that actions be taken to reform and improve the Company s corporate governance and internal procedures to comply with applicable laws and to protect the Company s shareholders from a repeat of the alleged damaging events; an award of unspecified exemplary damages; restitution; costs and disbursements, including reasonable attorneys and experts fees, costs and expenses; and such other and further equitable relief as the court may deem just and proper.

On October 31, 2014, a complaint in a shareholder derivative lawsuit nearly identical to the Moore Litigation was filed against all of the Company s current directors in the United States District Court for the Southern District of Indiana under the following caption: *Victor Veloso, Derivatively on Behalf of Endocyte, Inc. v. John C. Aplin, et al.* (the Veloso Litigation). The Company was named as a nominal defendant in the case. The complaint alleged, among other things, that the defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry and good faith by causing the Company to issue false and misleading statements concerning its financial condition, resulting in significant damages, not only monetarily, but also to its corporate image and goodwill, including costs associated with defending securities lawsuits, severe damage to its share price, resulting in an increased cost of capital, the waste of corporate assets and reputational harm. The complaint sought: unspecified damages from all of the defendants; an order directing that the Company take all necessary actions to reform and improve its corporate governance and internal procedures, to comply with existing governance obligations and all applicable laws and to protect the Company and its investors from a recurrence of the alleged damaging events; costs and disbursements, including reasonable attorneys fees, accountants and experts fees, costs and expenses; and such other and further relief as the court deems just and proper.

On December 31, 2014, the court appointed co-lead counsel and consolidated the Moore Litigation with the Veloso Litigation under the following caption: *In re Endocyte, Inc. Derivative Litigation* (the Endocyte Derivative Litigation). An amended complaint was filed on February 28, 2015 which contains allegations and requests for relief that are substantially the same as the complaints in the Moore Litigation and the Veloso Litigation. Although this lawsuit is brought nominally on behalf of the Company, the Company expects to incur defense costs and other expenses in connection with the lawsuit. Discovery and other proceedings in this matter are currently stayed pursuant to agreement of the parties pending resolution of the March 6, 2015 motion to dismiss in the Vallabhaneni Litigation.

On November 6, 2014, a complaint was filed against the Company, two of its executive officers, Merck and one of Merck s officers in the Superior Court of Tippecanoe County, Indiana under the following caption: *Mohamad Hage and Jamele Hage v. Endocyte, Inc., P. Ron Ellis, Mike A. Sherman, Eric Rubin and Merck & Co., Inc.* (the Hage Litigation). The complaint alleged, among other things, that the defendants: made false and misleading statements about the efficacy of vintafolide and the likelihood that it would be approved for sale; employed devices, schemes and artifices to defraud; made untrue statements of material facts and omitted to state material facts necessary in order to make the statements made about the Company and its business operations not misleading; and breached fiduciary duties owed to the plaintiffs. The complaint alleged that as a result of the alleged fraudulent misrepresentations,

non-disclosures and schemes of the defendants, plaintiffs have suffered pecuniary losses. The plaintiffs seek an award of unspecified actual, compensatory, consequential, incidental and punitive damages, reasonable costs, expert fees and attorneys fees, and such equitable/injunctive or other relief as the court may deem just and proper. The Company believes that it may have an obligation to indemnify Merck and its named officer in connection with the Hage Litigation, depending on certain factors. On January 9, 2015, the defendants filed a Motion to Stay the Proceeding or in the Alternative to Stay Discovery (the Motion to Stay). A hearing on the Motion to Stay was held on February 19, 2015 and the parties are waiting for the court to rule. The Company believes that this lawsuit is without merit and has defended, and intends to continue to defend, itself vigorously against the allegations made in the complaint.

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

16. Commitments and Contingencies (continued)

The Company also has certain obligations to indemnify, and advance expenses to, its directors and officers in connection with various actions, suits and proceedings.

17. Restructuring Costs

The Company terminated the PROCEED trial in May 2014 after the interim futility analysis indicated that vintafolide did not demonstrate efficacy on the pre-specified outcome of progression-free survival for the treatment of PROC. As a result, the Company ceased its pre-launch commercial activities and implemented staff reductions in Europe and in the U.S. Included in general and administrative expenses for the year ended December 31, 2014, were expenses for employee termination benefits and contract termination costs of $1.3 million, and included in research and development expenses were $4.1 million of expenses for the PROCEED trial, including continued patient therapy costs for the patients who chose to stay on treatment, as well as site close-out expenses. As of December 31, 2014, all severance had been paid, and the Company had a clinical trial accrual balance related to the PROCEED trial termination of $1.3 million, which is expected to be fully paid by June 2015.

