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FORM 10-K

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

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

Commission file number 0-20713

CASI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	58-1959440
(State of Incorporation)	(I.R.S. Employer Identification No.)
9620 Medical Center Drive, Suite 300, Rockville, MD	20850
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (240) 864-2600

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

Common Stock, $0.01 par value	**The NASDAQ Stock Market LLC**
(Title of each class)	**(Name of each exchange on which registered)**

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 ___No X

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15 (d) of the Act. Yes___ No X

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 X No ___

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes X No___

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 [ ]

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company X

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

As of June 30, 2014, the aggregate market value of the shares of common stock held by non-affiliates was approximately $36,475,677.

As of March 18, 2015, 32,445,811 shares of the Company's common stock were outstanding.

Documents Incorporated By Reference

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2014. The proxy statement is incorporated herein by reference into the following parts of the Form 10K:

Part III, Item 10, Directors, Executive Officers and Corporate Governance;
Part III, Item 11, Executive Compensation;
Part III, Item 12, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters;
Part III, Item 13, Certain Relationships and Related Transactions, and Director Independence; and
Part III, Item 14, Principal Accounting Fees and Services.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains certain forward-looking statements within the meaning of Section 27A of the Securities Exchange Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements also may be included in other statements that we make. All statements that are not descriptions of historical facts are forward-looking statements. These statements can generally be identified by the use of forward-looking terminology such as "believes," "expects," "intends," "may," "will," "should," or "anticipates" or similar terminology. These forward-looking statements include, among others, statements regarding the timing of our clinical trials, our cash position and future expenses, and our future revenues.

Actual results could differ materially from those currently anticipated due to a number of factors, including: the risk that we may be unable to continue as a going concern as a result of our inability to raise sufficient capital for our operational needs; the possibility that we may be delisted from trading on the Nasdaq Capital Market; the volatility in the market price of our common stock; the difficulty of executing our business strategy in China; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; risks relating to the need for additional capital and the uncertainty of securing additional funding on favorable terms; risks associated with our product candidates; risks associated with any early-stage products under development; the risk that results in preclinical models are not necessarily indicative of clinical results; uncertainties relating to preclinical and clinical trials, including delays to the commencement of such trials; the lack of success in the clinical development of any of our products; dependence on third parties; risks relating to the commercialization, if any, of our proposed products (such as marketing, safety, regulatory, patent, product liability, supply, competition and other risks); risks relating to interests of our largest stockholders that differ from our other stockholders; and the risk of substantial dilution of existing stockholders in future stock issuances.

We caution investors that actual results or business conditions may differ materially from those projected or suggested in forward-looking statements as a result of various factors including, but not limited to, those described above and in Section IA, "Risk Factors" of this Annual Report on Form 10-K for the fiscal year ended December 31, 2014 (this "Annual Report") and our other filings with the Securities and Exchange Commission ("SEC"). We cannot assure you that we have identified all the factors that create uncertainties. Moreover, new risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. Readers should not place undue reliance on forward-looking statements. We undertake no obligation to publicly release the result of any revision of these forward-looking statements to reflect events or circumstances after the date they are made or to reflect the occurrence of unanticipated events.

PART I

ITEM 1. BUSINESS.

CASI Pharmaceuticals, Inc. ("CASI" or the "Company") (Nasdaq: CASI) is a biopharmaceutical company focused on the acquisition, development and commercialization of innovative therapeutics addressing cancer and other unmet medical needs with a strategic commercial focus on the greater China market. Our mission is to deliver pharmaceutical drugs to patients with unmet medical needs directly in China, and in the rest of the world by establishing partnerships for global development and commercialization. We intend to become fully integrated with drug development and commercial operations.

We employ a diversified and risk-managed approach to our pipeline that includes (1) internal development of our lead proprietary drug candidate, ENMD-2076, leveraging resources and dual development in North America and China, (2) in-license or acquisition of late-stage clinical drug candidates, such as ZEVALIN®, MARQIBO®, and CE Melphalan, and (3) internal development of new drug candidates with clinically proven targets using our proprietary new drug delivery technology platform. Through partnerships, collaborations and strategic acquisitions, we intend to add additional drug candidates to our pipeline. The Company uses a market-oriented approach to identify pharmaceutical candidates that it believes have the potential for gaining widespread market acceptance, either globally or in China, and for which development can be accelerated under the Company's drug development strategy.

Our lead internal drug candidate is ENMD-2076, a selective Aurora A and angiogenic kinase inhibitor for the treatment of cancer, which we will continue to develop with approval by the United States Food and Drug Administration (the "FDA"). In parallel, we will include ENMD-2076 in clinical sites in China as an import drug as well as develop ENMD-2076 in China locally under the China Food and Drug Administration ("CFDA").

In September 2014, we acquired from Spectrum Pharmaceuticals, Inc. and certain of its affiliates (together referred to as "Spectrum") exclusive rights in greater China (including Taiwan, Hong Kong and Macau) to three in-licensed oncology products, including ZEVALIN® (ibritumomab tiuxetan) approved in the U.S. for advanced non-Hodgkin's lymphoma, MARQIBO® (vinCRIStine sulfate LIPOSOME injection) approved in the U.S. for advanced adult Ph- acute lymphoblastic leukemia (ALL), as well as Captisol Enabled™ melphalan (CE melphalan), which is the subject of a New Drug Application filed with FDA by Spectrum in 2014. We have initiated the regulatory and development process to obtain marketing approval for ZEVALIN and MARQIBO in our territorial region, and will initiate commercial activities of ZEVALIN in Hong Kong. We will continue to seek to expand our pipeline by acquiring additional drug candidates through in-license and acquisitions.

The Company's pipeline also includes 2ME2 (2-methoxyestradial), an orally active compound that has antiproliferative, antiangiogenic and anti-inflammatory properties. We intend to advance 2ME2 to clinical trials in using a new drug delivery form. Under the Company's new drug delivery technology platform, we intend to develop additional new drug candidates with clinically proven targets.

In order to capitalize on the drug development and capital resources available in China, the Company is doing business in China through its wholly-owned Chinese subsidiary that will execute the China portion of the Company's drug development strategy, including conducting clinical trials in China, pursuing local funding opportunities and strategic collaborations, and implementing the Company's plan for development and commercialization in the China market.

ENMD-2076

Our lead internal drug candidate is ENMD-2076. ENMD-2076 is an orally-active, Aurora A/angiogenic kinase inhibitor with a unique kinase selectivity profile and multiple mechanisms of action that has shown anti-angiogenic and anti-proliferative properties in multiple preclinical and clinical cancer studies. ENMD-2076 has been shown to inhibit a distinct profile of angiogenic tyrosine kinase targets in addition to the Aurora A kinase. Aurora kinases are key regulators of mitosis (cell division), and are often over-expressed in human cancers. ENMD-2076

also targets the VEGFR, Flt-3 and FGFR3 kinases, which have been shown to play important roles in the pathology of several cancers.

ENMD-2076 has demonstrated significant, dose-dependent preclinical activity as a single agent, including tumor regression, in multiple xenograft models (e.g. breast, colon, leukemia), as well as activity towards ex vivo-treated human leukemia patient cells. ENMD-2076 has shown promising activity in a completed Phase 1 clinical trial in various different solid tumor cancers including ovarian, breast, liver, renal and sarcoma, as well as in leukemia, and multiple myeloma, and has also completed a Phase 2 clinical trial in advanced ovarian cancer. In 2014 we completed a healthy volunteer crossover bioavailability and food effect study of ENMD-2076. We are currently conducting multiple Phase 2 studies of ENMD-2076 in triple-negative breast cancer (TNBC), advanced/metastatic soft tissue sarcoma (STS), and in advanced ovarian clear cell carcinomas (OCCC) in North America. In March 2015, the Company initiated a Phase 2 clinical trial of ENMD-2076 in TNBC at the Cancer Hospital of Chinese Academy of Medical Sciences in Beijing, China**,** as part of the Company's ongoing trial in TNBC in the U.S. The clinical trials in China will supplement our ongoing Phase 2 TNBC trial currently underway at the University of Colorado and Indiana University. In June 2013, we filed a new drug global clinical trial application (CTA) with the CFDA to expand our Phase 2 clinical trial of ENMD-2076 in advanced/metastatic sarcoma. In November 2014, the Company received CFDA's CTA approval to start an advanced/metastatic trial in China and currently is in the planning and discussion stage. The CFDA's approval of our application allows us to conduct clinical trials in China and supplement our ongoing Phase 2 advanced/metastatic sarcoma trial currently underway at Princess Margaret Hospital. The status of ENMD-2076 current trials is outlined below:

Disease Indication	***Status***	***Sites***
Triple-Negative Breast Cancer	U.S. Phase 2 trial being completed, enrollment closed	• University of Colorado • Indiana University
	China Phase 2 trial currently enrolling	• Cancer Hospital of Chinese Academy of Medical Sciences • Additional China site(s) to be determined
Advanced/Soft Tissue Sarcoma	Phase 2 trial currently enrolling	• Princess Margaret Hospital
	Received CFDA clinical trial application approval	• China site(s) to be determined
Advanced Ovarian Clear Cell Carcinoma	Phase 2 trial currently enrolling	• Princess Margaret Hospital
	New trial application accepted by CFDA, pending review and approval	• China site(s) to be determined

In January 2014, we filed a new drug global clinical trial application with the CFDA to expand our Phase 2 clinical trial of ENMD-2076 in advanced ovarian clear cell carcinoma. The CFDA has accepted our application package, and we are working with the CFDA to move the process forward towards approval. The CFDA's approval of our application would allow us to conduct clinical trials in China and supplement our ongoing Phase 2 ovarian clear cell carcinoma trial currently underway at Princess Margaret Hospital.

In September 2014, CASI filed an Investigational New Drug application (IND) with the FDA to conduct a Phase 2 trial in advanced fibrolamellar carcinoma (FLC). In February 2015, we conducted a meeting with the FDA and received formal guidance from the FDA regarding the clinical and regulatory path that may lead to market

approval of ENMD-2076 for the treatment of FLC. We also will be conducting a food effect study of ENMD-2076 in healthy human subjects and intend to move forward and are working with our principal investigators and the FLC patient community to initiate a trial in 2015.