The following table summarizes the restructuring accruals for the year ended December 31, 2014:

	Employee and Contract Termination Accrual	PROCEED Trial Termination Accrual	Total
Balance, January 1, 2014	$	$	$
Charges for the year ended December 31, 2014	1,300,000	4,100,000	5,400,000
Amounts paid in the year ended December 31, 2014	(1,300,000)	(2,800,000)	(4,100,000)
Balance, December 31, 2014	$	$1,300,000	$1,300,000

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ENDOCYTE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

18. Selected Quarterly Financial Data (unaudited)

The following table summarizes the unaudited statements of operations for each quarter of 2014 and 2013 (in thousands except share and per share amounts):

	Quarters Ended			
	March 31	June 30	September 30	December 31
2014				
Revenue	$17,269	$49,168	$3,904	$12
Operating Expenses:				
Research and development	12,987	18,990	5,675	3,998
General and administrative	7,501	7,968	4,007	4,201
Income (loss) from operations	(3,219)	22,210	(5,778)	(8,187)
Interest, net	85	168	161	164
Other	(7)	(22)	(58)	(58)
Net income (loss)	$(3,141)	$22,356	$(5,675)	$(8,081)
Basic net income (loss) per share[1]	$(0.09)	$0.54	$(0.14)	$(0.19)
Diluted net income (loss) per share[1]	$(0.09)	$0.52	$(0.14)	$(0.19)
Weighted average common shares outstanding basic	36,193,942	41,398,251	41,564,840	41,736,930
Weighted average common shares outstanding diluted	36,193,942	43,196,754	41,564,840	41,736,930

	Quarters Ended			
	March 31	June 30	September 30	December 31
2013				
Revenue	$14,514	$16,483	$16,600	$17,274
Operating Expenses:				
Research and development	12,259	18,607	13,501	13,533
General and administrative	6,256	6,211	6,143	6,704
Loss from operations	(4,001)	(8,335)	(3,044)	(2,963)
Interest, net	139	126	111	89
Other		(18)	(108)	(28)
Net loss	$(3,862)	$(8,227)	$(3,041)	$(2,902)
Basic and diluted net loss per share[1]	$(0.11)	$(0.23)	$(0.08)	$(0.08)
Weighted average common shares outstanding basic and diluted[2]	35,930,265	35,991,402	36,077,440	36,146,061

(1)

(2) Per common share amounts for the quarters and full years have been calculated separately. Accordingly, the sum of quarterly amounts may not equal the annual amount because of differences in the weighted average common shares outstanding during each period, principally due to the effect of share issuances by the Company during the year. Diluted weighted average common shares outstanding are identical to basic weighted average common shares outstanding and diluted net loss per share is identical to basic net loss per share for all quarters of 2013 because common share equivalents are excluded from the calculations of diluted weighted average common shares outstanding for those quarters, as their effect is anti-dilutive.

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Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. *Controls and Procedures*

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2014, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Because of inherent limitations, any controls and procedures, no matter how well designed and operated, can provide only reasonable, and not absolute, assurance of achieving the desired control objective. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2014, the design and operation of our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2014, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the *Internal Control Integrated Framework* issued by the Committee of Sponsoring

Organizations of the Treadway Commission (2013 Framework). Management s assessment included evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on this evaluation, our management concluded that, as of December 31, 2014, our internal control over financial reporting was effective based on such criteria.

Attestation in Internal Control over Financial Reporting

Ernst & Young LLP, our independent registered public accounting firm, has audited our consolidated financial statements for the year ended December 31, 2014 and has issued an audit report on the effectiveness of the Company s internal control over financial reporting as of December 31, 2014, which is included in Item 8 of this Annual Report on Form 10-K.

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Item 9B. *Other Information*

On March 9, 2015, Binh Nguyen, M.D., Ph.D., the Company s Vice President of Medical Affairs, notified the Company of his decision to resign from the Company, effective March 23, 2015, in order to accept a consulting opportunity that is more aligned with the current phase of his career. The Company expects no delay or other adverse impact with respect to its ongoing clinical programs by reason of Dr. Nguyen's departure.