ENMD-2076 has received orphan drug designation from the FDA for the treatment of ovarian cancer, multiple myeloma, acute myeloid leukemia and hepatocellular carcinoma (HCC). In the United States, the Orphan Drug Act is intended to encourage companies to develop therapies for the treatment of diseases that affect fewer than 200,000 people in this country. Orphan drug designation provides us with seven years of market exclusivity that begins once ENMD-2076 receives FDA marketing approval for a specific indication. It also provides certain financial incentives that can help support the development of ENMD-2076.

ENMD-2076 development is based on comprehensive research into the relationship between malignancy and angiogenesis (the growth of new blood vessels). ENMD-2076 acts on the cellular pathways that affect biological processes important in multiple diseases, specifically angiogenesis and cell cycle regulation through the inhibition of key kinases. ENMD-2076 has potential applications in oncology and other diseases that are dependent on the regulation of these processes.

ZEVALIN®

ZEVALIN® injection for intravenous use is a CD20-directed radiotherapeutic antibody. It is indicated for the treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL). ZEVALIN® is also indicated for the treatment of patients with previously untreated follicular non-Hodgkin's Lymphoma who achieve a partial or complete response to first-line chemotherapy. ZEVALIN® therapeutic regimen consists of two components: rituximab, and Yttrium-90 (Y-90) radiolabeled ZEVALIN® for therapy. ZEVALIN® builds on the combined effect of a targeted biologic monoclonal antibody augmented with the therapeutic effects of a beta-emitting radioisotope. Since ZEVALIN® is already approved in the U.S. and marketed by Spectrum, we expect that gaining approval from local regulatory authorities for commercialization in greater China will require a shorter timeframe compared to clinical-stage drugs. We are currently preparing the applications to initiate the regulatory and development process to obtain marketing approval for ZEVALIN in China and our other territorial regions and plan to initiate commercial activities of ZEVALIN in Hong Kong in 2015.

MARQIBO®

MARQIBO® is a novel, sphingomyelin/cholesterol liposome-encapsulated, formulation of vincristine sulfate, a microtubule inhibitor. MARQIBO® is approved by the FDA for the treatment of adult patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. MARQIBO® is already approved in the U.S. and marketed by our partner Spectrum. We are currently preparing the applications to initiate the regulatory and development process to obtain marketing approval for MARQIBO in China and our other territorial regions.

CE MELPHALAN

CE melphalan is a new intravenous formulation of melphalan being investigated by our licensor in the multiple myeloma transplant setting. The formulation avoids the use of propylene glycol, which is used as a co-solvent in the current formulation of melphalan and has been reported to cause renal and cardiac side-effects that limit the ability to deliver higher quantities of intended therapeutic compounds. The use of Captisol technology to reformulate melphalan is anticipated to allow for longer administration durations and slower infusion rates, potentially enabling clinicians to avoid reductions and safely achieve a higher dose intensity of pre-transplant chemotherapy. CE-Melphalan is the subject of a New Drug Application, which was filed by our partner Spectrum in 2014. We intend to submit our import drug registration application for CE melphalan in greater China after its approval by the FDA in the U.S.

2ME2 AND NEW DRUG DELIVERY TECHNOLOGY PLATFORM

Our pipeline also includes 2ME2 (2-methoxyestradial), an orally active compound that has antiproliferative, antiangiogenic and anti-inflammatory properties. The inhibition of angiogenesis is an important approach to the treatment of both cancer and autoimmune diseases such as rheumatoid arthritis. 2ME2 has potential as a single agent in rheumatoid arthritis based on its antiangiogenic, anti-inflammatory, and anti-osteoclastic (bone resorption) properties, and for which we have an approved IND. 2ME2 has also demonstrated positive preclinical results for multiple sclerosis. 2ME2 is currently under internal development using our new drug delivery technology platform. The Company intends to advance 2ME2 under its new drug delivery form into a clinical trial in 2015, and also intends to introduce other new drug candidates under this new drug delivery technology platform.

PRECLINICAL

Our focus is on clinical-stage or clinical-stage ready drug candidates so that we can immediately employ our U.S. and China drug development model to accelerate clinical and regulatory progress. We will however be opportunistic with innovative compounds presented to us and will continue to foster our deep relationships with the science, research and academic communities.

OPERATING LOSSES

To date, we have been engaged exclusively in research and development activities. As a result, we have incurred operating losses through December 31, 2014 and expect to continue to incur operating losses for the foreseeable future before commercialization of any products in key markets such as China. We spent $2,765,000 on research and development in 2014, as compared to $2,677,000 in 2013. The increase in research and development spending is associated with our China operations primarily related to the development our new drug delivery platform and also regulatory costs associated with Zevalin, as well as manufacturing costs associated with 2ME2, offset by a decrease in clinical trial costs related to the crossover bioavailability and food effect study of ENMD-2076 that took place in 2013. To accomplish our business goals, we, or prospective development partners, will be required to conduct substantial development activities for ENMD-2076 and any future product candidates that we intend to pursue to commercialization. We may continue to raise capital through the public or private sale of securities. There can be no assurance that we will be successful in securing such additional capital on favorable terms, if at all.

MANAGEMENT

The current senior management team includes: Dr. Ken K. Ren, Chief Executive Officer; Cynthia W. Hu, Chief Operating Officer, General Counsel & Secretary; and Sara B. Capitelli, Vice President, Finance & Principal Accounting Officer. As of March 1, 2015, Dr. Rong Chen has joined the Company as our Chief Medical Officer. The Company, as part of its normal operations, also has consulting relationships with a core team of experts in clinical trial design, FDA and CFDA strategy, scientific research, manufacturing and formulation, among others.

Our management team promotes and instills a corporate culture of prudent resource management, fiscal responsibility and accountability, while maintaining an environment of innovation and entrepreneurialism in order to quickly respond to opportunities and to react to any changes in market conditions and in the regulatory landscape.

BUSINESS DEVELOPMENT AND COMMERCIALIZATION STRATEGY

We intend to become fully integrated with drug development and commercial operations and deliver pharmaceutical drugs to patients with unmet medical needs directly in China, and in the rest of the world by establishing partnerships for global development and commercialization. Our diversified and risk-managed approach to expanding our pipeline includes (1) internal development of proprietary innovative drug candidates, such as our ENMD-2076, (2) in-license or acquisition of late-stage clinical drug candidates, such as ZEVALIN®, MARQIBO®, and CE Melphalan, and (3) internal development of new drug candidates with clinically proven targets using our proprietary new drug delivery technology platform. Our current external business development effort is

concentrated on acquiring additional drug candidates through in-license and acquisitions. We use a market-oriented approach to identify pharmaceutical candidates that we believe have the potential for gaining widespread market acceptance, either globally or in China, and for which development can be accelerated under the Company's drug development strategy. Although oncology is our principal clinical and commercial focus, we will be opportunistic about other pharmaceuticals that can address unmet medical needs.

We believe that ENMD-2076 has therapeutic potential in a broad range of tumor types. We will continue to advance ENMD-2076 in our current indications. We believe that for these indications ENMD-2076 represents a potential Phase 3 partnering opportunity for large pharmaceutical companies for territory rights outside of greater China. As a result, our strategy is to pursue the development of ENMD-2076, obtain additional clinical data while being selective and opportunistic in exploring strategic alliances for territories outside of greater China. We also intend to advance ENMD-2076 in fibrolamellar carcinoma, and for this smaller indication, we intend to maintain our global rights and commercialize on our own. Similarly, we believe that 2ME2 and other new drug candidates from our new drug delivery platform represent future partnering opportunities for large pharmaceutical companies for territory rights outside of greater China.

In 2012, we established a wholly-owned Chinese subsidiary that is executing the China portion of our drug development strategy, including conducting clinical trials in China, pursuing local funding opportunities and strategic collaborations, and implementing our plan for accelerated development and commercialization in the Chinese market.

RELATIONSHIPS RELATING TO CLINICAL PROGRAMS

Contract Manufacturing. The manufacturing efforts for the production of our clinical trial materials are performed by contract manufacturing organizations. Established relationships, coupled with supply agreements, have secured the necessary resources to supply clinical materials for our clinical development program. We believe that our current strategy of outsourcing manufacturing is cost-effective and allows for the flexibility we require.

Sponsored Research Agreements. To support development efforts, we may enter into sponsored research agreements with outside scientists to conduct specific projects. Under these agreements, we have secured the rights to intellectual property and to develop under exclusive license any discoveries resulting from these collaborations. The funds, if any, we provide in accordance with these agreements partially support the scientists' laboratory, research personnel and research supplies.

Clinical Trial Centers. As of March 24, 2015, we are conducting clinical trials for ENMD-2076 at the following institutions:

Clinical Trial	***Institution***
Phase 2 Triple-Negative Breast Cancer (being completed and enrollment closed in the U.S.; currently enrolling in China)	• University of Colorado Cancer Center, Aurora, CO • Indiana University Melvin & Bren Simon Cancer Center, Indianapolis, IN • Cancer Hospital of Chinese Academy of Medical Sciences, Beijing, China
Phase 2 Advanced/Soft Tissue Sarcoma (currently enrolling)	• Princess Margaret Hospital, Toronto, Ontario
Phase 2 Advanced Ovarian Clear Cell Carcinoma (currently enrolling)	• Princess Margaret Hospital, Toronto, Ontario

INTELLECTUAL PROPERTY

We generally seek patent protection for our technology and product candidates in the United States, Canada, China and other key markets. The patent position of biopharmaceutical companies generally is highly uncertain and involves complex legal and factual questions. Our success will depend, in part, on whether we can: (i) obtain patents to protect our own products; (ii) obtain licenses to use the technologies of third parties, which may be

protected by patents; (iii) protect our trade secrets and know-how; and (iv) operate without infringing the intellectual property and proprietary rights of others.

With respect to our internal lead drug candidate, ENMD-2076, we directly own 11 granted patents or allowed patent applications (including 2 granted United States patents, 1 granted Chinese patent, and 6 granted patents and 5 additional pending patent applications in other countries). The patent term for U.S. Patent No. 7,563,787 will expire March 5, 2027, assuming all maintenance fees are paid. If and when the FDA approves ENMD-2076, this patent term may be extended. The patent terms of our granted patents (including any patents issuing from our pending patent applications) in other countries will expire September 29, 2026, assuming all annuities are paid and not considering any term extensions for regulatory approval that might be available.

With respect to our internal drug candidate, 2ME2, we directly own 3 issued US patents, 1 pending US application, 5 granted foreign patents, and 1 pending foreign application. Assuming all maintenance fees are paid not considering any term extensions for regulatory approval that might be available, the patent term of US Patent No. 7,087,592 expires March 12, 2022, the patent term of US Patent No. 7,235,540 expires August 23, 2020, the patent term of US Patent No. 8,399,440 expires September 10, 2029, and, if granted, the patent term of US 13/789,849 will expire March 8, 2033. The corresponding foreign patents will expire August 23, 2020, and March 20, 2027, assuming all annuities are paid and not considering any term extensions for regulatory approval that might be available.

With regard to our in-licensed drug candidates, we have acquired exclusive licenses to intellectual property to enable us to develop and commercialize the drug candidates in our commercial markets.

We have pending trademark applications for CASI and CASI PHARMACEUTICALS.

We review and assess our portfolio on a regular basis to secure protection and to align our patent strategy with our overall business strategy.

GOVERNMENT REGULATION

U.S. Food and Drug Administration (FDA)

Our development, manufacture, and potential sale of therapeutics in the United States, China and other countries are subject to extensive regulations by federal, state, local and foreign governmental authorities.

In the United States, the FDA regulates product candidates currently being developed as drugs or biologics. New drugs are subject to regulation under the Federal Food, Drug, and Cosmetic Act (FFDCA), and biological products, in addition to being subject to certain provisions of that Act, are regulated under the Public Health Service Act (PHSA). We believe that the FDA will regulate the products currently being developed by us or our collaborators as new drugs. Both the FFDCA and PHSA and corresponding regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, storage, recordkeeping, advertising and other promotion of biologics or new drugs, as the case may be. FDA clearances or approvals must be obtained before clinical testing, and before manufacturing and marketing of biologics or drugs.

Preparing drug candidates for regulatory approval has historically been a costly and time-consuming process. Generally, in order to gain FDA permission to test a new agent, a developer first must conduct preclinical studies in the laboratory and in animal model systems to gain preliminary information on an agent's effectiveness and to identify any safety problems. The results of these studies are submitted as a part of an Investigational New Drug Application ("IND") for a drug or biologic, which the FDA must review before human clinical trials of an investigational drug can begin. In addition to the known safety and effectiveness data on the drug or biologic, the IND must include a detailed description of the clinical investigations proposed. Based on the current FDA organizational structure, ENMD-2076 is regulated as a new chemical entity by the FDA's Center for Drug Evaluation and Research. Generally, as new chemical entities like our small molecules are discovered, formal IND-directed toxicology studies are required prior to initiating human testing. Clinical testing may begin 30 days after

submission of an IND to the FDA unless FDA objects to the initiation of the study or has outstanding questions to discuss with the IND sponsor.

In order to commercialize any drug or biological products, we or our collaborators must sponsor and file an IND and conduct clinical studies to demonstrate the safety and effectiveness necessary to obtain FDA approval of such products. For studies conducted under INDs sponsored by us or our collaborators, we or our collaborators will be required to select qualified investigators (usually physicians within medical institutions) to supervise the administration of the products, test or otherwise assess patient results, and collect and maintain patient data; monitor the investigations to ensure that they are conducted in accordance with applicable requirements, including the requirements set forth in the general investigational plan and protocols contained in the IND; and comply with applicable reporting and recordkeeping requirements.

Clinical trials of drugs or biologics are normally done in three phases, although the phases may overlap. Phase 1 trials for drug candidates to be used to treat cancer patients are concerned primarily with the safety and preliminary effectiveness of the drug, involve a small group ranging from 15 - 40 subjects, and may take from six months to over one year to complete. Phase 2 trials normally involve 30 - 200 patients and are designed primarily to demonstrate effectiveness in treating or diagnosing the disease or condition for which the drug is intended, although short-term side effects and risks in people whose health is impaired may also be examined. Phase 3 trials are expanded clinical trials with larger numbers of patients which are intended to evaluate the overall benefit-risk relationship of the drug and to gather additional information for proper dosage and labeling of the drug. Phase 3 clinical trials generally take two to five years to complete, but may take longer. The FDA receives reports on the progress of each phase of clinical testing, as well as reports of unexpected adverse experiences occurring during the trial. The FDA may require the modification, suspension, or termination of clinical trials, if it concludes that an unwarranted risk is presented to patients, or, in Phase 2 and 3, if it concludes that the study protocols are deficient in design to meet their stated objectives.

If clinical trials of a new drug candidate are completed successfully, the sponsor of the product may seek FDA marketing approval. If the product is classified as a new drug, an applicant must file a New Drug Application (NDA) with the FDA and receive approval before marketing the drug commercially. The NDA must include detailed information about the product and its manufacturer and the results of product development, preclinical studies and clinical trials.

The testing and approval processes require substantial time and effort, and there can be no assurance that any approval will be obtained on a timely basis, if at all. Although it is the policy of the FDA to complete the review of the initial submission of NDAs within six to twelve months, the entire FDA review process may take several years. Notwithstanding the submission of relevant data, the FDA may ultimately decide that the NDA does not satisfy its regulatory criteria and deny the approval. Further, the FDA may require additional clinical studies before making a decision on approval. In addition, the FDA may condition marketing approval on the conduct of specific post-marketing studies to further evaluate safety and effectiveness. Even if FDA regulatory clearances are obtained, a marketed product is subject to continuing regulatory requirements and review relating to Good Manufacturing Practices, adverse event reporting, promotion and advertising, and other matters. Discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions.

China Food and Drug Administration (CFDA)

We are also subject to regulation and oversight by different levels of the food and drug administration in China, in particular, the CFDA. Our development activities in China follow two purposes: (1) to obtain clinical data to support our global FDA-regulated trials, and (2) to obtain clinical data to support local registration with the CFDA. The "Law of the PRC on the Administration of Pharmaceuticals," as amended on February 28, 2001, provides the basic legal framework for the administration of the production and sale of pharmaceuticals in China and covers the manufacturing, distributing, packaging, pricing and advertising of pharmaceutical products in China. Its implementation regulations set out detailed implementation rules with respect to the administration of

pharmaceuticals in China. We are also subject to other PRC laws and regulations that are applicable to manufacturers and distributors in general.

Product Manufacturing. To support local registration with the CFDA, both drug substance and drug product need to be manufactured locally in China through either a self-owned facility or a contract manufacturing organization. The drug substance and drug product to be used for clinical trials must be manufactured in compliance with CFDA Good Manufacturing Practice (GMP) guidelines. A manufacturer of pharmaceutical products and raw materials must obtain the GMP certification to produce pharmaceutical products and raw materials for marketing in China. GMP certification criteria include institution and staff qualifications, production premises and facilities, equipment, raw materials, hygiene conditions, production management, quality controls, product distributions, maintenance of sales records and manner of handling customer complaints and adverse reaction reports. A GMP certificate is valid for five years. The certificate must be renewed at least six months before its expiration date. A manufacturer is required to obtain GMP certificates to cover all of its production operations.

Our current drug substance and product for our China subsidiary has been and will be manufactured through contract manufacturing for clinical trials supporting local registration with the CFDA. They are all manufactured in compliance with CFDA GMP guidelines.

In addition, before commencing business, a pharmaceutical manufacturer must also obtain a business license from the relevant administration for industry and commerce.

Preclinical Research and Clinical Trials. Approval from the CFDA is required to conduct clinical trials. In order to apply for a clinical trial application approval to support local registration in China, a pharmaceutical company is required to conduct a series of preclinical research including research on chemistry, pharmacology, toxicology and pharmacokinetics of pharmaceuticals. This preclinical research should be conducted in compliance with the relevant regulatory guidelines issued by the CFDA. In particular, safety evaluation research must be conducted in compliance with China's Good Laboratory Practice.

After completion of preclinical studies and obtaining the clinical trial approval from the CFDA, clinical trials are conducted in compliance with China's Good Clinical Practice and include:

Phase 1 – preliminary trial of clinical pharmacology and human safety evaluation studies. The primary objective is to observe the pharmacokinetics and the tolerance level of the human body to the new medicine as a basis for ascertaining the appropriate methods of dosage.

Phase 2 – preliminary exploration on the therapeutic efficacy. The purpose is to assess preliminarily the efficacy and safety of pharmaceutical products on patients with the target indication of the pharmaceutical products and to provide the basis for the design and dosage tests for Phase 3. The dosing and methodology of research in this phase generally adopts double-blind, random methods with limited sample sizes.

Phase 3 – confirm the therapeutic efficacy. The objective is to further verify the efficacy and safety of pharmaceutical products on patients within the target indication, to evaluate the benefits and risks and finally to provide sufficient experimentally proven evidence to support the registration application of the pharmaceutical products. In general, the trial should adopt double-blind random methods with sufficient sample sizes.

Import Drug Registration or "Global" Clinical Trials. CFDA regulations allow foreign drug developers to conduct import drug registration or "global" clinical trials in China for a new drug as part of a global drug development program. A Global Clinical Trial Application needs to be filed with the CFDA and approval is required prior to conducting the trials. Before a Global Clinical Trial Application is filed with the CFDA, regulations require the investigational new product that is the subject of the trial to have at least completed a Phase 1 clinical trial overseas, and the new product must currently be in the process of later stages of development.

In order to apply for a Global Clinical Trial Application in China, a biopharmaceutical company is required

to submit a comprehensive investigation new drug application package filed with foreign regulatory agency, i.e. the FDA, in a format compliant with CFDA guidance.

After obtaining the global clinical trial approval from the CFDA, clinical trials are conducted in compliance with the both FDA/ICH and CFDA Good Clinical Practice guidelines.

New Drug Registration and Application. After completion of the 3 phases of clinical trials demonstrating the safety and effectiveness of a pharmaceutical in its targeted indication, a New Drug Registration Application needs to be filled with the CFDA, which includes research data of chemistry, manufacturing and controls, pre-clinical studies and clinical trials.

Once new drug registration approval is received, the product can be sold nationwide in China.

COMPETITION

Competition in the pharmaceutical, biotechnology and biopharmaceutical industries is intense and based significantly on scientific and technological factors, the availability of patent and other protection for technology and products, the ability and length of time required to obtain governmental approval for testing, manufacturing and marketing and the ability to commercialize products in a timely fashion. Moreover, the biopharmaceutical industry is characterized by rapidly evolving technology that could result in the technological obsolescence of any products that we develop.