Dr. Nguyen expressed his continued enthusiasm for the Company's development pipeline and confirmed that he expects to continue to be available to support the Company's medical affairs function through his new consulting role. The Company is assessing its medical affairs function and staffing and will consider alternative plans to replace Dr. Nguyen in the context of that assessment.

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Part III

Item 10. ***Directors, Executive Officers and Corporate Governance***

Directors

The information required by this item is set forth in our definitive Proxy Statement to be used in connection with the 2015 Annual Meeting of Stockholders (the 2015 Proxy Statement) and incorporated herein by reference.

Executive Officers

Information regarding our executive officers is set forth in Item 1 of Part I of this annual report under the caption Executive Officers of the Registrant.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our directors and officers and other employees, including our principal executive officer, principal financial officer and principal accounting officer. This code is publicly available through the Investors & News section of our website at *www.endocyte.com*. To the extent permissible under applicable law, the rules of the SEC or NASDAQ listing standards, we intend to post on our website any amendment to the code of business conduct and ethics, or any grant of a waiver from a provision of the code of business conduct and ethics, that requires disclosure under applicable law, the rules of the SEC or NASDAQ listing standards.

Audit Committee

The information required by this item relating to our audit committee is set forth in the 2015 Proxy Statement and incorporated herein by reference.

Section 16(a) Beneficial Ownership Reporting Compliance

The information required by this item relating to our compliance with Section 16(a) of the Exchange Act is set forth in the 2015 Proxy Statement and incorporated herein by reference.

Corporate Governance

The information required by this item relating to the procedures by which stockholders may recommend nominees to the board of directors is set forth in the 2015 Proxy Statement and incorporated herein by reference.

Item 11. ***Executive Compensation***

The information required by this item is set forth in the 2015 Proxy Statement and incorporated herein by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this item with respect to security ownership of certain beneficial owners and management is set forth in the 2015 Proxy Statement and incorporated herein by reference.

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Equity Compensation Plan Information

The following table provides information regarding our equity compensation plans as of December 31, 2014:

	Equity Compensation Plan Information		
Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders:[1]	5,503,509[2]	$ 7.29 [3]	1,260,487 [4]
Equity compensation plans not approved by security holders:			
Total	5,503,509	$ 7.29	1,260,487

(1) Consists of the 1997 Stock Plan, the 2007 Stock Plan and the 2010 Equity Incentive Plan.

(2) Includes shares which may be issued pursuant to:
5,096,674 outstanding stock options;
161,439 outstanding restricted stock units, or RSUs; and
245,396 outstanding performance-based restricted stock units, or PRSUs, which assumes that the outstanding PRSUs are earned at the maximum award level.

(3) Represents the weighted average exercise price of outstanding stock options. Does not take into account the outstanding PRSUs and RSUs which, once earned and vested, will be settled in shares of our common stock on a one-for-one basis at no additional cost.

(4) Assumes that outstanding PRSUs are earned at the maximum award level. Consists of shares available for awards under the 2010 Equity Incentive Plan. As of December 31, 2014 there were no shares available for awards under the 1997 Stock Plan or the 2007 Stock Plan. The original number of shares available for awards under the 2010 Equity Incentive Plan was 1,498,929. The 2010 Equity Incentive Plan provides for an annual increase in the number of shares available for issuance under that plan. Between the date of stockholder approval of the 2010 Equity Incentive Plan, January 10, 2011, and December 31, 2014, an aggregate of 4,276,000 shares have become available for issuance under the 2010 Equity Incentive Plan pursuant to the annual increase provision. The 2010 Equity Incentive Plan also provides that shares of common stock subject to outstanding awards under the 1997 Stock Plan or the 2007 Stock Plan that expire, terminate, are forfeited or are repurchased become available for issuance under the 2010 Equity Incentive Plan. Between January 10, 2011 and December 31, 2014, an aggregate of 40,884 shares underlying outstanding awards under the 1997 Stock Plan and the 2007 Stock Plan expired, terminated, were forfeited or were repurchased and therefore became available under the 2010 Equity Incentive Plan. Effective January 1, 2015, the Board of Directors increased the number of shares available for awards under

the 2010 Equity Incentive Plan by 1,671,000 shares pursuant to the annual increase provision of the 2010 Equity Incentive Plan.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this item is set forth in the 2015 Proxy Statement and incorporated herein by reference.

Item 14. ***Principal Accounting Fees and Services***

The information required by this item is set forth in the 2015 Proxy Statement and incorporated herein by reference.