We compete with many specialized biopharmaceutical firms, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. It is probable that the number of companies seeking to develop products and therapies for the treatment of unmet needs in oncology will increase. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including oncology and inflammation, and many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants.

The biopharmaceutical industry has undergone, and is expected to continue to undergo, rapid and significant technological change. Consolidation and competition are expected to intensify as technical advances in each field are achieved and become more widely known. In order to compete effectively, we will be required to continually expand our scientific expertise and technology, identify and retain capable personnel and pursue scientifically feasible and commercially viable opportunities.

Our competition will be determined in part by the potential indications for which our product candidates may be developed and ultimately approved by regulatory authorities. The relative speed with which we develop new products, complete clinical trials, obtain regulatory approvals, and complete the other requirements to get a pharmaceutical product on the market are critical factors in gaining a competitive advantage. We may rely on third parties to commercialize our products, and accordingly, the success of these products will depend in significant part on these third parties' efforts and ability to compete in these markets. The success of any collaboration will depend in part upon our collaborative partners' own competitive, marketing and strategic considerations, including the relative advantages of alternative products being developed and marketed by our collaborative partners and our competitors.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. In addition, many of these competitors have extensive experience in preclinical testing and human clinical trials and in obtaining regulatory approvals. The existence of competitive products, including products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of products that we may develop. Our competitors’ drugs may be more effective than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing our product candidates.

EMPLOYEES

Our work force, based in Rockville, Maryland and Beijing, China, currently consists of 20 full-time employees and 2 part-time employees. Certain of our activities, such as manufacturing and clinical trial operations, are outsourced at the present time. We may hire additional personnel, in addition to utilizing part-time or temporary consultants, on an as-needed basis. None of our employees are represented by a labor union, and we believe our relations with our employees are satisfactory.

CORPORATE HEADQUARTERS

We were incorporated under Delaware law in 1991. Our principal executive offices are located at 9620 Medical Center Drive, Suite 300, Rockville, Maryland 20850, and our telephone number is (240) 864-2600. We also lease office space in Beijing, China, where our China operations are based, and also lease laboratory space in Beijing, China which serves as our R&D Center.

CHINA OPERATIONS

In August 2012, we established a wholly-owned Chinese subsidiary and an office in Beijing, and in 2014, established a R&D Center in Beijing. Our staff in Beijing currently consists of 15 full-time employees. Among its activities, our Beijing office helps to oversee the Company's local manufacturing and formulation activities, as well as its CFDA regulatory activities. In addition, the Beijing office provides support to our business development activities.

AVAILABLE INFORMATION

Through our website at *www.casipharmaceuticals.com*, we make available, free of charge, our filings with the SEC, including our annual proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and all amendments thereto, as soon as reasonably practicable after such reports are filed with or furnished to the SEC. Our filings are also available through the SEC via their website, *http://www.sec.gov*. You may also read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The information contained on our website is not incorporated by reference in this Annual Report on Form 10-K (this "Annual Report") and should not be considered a part of this report.

ITEM 1A. RISK FACTORS.

Risks Relating to our Financial Position and Need for Additional Capital

We Have a History of Losses and Anticipate Future Losses and May Never Become Profitable on a Sustained Basis

To date, we have been engaged primarily in research and development activities. Although in the past we have received limited revenues on royalties from the sales of pharmaceuticals, license fees and research and development funding from a former collaborator and limited revenues from certain research grants, we have not derived significant revenues from operations.

We have experienced losses in each year since inception. Through December 31, 2014, we had an accumulated deficit of approximately $425 million. We will seek to raise capital to continue our operations and although we have been successfully funded to date through the sales of our equity securities and through limited royalty payments, there is no assurance that our capital-raising efforts will be able to attract the funding needed to sustain our operations. If we are unable to obtain additional funding for operations, we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations. In any such event, investors may lose a portion or all of their investment.

We expect that our ongoing clinical and corporate activities will result in operating losses for the foreseeable future before we commercialize any products, if ever. In addition, to the extent we rely on others to develop and commercialize our products, our ability to achieve profitability will depend upon the success of these other parties. To support our research and development of certain product candidates, we may seek and rely on cooperative agreements from governmental and other organizations as a source of support. If a cooperative agreement were to be reduced to any substantial extent, it may impair our ability to continue our research and development efforts. Even if we do achieve profitability, we may be unable to sustain or increase it.

Our Common Stock May be Delisted From The NASDAQ Capital Market, Which Could Negatively Impact the Price of Our Common Stock and Our Ability to Access the Capital Markets

If we are not able to comply with the listing standards of the Nasdaq Capital Market, our common stock will be delisted from Nasdaq and an associated decrease in liquidity in the market for our common stock will occur. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets, and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital on terms acceptable to us or at all. Delisting from The NASDAQ Capital Market could also result in other negative implications, including the potential loss of confidence by our research partners and suppliers, the loss of institutional investor interest and fewer business development opportunities.

We May Engage in Strategic and Other Corporate Transactions, Which Could Negatively Affect Our Financial Condition and Prospects

We may consider strategic and other corporate transactions as opportunities present themselves. There are risks associated with such activities. These risks include, among others, incorrectly assessing the quality of a prospective strategic partner, encountering greater than anticipated costs in integration, being unable to profitably deploy assets acquired in the transaction, such as drug candidates, possible dilution to our stockholders, and the loss of key employees due to changes in management. Further, strategic transactions may place additional constraints on our resources by diverting the attention of our management from our business operations. To the extent we issue securities in connection with additional transactions, these transactions and related issuances may have a dilutive effect on earnings per share and our ownership. Our financial condition and prospects after an acquisition depend in part on our ability to successfully integrate the operations of the acquired business or technologies. We may be unable to integrate operations successfully or to achieve expected cost savings. Any cost savings which are realized may be offset by losses in revenues or other charges to earnings.

The Current Capital and Credit Market Conditions May Adversely Affect the Company's Access to Capital, Cost of Capital, and Ability to Execute its Business Plan as Scheduled

Access to capital markets is critical to our ability to operate. Traditionally, biopharmaceutical companies (such as we) have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets over the past few years have severely restricted raising new capital in amounts sufficient to conduct our ENMD-2076 program and have affected our ability to continue to expand or fund research and development efforts with our other product candidates. We require significant capital for research and development for our product candidates and clinical trials. In recent years, the general economic and capital market conditions in the United States have deteriorated significantly and have adversely affected our access to capital and increased the cost of capital, and there is no certainty that a recovery in the capital and credit markets, enabling us to raise capital in an amount to sufficiently fund our short-term and long-term plans, will occur in 2015. If these economic conditions continue or become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, our inability to access the capital markets on favorable terms because of our low stock price, or upon our delisting from the NASDAQ Capital Market if we fail to satisfy a listing requirement, could affect our ability to execute our business plan as scheduled. Moreover, we rely and intend to rely on third parties, including our clinical research organizations, third party manufacturers, and certain other important vendors and consultants. As a result of the current volatile and unpredictable global economic situation, there may be a disruption or delay in the performance of our third-party contractors and suppliers. If such third parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

We Do Not Have Any Active Revenue Streams and We Are Uncertain Whether Additional Funding Will Be Available For Our Future Capital Needs and Commitments. If We Cannot Raise Additional Funding, or Access the Capital Markets, We May Be Unable to Complete Development of Our Product Candidates

We will require substantial funds in addition to our existing working capital to develop our product candidates and otherwise to meet our business objectives. We have never generated sufficient revenue during any period since our inception to cover our expenses and have spent, and expect to continue to spend, substantial funds to continue our clinical development programs. Any one of the following factors, among others, could cause us to require additional funds or otherwise cause our cash requirements in the future to increase materially:

- progress of our clinical trials or correlative studies;
- results of clinical trials;
- changes in or terminations of our relationships with strategic partners;
- changes in the focus, direction, or costs of our research and development programs;
- competitive and technological advances;
- establishment of marketing and sales capabilities;
- manufacturing;
- the regulatory approval process; or
- product launch.

At December 31, 2014, we had cash of approximately $10,670,000. We currently have no commitments or arrangements for any new additional financing. We may continue to seek additional capital through public or private financing or collaborative agreements in 2015 and beyond. Our operations require significant amounts of cash. We may be required to seek additional capital for the future growth and development of our business. We can give no assurance as to the availability of such additional capital or, if available, whether it would be on terms acceptable to us. In addition, we may continue to seek capital through the public or private sale of securities, if market conditions are favorable for doing so. If we are successful in raising additional funds through the issuance of equity securities, stockholders will likely experience substantial dilution. If we are not successful in obtaining sufficient capital because we are unable to access the capital markets on favorable terms, it could reduce our research and development efforts, curtail significantly our development of ENMD-2076 and materially adversely affect our future growth, results of operations and financial results.

Risks Relating to Our Business

We Plan To Conduct Development And Operations In China, Which Exposes Us To Risks Inherent In Doing Business In China

We expect to continue to conduct clinical development related activities in China in 2015. To be successful in China we will need to: establish clinical trials; attract and retain qualified personnel to operate our Chinese subsidiary; and attract and retain research and development employees. We cannot assure you that we will be able to do any of these. Employee turnover in China is high due to the intensely competitive and fluid market for skilled labor. Operations in China are subject to greater political, legal and economic risks than our operations in other countries. In particular, the political, legal and economic climate in China, both nationally and regionally, is fluid and unpredictable. Our ability to operate in China may be adversely affected by changes in Chinese laws and regulations such as those related to, among other things, taxation, import and export tariffs, environmental regulations, land use rights, intellectual property, employee benefits and other matters. In addition, we may not obtain or retain the requisite legal permits to operate in China, and costs or operational limitations may be imposed in connection with obtaining and complying with such permits. Any one of the factors cited above, or a combination of them, could result in unanticipated costs, which could materially and adversely affect our business and planned operations and development in China.

We May Not Be Able To Successfully Identify And Acquire New Product Candidates

Our growth strategy relies on our in-license of new product candidates from third parties. Our pipeline will be dependent upon the availability of suitable acquisition candidates at favorable prices and upon advantageous terms and conditions. Even if such opportunities are present, we may not be able to successfully identify appropriate acquisition candidates. Moreover, other companies, many of which may have substantially greater financial resources are competing with us for the right to acquire such product candidates.

If a product candidate is identified, the third parties with whom we seek to cooperate may not select us as a potential partner or we may not be able to enter into arrangements on commercially reasonable terms or at all. Furthermore, the negotiation and completion of collaborative and license arrangements could cause significant diversion of management's time and resources and potential disruption of our ongoing business**.**

Development of Our Products is Uncertain

ENMD-2076 is in Phase 2 development and our other product candidates were in the early stage of clinical development and require significant, time-consuming and costly research and development, testing and regulatory clearances. In developing our products, we are subject to risks of failure that are inherent in the development of these product candidates. For example, it is possible that any or all of our proposed products will be ineffective or toxic, or otherwise will fail to receive necessary FDA and CFDA clearances. There is a risk that the proposed products will be uneconomical to manufacture or market or will not achieve market acceptance. There is also a risk that third parties may hold proprietary rights that preclude us from marketing our proposed products or that others will market a superior or equivalent product. Further, our research and development activities might never result in commercially viable products.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials. Since ENMD-2076 is our primary product candidate any significant clinical setback or an unfavorable outcome in our Phase 2 trials for ENMD-2076 may require us to delay, reduce the scope of, or eliminate this program and could have a material adverse effect on our company and the value of our common stock.

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including:

- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated retention rate of patients in clinical trials;
- serious adverse events or side effects experienced by participants; and
- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

Many of these factors may also ultimately lead to denial of regulatory approval of a product candidate. If we experience delays, suspensions or terminations in a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

Although product candidates may demonstrate promising results in early clinical (human) trials and preclinical (animal) studies, they may not prove to be effective in subsequent clinical trials. For example, testing on animals may occur under different conditions than testing in humans and therefore the results of animal studies may not accurately predict human experience. Likewise, early clinical studies may not be predictive of eventual safety or effectiveness results in larger-scale pivotal clinical trials. Our clinical development primary focus is on ENMD-2076, and as such we do not expect to internally pursue clinical investigation of our other product candidates.

There are many regulatory steps that must be taken before any of these product candidates will be eligible for regulatory approval and subsequent sale, including the completion of preclinical and clinical trials. We do not expect that our product candidates will be commercially available for several years, if ever.

We May Not Be Able to Commercialize Our Drugs or Drug Candidates in China

We have exclusive licenses to develop and commercialize MARQIBO® (vinCRIStine sulfate LIPOSOME injection), Captisol-Enabled™ (propylene glycol-free) melphalan (CE melphalan) and ZEVALIN® (ibritumomab tiuxetan) in Greater China. Our success in commercializing these drugs may be inhibited by a number of factors, including:

- our inability to obtain regulatory approvals;
- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we decide to rely on third parties to sell, market and distribute our product candidates, we may not be successful in entering into arrangements with such third parties or may be unable to do so on terms that are favorable to us. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates, which would adversely affect our business and financial condition.

Developments By Competitors May Render Our Products Obsolete

If competitors were to develop superior drug candidates, our products could be rendered noncompetitive or obsolete, resulting in a material adverse effect to our business. Developments in the biotechnology and pharmaceutical industries are expected to continue at a rapid pace. Success depends upon achieving and maintaining a competitive position in the development of products and technologies. Competition from other biotechnology and pharmaceutical companies can be intense. Many competitors have substantially greater research and development capabilities, marketing, financial and managerial resources and experience in the industry. Even if a competitor creates a product that is not superior, we may not be able to compete.

We Must Show the Safety and Efficacy of Our Product Candidates Through Clinical Trials, the Results of Which are Uncertain

Before obtaining regulatory approvals for the commercial sale of our products, we must demonstrate, through preclinical studies (animal testing) and clinical trials (human testing), that our proposed products are safe and effective for use in each target indication. Testing of our product candidates will be required, and failure can occur at any stage of testing. Clinical trials may not demonstrate sufficient safety and efficacy to obtain the required regulatory approvals or result in marketable products. The failure to adequately demonstrate the safety and efficacy of a product under development could delay or prevent regulatory approval of the potential product.

Clinical trials for the product candidates we are developing may be delayed by many factors, including that potential patients for testing are limited in number. The failure of any clinical trials to meet applicable regulatory

standards could cause such trials to be delayed or terminated, which could further delay the commercialization of any of our product candidates. Newly emerging safety risks observed in animal or human studies also can result in delays of ongoing or proposed clinical trials. Any such delays will increase our product development costs. If such delays are significant, they could negatively affect our financial results and the commercial prospects for our products.

The Independent Clinical Investigators and Contract Research Organizations That We Rely Upon to Assist in the Conduct of Our Clinical Trials May Not Be Diligent, Careful or Timely, and May Make Mistakes, in the Conduct of Our Trials

We depend on independent clinical investigators and contract research organizations, or CROs, to assist in the conduct of our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, it could delay the approval of our FDA applications and our introduction of new drugs. The CROs we contract with to assist with the execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our products.

The Success of Our Business Depends Upon the Members of Our Senior Management Team, Our Clinical Development Expertise in Both U.S. and China, and Our Ability to Continue to Attract and Retain Qualified Clinical, Technical and Business Personnel

We are dependent on the principal members of our senior management team and clinical development team for our business success. The loss of any of these people could impede the achievement of our development and business objectives. We do not carry key man life insurance on the lives of any of our key personnel. There is intense competition for human resources, including management, in the scientific fields in which we operate and there can be no assurance that we will be able to attract and retain qualified personnel necessary for the successful development of ENMD-2076 and any new product candidates, and any expansion into areas and activities requiring additional expertise. In addition, there can be no assurance that such personnel or resources will be available when needed. In addition, we rely on a significant number of consultants to assist us in formulating our clinical strategy and other business activities. All of our consultants may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

We May Need New Collaborative Partners to Further Develop and Commercialize Products, and if We Enter Into Such Arrangements, We May Give Up Control Over the Development and Approval Process and Decrease our Potential Revenue

We plan to develop and commercialize our product candidates both with and without corporate alliances and partners. Nonetheless, we intend to explore opportunities for new corporate alliances and partners to help us develop, commercialize and market our product candidates. We expect to grant to our partners certain rights to commercialize any products developed under these agreements, and we may rely on our partners to conduct research and development efforts and clinical trials on, obtain regulatory approvals for, and manufacture and market any products licensed to them. Each individual partner will seek to control the amount and timing of resources devoted to these activities generally. We anticipate obtaining revenues from our strategic partners under such relationships in the form of research and development payments and payments upon achievement of certain milestones. Since we generally expect to obtain a royalty for sales or a percentage of profits of products licensed to third parties, our revenues may be less than if we retained all commercialization rights and marketed products directly. In addition, there is a risk that our corporate partners will pursue alternative technologies or develop competitive products as a means for developing treatments for the diseases targeted by our programs.

We may not be successful in establishing any collaborative arrangements. Even if we do establish such collaborations, we may not successfully commercialize any products under or derive any revenues from these arrangements. There is a risk that we will be unable to manage simultaneous collaborations, if any, successfully. With respect to existing and potential future strategic alliances and collaborative arrangements, we will

depend on the expertise and dedication of sufficient resources by these outside parties to develop, manufacture, or market products. If a strategic alliance or collaborative partner fails to develop or commercialize a product to which it has rights, we may not recognize any revenues on that particular product.

We Have No Current Manufacturing or Marketing Capacity and Rely on Only One Supplier For Some of Our Products

We do not expect to manufacture or market products in the near term, but we may try to do so in certain cases. We do not currently have the capacity to manufacture or market products and we have limited experience in these activities. The manufacturing processes for all of the small molecules we are developing have not yet been tested at commercial levels, and it may not be possible to manufacture these materials in a cost-effective manner. If we elect to perform these functions, we will be required to either develop these capacities, or contract with others to perform some or all of these tasks. We may be dependent to a significant extent on corporate partners, licensees, or other entities for manufacturing and marketing of products. If we engage directly in manufacturing or marketing, we will require substantial additional funds and personnel and will be required to comply with extensive regulations. We may be unable to develop or contract for these capacities when required to do so in connection with our business.

We depend on our third-party manufacturers to perform their obligations effectively and on a timely basis. These third parties may not meet their obligations and any such non-performance may delay clinical development or submission of products for regulatory approval, or otherwise impair our competitive position. Any significant problem experienced by one of our suppliers could result in a delay or interruption in the supply of materials to us until such supplier resolves the problem or an alternative source of supply is located. Any delay or interruption would likely lead to a delay or interruption of manufacturing operations, which could negatively affect our operations. Although we have identified alternative suppliers for our product candidates, we have not entered into contractual or other arrangements with them. If we needed to use an alternate supplier for any product, we would experience delays while we negotiated an agreement with them for the manufacture of such product. In addition, we may be unable to negotiate manufacturing terms with a new supplier as favorable as the terms we have with our current suppliers.

Problems with any manufacturing processes could result in product defects, which could require us to delay shipment of products or recall products previously shipped. In addition, any prolonged interruption in the operations of the manufacturing facilities of one of our sole-source suppliers could result in the cancellation of shipments. A number of factors could cause interruptions, including equipment malfunctions or failures, or damage to a facility due to natural disasters or otherwise. Because our manufacturing processes are or are expected to be highly complex and subject to a lengthy regulatory approval process, alternative qualified production capacity may not be available on a timely basis or at all. Difficulties or delays in our manufacturing could increase our costs and damage our reputation.

The manufacture of pharmaceutical products can be an expensive, time consuming, and complex process. Manufacturers often encounter difficulties in scaling-up production of new products, including quality control and assurance and shortages of personnel. Delays in formulation and scale-up to commercial quantities could result in additional expense and delays in our clinical trials, regulatory submissions, and commercialization.

Failure of Manufacturing Facilities Producing Our Product Candidates to Maintain Regulatory Approval Could Delay or Otherwise Hinder Our Ability to Market Our Product Candidates

Any manufacturer of our product candidates will be subject to applicable Good Manufacturing Practices (GMP) prescribed by the FDA or other rules and regulations prescribed by the CFDA and other foreign regulatory authorities. We and any of our collaborators may be unable to enter into or maintain relationships either domestically or abroad with manufacturers whose facilities and procedures comply or will continue to comply with GMP and who are able to produce our small molecules in accordance with applicable regulatory standards. Failure by a manufacturer of our products to comply with GMP could result in significant time delays or our inability to obtain marketing approval or, should we have market approval, for such approval to continue. Changes in our manufacturers could require new product testing and facility compliance inspections. In the United States, failure to

comply with GMP or other applicable legal requirements can lead to federal seizure of violated products, injunctive actions brought by the federal government, inability to export product, and potential criminal and civil liability on the part of a company and its officers and employees.