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PART IV

Item 15. ***Exhibits, Financial Statement Schedules.***

(a) 1. *Financial Statements*

The following financial statements of Endocyte, Inc. and its subsidiaries are set forth in Part II, Item 8.

2. *Financial Statement Schedules*

Financial statement schedules are omitted because they are not applicable or the required information is shown in the financial statements or the notes thereto.

3. *Exhibits*

A list of exhibits required to be filed as part of this report is set forth in the Index to Exhibits, which immediately precedes such exhibits and is incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ENDOCYTE, INC.

By: **/s/ P. Ron Ellis**

P. Ron Ellis
President and Chief Executive Officer
Date: March 13, 2015

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ P. Ron Ellis **P. Ron Ellis**	Director, President and Chief Executive Officer (Principal Executive Officer)	March 13, 2015
/s/ Michael A. Sherman **Michael A. Sherman**	Chief Operating Officer and Chief Financial Officer (Principal Financial Officer)	March 13, 2015
/s/ Beth A. Taylor **Beth A. Taylor**	Corporate Controller (Principal Accounting Officer)	March 13, 2015
/s/ John C. Aplin **John C. Aplin**	Chairman of the Board of Directors	March 13, 2015
/s/ Philip S. Low **Philip S. Low**	Director and Chief Science Officer	March 13, 2015
/s/ Keith E. Brauer **Keith E. Brauer**	Director	March 13, 2015
/s/ Colin Goddard **Colin Goddard**	Director	March 13, 2015
/s/ Ann F. Hanham **Ann F. Hanham**	Director	March 13, 2015
/s/ Marc D. Kozin **Marc D. Kozin**	Director	March 13, 2015
/s/ Peter D. Meldrum	Director	March 13, 2015

Peter D. Meldrum **/s/ Fred A. Middleton**		
	Director	March 13, 2015
Fred A. Middleton **/s/ Lesley Russell**		
	Director	March 13, 2015
Lesley Russell		

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EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Endocyte, Inc. (incorporated by reference to Exhibit 3.1 to Annual Report on Form 10-K for the year ended December 31, 2010 filed March 18, 2011).
3.2	Amended and Restated Bylaws of Endocyte, Inc. (incorporated by reference to Exhibit 3.2 to Annual Report on Form 10-K for the year ended December 31, 2010 filed March 18, 2011).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of Amendment No. 3 to Form S-1 (Registration No. 333-168904) filed January 12, 2011).
4.2	Third Amended and Restated Investor Rights Agreement dated March 9, 2007, among Endocyte, Inc. and the parties set forth therein, as amended (incorporated by reference to Exhibit 4.2 of Amendment No. 1 to Form S-1 (Registration No. 333-168904) filed September 28, 2010).
4.3	Warrant to Purchase Shares of Series C-3 Preferred Stock issued by Endocyte, Inc. to General Electric Capital Corporation on December 31, 2007 (incorporated by reference to Exhibit 4.3 to Form S-1 (Registration No. 333-168904) filed August 17, 2010).
10.1*	Form of Director and Executive Officer Indemnification Agreement (incorporated by reference to Exhibit 10.1 to Form S-1 (Registration No. 333-168904) filed August 17, 2010).
10.2*	1997 Stock Plan and forms of option agreements thereunder (incorporated by reference to Exhibit 10.2 to Form S-1 (Registration No. 333-168904) filed August 17, 2010).
10.3*	2007 Stock Plan and forms of option agreements thereunder (incorporated by reference to Exhibit 10.3 to Form S-1 (Registration No. 333-168904) filed August 17, 2010).
10.4*	2010 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to Form S-1 (Registration No. 333-168904) filed August 17, 2010).
10.5*	Form of Option Agreement under the 2010 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to Annual Report on Form 10-K for the year ended December 31, 2010 filed March 18, 2011).
10.6*	Form of Endocyte, Inc. 2010 Equity Incentive Plan Performance-Based Restricted Stock Unit Award Agreement (2011 RSU Program) (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed June 2, 2011).
10.7*	Form of Endocyte, Inc. 2010 Equity Incentive Plan Time-Based Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed February 10, 2014).
10.8*	2010 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to Form S-1 (Registration No. 333-168904) filed August 17, 2010).
10.9	Lease dated May 30, 2008 between Endocyte, Inc. and Zeller Management Corporation, amended (incorporated by reference to Exhibit 10.7 to Form S-1 (Registration No. 333-168904) filed August 17, 2010).
10.10	Third Amendment to Office Lease dated July 31, 2012 between Endocyte, Inc. and Zeller Management Corporation (incorporated by reference to Exhibit 10.8 to Annual Report on Form 10-K for the year ended December 31, 2012 filed March 18, 2013).
10.11	Lease Agreement dated January 30, 2013 between Endocyte, Inc. and Purdue Research Foundation (incorporated by reference to Exhibit 10.9 to Annual Report on Form 10-K for the year ended December 31, 2012 filed March 18, 2013).