We Depend on Patents and Other Proprietary Rights, Some of Which are Uncertain

Our success will depend in part on our ability to obtain and maintain patents for ENMD-2076 and our other products, in the United States, China and elsewhere. The patent position of biotechnology and pharmaceutical companies in general is highly uncertain and involves complex legal and factual questions. Risks that relate to patenting our products include the following:

- our failure to obtain additional patents;
- challenge, invalidation, or circumvention of patents already issued to us;
- failure of the rights granted under our patents to provide sufficient protection;
- independent development of similar products by third parties; or
- ability of third parties to design around patents issued to our collaborators or us.

Our potential products may conflict with composition, method, and use of patents that have been or may be granted to competitors, universities or others. As the biotechnology industry expands and more patents are issued, the risk increases that our potential products may give rise to claims that may infringe the patents of others. Such other persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected products. Any such litigation could result in substantial cost to us and diversion of effort by our management and technical personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. We may not prevail in any action and any license required under any needed patent might not be made available on acceptable terms, if at all.

We also rely on trade secret protection for our confidential and proprietary information. However, trade secrets are difficult to protect and others may independently develop substantially equivalent proprietary information and techniques and gain access to our trade secrets and disclose our technology. We may be unable to meaningfully protect our rights to unpatented trade secrets. We require our employees to complete confidentiality training that specifically addresses trade secrets. All employees, consultants, and advisors are required to execute a confidentiality agreement when beginning an employment or a consulting relationship with us. The agreements generally provide that all trade secrets and inventions conceived by the individual and all confidential information developed or made known to the individual during the term of the relationship automatically become our exclusive property. Employees and consultants must keep such information confidential and may not disclose such information to third parties except in specified circumstances. However, these agreements may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure of such information.

To the extent that consultants, key employees, or other third parties apply technological information independently developed by them or by others to our proposed projects, disputes may arise as to the proprietary rights to such information. Any such disputes may not be resolved in our favor. Certain of our consultants are employed by or have consulting agreements with other companies and any inventions discovered by them generally will not become our property.

Our Potential Products Are Subject to Government Regulatory Requirements and an Extensive Approval Process

Our research, development, preclinical and clinical trials, manufacturing, and marketing of our product candidates are subject to an extensive regulatory approval process by the FDA, the CFDA in China and other regulatory agencies. The process of obtaining FDA, CFDA and other required regulatory approvals for drug and biologic products, including required preclinical and clinical testing, is time consuming and expensive. Even after

spending time and money, we may not receive regulatory approvals for clinical testing or for the manufacturing or marketing of any products. Our collaborators or we may encounter significant delays or costs in the effort to secure necessary approvals or licenses. Even if we obtain regulatory clearance for a product, that product will be subject to continuing review. Later discovery of previously unknown defects or failure to comply with the applicable regulatory requirements may result in restrictions on a product's marketing or withdrawal of the product from the market, as well as possible civil or criminal penalties.

Potential Products May Subject Us to Product Liability for Which Insurance May Not Be Available

The use of our potential products in clinical trials and the marketing of any pharmaceutical products may expose us to product liability claims. We have obtained a level of liability insurance coverage that we believe is adequate in scope and coverage for our current stage of development. However, our present insurance coverage may not be adequate to protect us from liabilities we might incur. In addition, our existing coverage will not be adequate as we further develop products and, in the future, adequate insurance coverage and indemnification by collaborative partners may not be available in sufficient amounts or at a reasonable cost. If a product liability claim or series of claims are brought against us for uninsured liabilities, or in excess of our insurance coverage, the payment of such liabilities could have a negative effect on our business and financial condition.

Risks Relating to Our Common Stock

The Market Price of Our Common Stock May Be Highly Volatile or May Decline Regardless of Our Operating Performance

Our common stock price has fluctuated from year-to-year and quarter-to-quarter and will likely continue to be volatile. During 2014, our stock price has ranged from $1.16 to $2.17. We expect that the trading price of our common stock is likely to be highly volatile in response to factors that are beyond our control. The valuations of many biotechnology companies without consistent product revenues and earnings are extraordinarily high based on conventional valuation standards, such as price to earnings and price to sales ratios. These trading prices and valuations may not be sustained. In the future, our operating results in a particular period may not meet the expectations of any securities analysts whose attention we may attract, or those of our investors, which may result in a decline in the market price of our common stock. Any negative change in the public's perception of the prospects of biotechnology companies could depress our stock price regardless of our results of operations. These factors may materially and adversely affect the market price of our common stock.

IDG and Spectrum Are Our Largest Holders Of Common Stock And May Have Different Interests Than Our Other Stockholders

IDG-Accel China and its affiliated entities (collectively, "IDG") hold approximately 16.80% of the outstanding shares of our common stock (excluding the shares issuable under the warrants held by IDG). Spectrum Pharmaceuticals, Inc., a Delaware corporation and its affiliate, Spectrum Pharmaceuticals Cayman, L.P., an Exempted Limited Partnership organized under the laws of the Cayman Islands (together "Spectrum") hold approximately 16.66% of the outstanding shares of our common stock. IDG and Spectrum are each permitted to have one representative on the Board of Directors and may have interests that are different from the interests of our other stockholders. We cannot assure that IDG and Spectrum will not seek to influence our business in a manner that is contrary to our goals or strategies or the interests of our other stockholders. In addition, the significant concentration of ownership in our common stock may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with significant stockholders. IDG and Spectrum, if they acted together, could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. IDG and Spectrum together may be able to determine all matters requiring stockholder approval.

Subsequent Resales Of Shares Of Our Common Stock In The Public Market May Cause The Market Price Of Our Common Stock To Fall

The market value of our common stock could decline as a result of sales by investors from time to time, or perceptions that such sales may occur, of a substantial amount of the shares of common stock held by them.

Issuances of Additional Shares of Our Common Stock May Cause Substantial Dilution of Existing Stockholders

Spectrum has a contingent right to purchase shares of our common stock at par value ($0.01 per share) in order to maintain its post-investment equity ownership percentage as of September 17, 2014, which was 16.66%, if we issue securities (subject to a limited exception for certain equity compensation grants) in the future. This right expires upon the earliest of (1) the date on which we have raised, in the aggregate, $50 million in net proceeds through capital raising activities or (2) September 17, 2019 (subject to extension for certain outstanding derivative securities). The future exercise of this contingent purchase right will subject our existing stockholders to immediate dilution of their ownership interests. We may also issue additional shares of common stock or other securities that are convertible into or exercisable for common stock in connection with future acquisitions, future sales of our securities for capital raising purposes, future strategic relationships, or for other business purposes. The future issuance of any additional shares of our common stock may create downward pressure on the trading price of our common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock are then traded.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 2. PROPERTIES.

As of December 31, 2014, we leased approximately 4,200 square feet of office space in Rockville, Maryland where our headquarters are located. In addition, as of December 31, 2014, we leased approximately 2,000 square feet of office space in Beijing, China where our China operations are based and approximately 3,200 square feet of laboratory space in Beijing, China. We believe that our existing facilities are adequate to meet our needs for the foreseeable future. We do not own any real property.

ITEM 3. LEGAL PROCEEDINGS.

CASI is subject in the normal course of business to various legal proceedings in which claims for monetary or other damages may be asserted. Management does not believe such legal proceedings, except as otherwise disclosed herein, are material.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market for Common Equity

The following table sets forth the high and low closing price for our common stock by quarter, as reported by the NASDAQ Capital Market, for the periods indicated:

Closing Prices	HIGH	LOW
2013:		
First Quarter	$ 3.47	$ 1.38
Second Quarter	2.25	1.73
Third Quarter	2.04	1.75
Fourth Quarter	1.90	1.55
2014:		
First Quarter	$ 2.17	$ 1.69
Second Quarter	1.97	1.62
Third Quarter	2.03	1.55
Fourth Quarter	1.79	1.16

On March 18, 2015, the closing price of our common stock, as reported by The NASDAQ Capital Market, was $1.50 per share. As of March 18, 2015 there were approximately 391 holders of record of our common stock.

Dividend Policy

Since our initial public offering in 1996, we have not paid cash dividends on our common stock. We currently anticipate that any earnings will be retained for the continued development of our business and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion should be read in conjunction with the Consolidated Financial Statements and Notes thereto appearing elsewhere in this report. See also “Risk Factors” in Item 1A of this Annual Report.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of innovative therapeutics addressing cancer and other unmet medical needs with a strategic commercial focus on the greater China market. Our mission is to deliver pharmaceutical drugs to patients with unmet medical needs directly in China, and in the rest of the world by establishing partnerships for global development and commercialization. We intend to become fully integrated with drug development and commercial operations.

We employ a diversified and risk-managed approach to our pipeline that includes (1) internal development of our lead proprietary drug candidate, ENMD-2076, leveraging resources and dual development in North America and China, (2) in-license or acquisition of late-stage clinical drug candidates, such as ZEVALIN®, MARQIBO®, and CE Melphalan, and (3) internal development of new drug candidates with clinically proven targets using our proprietary new drug delivery technology platform. Through partnerships, collaborations and strategic acquisitions,

we intend to add additional drug candidates to our pipeline. The Company uses a market-oriented approach to identify pharmaceutical candidates that it believes have the potential for gaining widespread market acceptance, either globally or in China, and for which development can be accelerated under the Company's drug development strategy.

Our lead internal drug candidate is ENMD-2076, a selective Aurora A and angiogenic kinase inhibitor for the treatment of cancer, which we will continue to develop with approval by the FDA. In parallel, we will include ENMD-2076 in clinical sites in China as an import drug as well as develop ENMD-2076 in China locally under the CFDA.

In September 2014, we acquired from Spectrum exclusive rights in greater China (including Taiwan, Hong Kong and Macau) to three in-licensed oncology products, including ZEVALIN® (ibritumomab tiuxetan) approved in the U.S. for advanced non-Hodgkin's lymphoma, MARQIBO® (vinCRIStine sulfate LIPOSOME injection) approved in the U.S. for advanced adult Ph- acute lymphoblastic leukemia (ALL), as well as Captisol Enabled™ melphalan (CE melphalan), which is the subject of a New Drug Application filed with the FDA by Spectrum in 2014. We have initiated the regulatory and development process to obtain marketing approval for ZEVALIN and MARQIBO in our territorial region, and will initiate commercial activities of ZEVALIN in Hong Kong. We will continue to seek to expand our pipeline by acquiring additional drug candidates through in-license and acquisitions.

The Company's pipeline also includes 2ME2 (2-methoxyestradial), an orally active compound that has antiproliferative, antiangiogenic and anti-inflammatory properties. We intend to advance 2ME2 to clinical trials in using a new drug delivery form. Under the Company's new drug delivery technology platform, we intend to develop additional new drug candidates with clinically proven targets.

We intend to advance clinical development of our drugs and drug candidates, and the implementation of our plans will include leveraging our resources in both the United States and China. In order to capitalize on the drug development and capital resources available in China, the Company is doing business in China through its wholly-owned Chinese subsidiary that will execute the China portion of the Company's drug development strategy, including conducting clinical trials in China, pursuing local funding opportunities and strategic collaborations, and implementing the Company's plan for development and commercialization in the China market.

ENMD-2076

Our lead internal drug candidate is ENMD-2076. ENMD-2076 is an orally-active, Aurora A/angiogenic kinase inhibitor with a unique kinase selectivity profile and multiple mechanisms of action that has shown anti-angiogenic and anti-proliferative properties in multiple preclinical and clinical cancer studies. ENMD-2076 has been shown to inhibit a distinct profile of angiogenic tyrosine kinase targets in addition to the Aurora A kinase. Aurora kinases are key regulators of mitosis (cell division), and are often over-expressed in human cancers. ENMD-2076 also targets the VEGFR, Flt-3 and FGFR3 kinases, which have been shown to play important roles in the pathology of several cancers.

ENMD-2076 has demonstrated significant, dose-dependent preclinical activity as a single agent, including tumor regression, in multiple xenograft models (e.g. breast, colon, leukemia), as well as activity towards ex vivo-treated human leukemia patient cells. ENMD-2076 has shown promising activity in a completed Phase 1 clinical trial in various different solid tumor cancers including ovarian, breast, liver, renal and sarcoma, as well as in leukemia, and multiple myeloma, and has also completed a Phase 2 clinical trial in advanced ovarian cancer. In 2014 we completed a healthy volunteer crossover bioavailability and food effect study of ENMD-2076. We are currently conducting multiple Phase 2 studies of ENMD-2076 in triple-negative breast cancer (TNBC), advanced/metastatic soft tissue sarcoma (STS), and in advanced ovarian clear cell carcinomas (OCCC) in North America. In March 2015, the Company initiated a Phase 2 clinical trial of ENMD-2076 in TNBC at the Cancer Hospital of Chinese Academy of Medical Sciences in Beijing, China**,** as part of the Company's ongoing trial in TNBC in the U.S. The clinical trials in China will supplement our ongoing Phase 2 TNBC trial currently underway at the University of Colorado and Indiana University. In June 2013, we filed a new drug global clinical trial application (CTA) with the CFDA to expand our Phase 2 clinical trial of ENMD-2076 in advanced/metastatic sarcoma. In November 2014, the

Company received CFDA's CTA approval to start an advanced/metastatic trial in China and currently is in the planning and discussion stage. The CFDA's approval of our application allows us to conduct clinical trials in China and supplement our ongoing Phase 2 advanced/metastatic sarcoma trial currently underway at Princess Margaret Hospital.

In January 2014, we filed a new drug global clinical trial application with the CFDA to expand our Phase 2 clinical trial of ENMD-2076 in advanced ovarian clear cell carcinoma. The CFDA has accepted our application package, and we are working with the CFDA to move the process forward towards approval. The CFDA's approval of our application would allow us to conduct clinical trials in China and supplement our ongoing Phase 2 ovarian clear cell carcinoma trial currently underway at Princess Margaret Hospital.

In September 2014, CASI filed an IND with the FDA to conduct a Phase 2 trial in advanced fibrolamellar carcinoma (FLC). In February 2015, we conducted a meeting with the FDA and received formal guidance from the FDA regarding the clinical and regulatory path that may lead to market approval of ENMD-2076 for the treatment of FLC. We also will be conducting a food effect study of ENMD-2076 in healthy human subjects and intend to move forward and are working with our principal investigators and the FLC patient community to initiate a trial in 2015.

ENMD-2076 has received orphan drug designation from the FDA for the treatment of ovarian cancer, multiple myeloma, acute myeloid leukemia and hepatocellular carcinoma (HCC).

ENMD-2076 development is based on comprehensive research into the relationship between malignancy and angiogenesis (the growth of new blood vessels). ENMD-2076 acts on the cellular pathways that affect biological processes important in multiple diseases, specifically angiogenesis and cell cycle regulation through the inhibition of key kinases. ENMD-2076 has potential applications in oncology and other diseases that are dependent on the regulation of these processes.

ZEVALIN®

ZEVALIN® injection for intravenous use is a CD20-directed radiotherapeutic antibody. It is indicated for the treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL). ZEVALIN® is also indicated for the treatment of patients with previously untreated follicular non-Hodgkin's Lymphoma who achieve a partial or complete response to first-line chemotherapy. ZEVALIN® therapeutic regimen consists of two components: rituximab, and Yttrium-90 (Y-90) radiolabeled ZEVALIN® for therapy. ZEVALIN® builds on the combined effect of a targeted biologic monoclonal antibody augmented with the therapeutic effects of a beta-emitting radioisotope. Since ZEVALIN® is already approved in the U.S. and marketed by Spectrum, we expect that gaining approval from local regulatory authorities for commercialization in greater China will require a shorter timeframe compared to clinical-stage drugs. We are currently preparing the applications to initiate the regulatory and development process to obtain marketing approval for ZEVALIN in China and our other territorial regions and plan to initiate commercial activities of ZEVALIN in Hong Kong in 2015.

MARQIBO®

MARQIBO® is a novel, sphingomyelin/cholesterol liposome-encapsulated, formulation of vincristine sulfate, a microtubule inhibitor. MARQIBO® is approved by the FDA for the treatment of adult patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. MARQIBO® is already approved in the U.S. and marketed by our partner Spectrum. We are currently preparing the applications to initiate the regulatory and development process to obtain marketing approval for MARQIBO in China and our other territorial regions.

CE MELPHALAN

CE melphalan is a new intravenous formulation of melphalan being investigated by our licensor in the multiple myeloma transplant setting. The formulation avoids the use of propylene glycol, which is used as a co-solvent in the current formulation of melphalan and has been reported to cause renal and cardiac side-effects that limit the ability to deliver higher quantities of intended therapeutic compounds. The use of Captisol technology to reformulate melphalan is anticipated to allow for longer administration durations and slower infusion rates, potentially enabling clinicians to avoid reductions and safely achieve a higher dose intensity of pre-transplant chemotherapy. CE Melphalan is the subject of a New Drug Application, which was filed by our partner Spectrum in 2014. We intend to submit our import drug registration application for CE melphalan in greater China after its approval by the FDA in the U.S.

2ME2 AND NEW DRUG DELIVERY TECHNOLOGY PLATFORM

Our pipeline also includes 2ME2 (2-methoxyestradial), an orally active compound that has antiproliferative, antiangiogenic and anti-inflammatory properties. The inhibition of angiogenesis is an important approach to the treatment of both cancer and autoimmune diseases such as rheumatoid arthritis. 2ME2 has potential as a single agent in rheumatoid arthritis based on its antiangiogenic, anti-inflammatory, and anti-osteoclastic (bone resorption) properties, and for which we have an approved IND. 2ME2 has also demonstrated positive preclinical results for multiple sclerosis. 2ME2 is currently under internal development using our new drug delivery technology platform. The Company intends to advance 2ME2 under its new drug delivery form into a clinical trial in 2015, and also intends to introduce other new drug candidates under this new drug delivery technology platform.

Since inception, we have incurred significant losses from operations and have incurred an accumulated deficit of $425.3 million. We expect to continue to incur operating losses for the foreseeable future due to, among other factors, our continuing clinical activities. We expect our current available cash and cash equivalents to meet our cash requirements for at least the next twelve months. We will continue to exercise tight controls over operating expenditures. In developing drug candidates, we intend to use and leverage resources available to us in both the United States and China. We intend to pursue additional financing opportunities as well as opportunities to raise capital through forms of non- or less- dilutive arrangements, such as partnerships and collaborations with organizations that have capabilities and/or products that are complementary to our capabilities and products in order to continue the development of our product candidate that we intend to pursue to commercialization. However, there can be no assurance that adequate additional financing under such arrangements will be available to us on terms that we deem acceptable, if at all.

On March 1, 2013, the Company entered into a definitive agreement with certain investors (the "2013 Investors") for a registered financing in the aggregate amount of approximately $10.8 million (the "2013 Financing"). In connection with the 2013 Financing, we entered into a Securities Purchase Agreement with the 2013 Investors pursuant to which the Company agreed to sell in a registered transaction 4,495,828 shares of the Company's common stock and warrants to purchase up to an aggregate of 2,247,912 shares of common stock (the "2013 Warrants"). The 2013 Warrants cover a number of shares of common stock equal to 50% of the number of shares purchased by each 2013 Investor. The 2013 Warrants have an exercise price of $2.91 per share and were exercisable beginning on September 4, 2013 and expire on September 4, 2016. The Company completed the closings on the 2013 Financing on March 14, 2013 and received net proceeds of approximately $10.3 million.

Additional funds raised by issuing equity securities may result in dilution to existing shareholders.

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. Our critical accounting policies, including the items in our financial statements requiring significant estimates and judgments, are as follows:

- *Revenue Recognition* - We recognize revenue in accordance with the provisions of authoritative guidance issued, whereby revenue is not recognized until it is realized or realizable and earned. Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price to the buyer is fixed and determinable and collectibility is reasonably assured.

- *Research and Development* - Research and development expenses consist primarily of compensation and other expenses related to research and development personnel, research collaborations, costs associated with preclinical testing and clinical trials of our product candidates, including the costs of manufacturing drug substance and drug product, regulatory maintenance costs, and facilities expenses. Research and development costs are expensed as incurred.