10.12**	Amended and Restated Exclusive License Agreement dated October 21, 1998 between Endocyte, Inc. and Purdue Research Foundation, as amended (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 filed August 8, 2014).

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Exhibit Number	Description
10.13**	Exclusive License Agreement effective March 1, 2010 between Endocyte, Inc. and Purdue Research Foundation, as amended (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 filed August 8, 2014).
10.14***	Master License Agreement effective July 1, 2013 between Endocyte, Inc. and Purdue Research Foundation.
10.15*	Form of Change in Control Agreements each dated August 25, 2010 between Endocyte, Inc. and certain of its named executive officers (incorporated by reference to Exhibit 10.13 of Amendment No. 1 to Form S-1 (Registration No. 333-168904) filed September 28, 2010).
10.16*	Change in Control Agreement dated August 25, 2010 between Endocyte, Inc. and P. Ron Ellis (incorporated by reference to Exhibit 10.14 of Amendment No. 1 to Form S-1 (Registration No. 333-168904) filed September 28, 2010).
10.17*	Change in Control Agreement dated August 25, 2010 between Endocyte, Inc. and Michael A. Sherman (incorporated by reference to Exhibit 10.15 of Amendment No. 1 to Form S-1 (Registration No. 333-168904) filed September 28, 2010).
10.18	Patent Assignment Agreement dated November 1, 2007 among Endocyte, Inc. and the parties set forth therein (incorporated by reference to Exhibit 10.16 of Amendment No. 1 to Form S-1 (Registration No. 333-168904) filed September 28, 2010).
10.19**	Collaboration, Exclusive License, and Companion Diagnostic Agreement, dated as of April 13, 2012, by and between Merck Sharp & Dohme GmbH and the Company (incorporated by reference to Exhibit 10.21 to Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 filed August 13, 2012).
10.20	First Amendment of Lease Agreement dated May 17, 2013 between Endocyte, Inc. and Purdue Research Foundation (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 filed August 9, 2013).
10.21	Second Amendment of Lease Agreement dated July 7, 2013 between Endocyte, Inc. and Purdue Research Foundation (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q for the quarter ended September 30, 2013 filed November 8, 2013).
10.22	Third Amendment of Lease Agreement dated January 31, 2014 between Endocyte, Inc. and Purdue Research Foundation (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 filed May 12, 2014).
10.23	Fourth Amendment of Lease Agreement dated April 1, 2014 between Endocyte, Inc. and Purdue Research Foundation (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 filed August 8, 2014).
10.24	Extension of Lease dated November 20, 2013 between Endocyte, Inc. and Purdue Research Foundation (incorporated by reference to Exhibit 10.21 to Annual Report on Form 10-K for the year ended December 31, 2013 filed March 5, 2014).
10.25	Extension of Lease dated December 9, 2014 between Endocyte, Inc. and Purdue Research Foundation.
10.26*	Separation Agreement and Release of Claims, effective as of July 21, 2014, between Endocyte, Inc. and David D. Meek (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 filed November 7, 2014).
23.1	Consent of Ernst & Young, LLP, Independent Registered Public Accounting Firm.
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.

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Exhibit Number	Description
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 Registrant s Annual Report on Form 10-K for the year ended December 31, 2014, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Consolidated Balance Sheets at December 31, 2013 and 2014, (ii) Consolidated Statements of Operations and Comprehensive Income (Loss) for the years ended December 31, 2012, 2013 and 2014, (iii) Consolidated Statements of Stockholders Equity (Deficit) for the years ended December 31, 2012, 2013 and 2014, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2013 and 2014 and (v) Notes to Consolidated Financial Statements.

* Indicates management contracts or compensatory plans or arrangements.

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

*** Application has been made to the Securities and Exchange Commission to seek confidential treatment of certain provisions of this exhibit. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.