- *Expenses for Clinical Trials* – Expenses for clinical trials are incurred from planning through patient enrollment to reporting of the data. We estimate expenses incurred for clinical trials that are in process based on patient enrollment and based on clinical data collection and management. Costs that are associated with patient enrollment are recognized as each patient in the clinical trial completes the enrollment process. Estimated clinical trial costs related to enrollment can vary based on numerous factors, including expected number of patients in trials, the number of patients that do not complete participation in a trial, and when a patient drops out of a trial. Costs that are based on clinical data collection and management are recognized in the reporting period in which services are provided. In the event of early termination of a clinical trial, we accrue an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial.

- *Stock-Based Compensation* – All share-based payment transactions are recognized in the financial statements at their fair values. Compensation expense associated with service, performance, market condition based stock options and other equity-based compensation is recorded in accordance with provisions of authoritative guidance. The fair value of awards whose fair values are calculated using the Black-Scholes option pricing model is generally being amortized on a straight-line basis over the requisite service period and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period. The fair value of awards with market conditions, which are valued using a binomial model, is being amortized based upon the estimated derived service period. Share based awards granted to employees with a performance condition are measured based on the probable outcome of that performance condition during the requisite service period. Such an award with a performance condition will be expensed if it is probable that a performance condition will be achieved. For the three months ended September 30, 2014, non-cash compensation expense of $686,600 was recorded for share awards with performance conditions that became probable during the period. Using the straight-line expense attribution method over the requisite service period, which is generally the option vesting term ranging from immediately to one to three years, share-based compensation expense recognized in the years ended December 31, 2014 and 2013 totaled approximately $2,189,000 and $2,044,000, respectively.

  The determination of fair value of stock-based payment awards on the date of grant using the Black-Scholes or binomial model is affected by our stock price, as well as the input of other subjective assumptions. These assumptions include, but are not limited to, the expected forfeiture rate and expected term of stock options and our expected stock price volatility over the term of the awards. Changes in the assumptions can materially affect the fair value estimates.

  Any future changes to our share-based compensation strategy or programs would likely affect the amount of compensation expense recognized.

- *Fair Value Measurements* – At each reporting period, we perform a detailed analysis of our assets and liabilities that are measured at fair value. All assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3 within the in accordance with the hierarchy established by U.S. GAAP. During the twelve months ended December 31, 2014, we measured the Contingent Rights and our promissory note issued to Spectrum at fair value at the date of issuance, and each quarter we

remeasured the Contingent Rights at fair value and will continue to do so at every balance sheet date until settlement. In measuring the fair value of both financial instruments we used Level 3 unobservable inputs, including such inputs as our estimated borrowing rate and our future capital requirements, and the timing, probability, size and characteristics of those capital raises, among other inputs.

RESULTS OF OPERATIONS

Years Ended December 31, 2014 and 2013.

Revenues and Cost of Product Sales. Revenues were approximately $23,700 in 2014. There was no revenue recorded in 2013. Our product sales in 2014 related to the dosing of Zevalin to one patient in Hong Kong for compassionate use purposes. The cost of this sale for 2014 was $7,467 related to the cost of the Zevalin Kit, Isotope purchase and upstream royalty payable. Approximately $960 was payable to Spectrum for the Zevalin Kit purchase.

Research and Development Expenses. Our 2014 research and development expenses totaled $2,765,000 as compared to $2,677,000 in 2013, a 3% increase. In 2014, our research and development expenses reflect direct project costs for ENMD-2076 of $970,000, $187,000 for 2ME2 and $419,000 for development of our new drug delivery platform that we began in late 2013 in China. The 2013 amount reflects direct project costs for ENMD-2076 of $1,418,000, $33,000 for 2ME2 and $65,000 for development of our new drug delivery platform. The increase in 2014 research and development spending reflects increased costs associated with our China operations primarily related to development of our new drug delivery platform and also regulatory costs associated with Zevalin, as well as manufacturing costs associated with 2ME2. This was offset by a decrease in clinical trial costs related to the crossover bioavailability and food effect study of ENMD-2076 that took place in 2013, as well as a decrease in non-cash stock-based compensation expense in 2014 as compared to 2013.

At December 31, 2014, accumulated direct project expenses for 2ME2 were $58,282,000 and, since acquired, accumulated direct project expenses for ENMD-2076 totaled $24,404,000, and for development of our new drug delivery platform, accumulated project expenses totaled $484,000. Our research and development expenses also include non-cash stock-based compensation totaling $690,000 and $763,000, respectively, for 2014 and 2013. The decrease in stock-based compensation expense is related to the decrease in stock options granted in 2014. The balance of our research and development expenditures includes facility costs and other departmental overhead, and expenditures related to the non-clinical support of our programs.

We expect the majority of our research and development expenses in 2015 to be devoted to the development of our ENMD-2076 program, advancement of our new drug delivery platform in China, as well as the submission of import drug registration applications to regulatory authorities in China for the drugs in-licensed from Spectrum. We expect our expenses in 2015 to increase based on our clinical development plan. We will continue to conduct research on ENMD-2076 in order to comply with stipulations made by the FDA, as well as to increase understanding of the mechanism of action and toxicity parameters of ENMD-2076 and its metabolites. Completion of clinical development may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate.

We estimate that clinical trials of the type we generally conduct are typically completed over the following timelines:

Global FDA Trial:

CLINICAL PHASE	***ESTIMATED COMPLETION PERIOD***
Phase 1	1-2 Years
Phase 2	2-3 Years
Phase 3	2-4 Years

Local CFDA Trial:

CLINICAL PHASE	***ESTIMATED COMPLETION PERIOD***
Phase 1	1 Year
Phase 2	2 Years
Phase 3	2-3 Years

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial protocol, including, among others, the following:

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that seems appropriate in view of the results;
- the number of clinical sites included in the trials; and
- the length of time required to enroll suitable patient subjects.

We test our potential product candidates in numerous preclinical studies to identify indications for which they may be product candidates. We may conduct multiple clinical trials to cover a variety of indications for each product candidate. As we obtain results from trials, we may elect to discontinue clinical trials for certain indications in order to focus our resources on more promising indications.

Our proprietary product candidates have also not yet achieved regulatory approval, which is required before we can market them as therapeutic products. In order to proceed to subsequent clinical trial stages and to ultimately achieve regulatory approval, regulatory agencies must conclude that our clinical data establish safety and efficacy. Historically, the results from preclinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

Our business strategy includes being opportunistic with collaborative arrangements with third parties to complete the development and commercialization of our product candidates. In the event that third parties take over the clinical trial process for one of our product candidates, the estimated completion date would largely be under the control of that third party rather than us. We cannot forecast with any degree of certainty which proprietary products or indications, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect our capital requirements.

As a result of the uncertainties discussed above, among others, we are unable to estimate the duration and completion costs of our research and development projects. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. There can be no assurance that we will be able to successfully access external sources of financing in the future. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

Research and development expenses consist primarily of compensation and other expenses related to research and development personnel, research collaborations, costs associated with internal and contract preclinical testing and clinical trials of our product candidates, including the costs of manufacturing drug substance and drug product, regulatory maintenance costs, and facilities expenses. Overall research and development expenses increased to $2,765,000 in 2014 from $2,677,000 in 2013.

The fluctuations in research and development expenses were specifically impacted by the following:

- *Outside Services* – We utilize outsourcing to conduct our product development activities. We spent $127,000 in 2014 and $41,000 in 2013. The increase in 2014 is primarily associated with greater regulatory activities for ENMD-2076 and Zevalin.

- *Clinical Trial Costs* – Clinical trial costs, which include clinical site fees, monitoring costs and data management costs, decreased to $175,000 in 2014, from $647,000 in 2013. This decrease relates to costs associated with enrolling patients in Phase 2 clinical trials for TNBC during 2013 as well as higher costs associated with clinical research organization fees related to our crossover bioavailability and food effect study of ENMD-2076 during 2013.

- *Contract Manufacturing Costs* – The costs of manufacturing the material used in clinical trials for our product candidates is reflected in contract manufacturing. These costs include bulk manufacturing, encapsulation and fill and finish services, and product release costs. Contract manufacturing costs increased in 2014 to $388,000, from $212,000 in 2013. The increase in 2014 primarily reflects the manufacturing costs incurred in 2014 in the U.S. related to the production of new formulated capsules of ENMD-2076 as well as manufacturing of 2ME2 in China.

- *Personnel Costs* – Personnel costs increased to $1,514,000 in 2014 from $1,331,000 in 2013. This variance is primarily attributed to increased salary and benefit costs associated with new employees in China during 2014.

- Also reflected in our 2014 research and development expenses are outsourced consultant costs of $151,000, and facility and related expenses of $214,000. In 2013, these expenses totaled $176,000 and $110,000, respectively. The fluctuation in outsourced consultant costs reflects the timing of clinical trial management, including site visits and regulatory activities. The increase in costs associated with facilities and related expenses in 2014 resulted from leased laboratory space in China.

General and Administrative Expenses. General and administrative expenses include compensation and other expenses related to finance, business development and administrative personnel, professional services and facilities.

General and administrative expenses increased to $3,757,000 in 2014 from $3,063,000 in 2013. This increase is primarily related to an increase of $218,000 related to non-cash stock-based compensation in 2014 due mainly to the vesting of performance based options during 2014, and an increase in outside professional fees associated with business development, investor relations and corporate name change activities during 2014.

In-process R&D. In September 2014, we acquired certain product rights and perpetual exclusive licenses from Spectrum to develop and commercialize the three commercial oncology drugs and drug candidates in China, Taiwan, Hong Kong and Macau. As consideration for the acquisition, we issued a total 5,405,382 shares of our common stock, a $1.5 million 0.5% secured promissory note due in March 2016, and certain contingent rights ("Contingent Rights") to purchase additional shares of our common stock. We accounted for the acquisition of the product rights and licenses as an "asset acquisition" and, accordingly, recorded the acquired product rights and licenses at their estimate fair values based on the fair value of the consideration exchanged (including transaction costs) of approximately $19.7 million. Because the products underlying the acquired product rights and licenses have not reached technological feasibility and have no alternative uses, they are considered "in-process research and development" costs; as such, we expensed the total purchase price at the acquisition date as acquired in-process R&D in the accompanying consolidated statements of operations.

Interest expense, net. Interest expense for the year ended December 31, 2014 was $28,064. This includes $2,142 accrued interest on our note payable and non-cash interest of $25,922 representing the amortization of the debt discount. There was no interest expense for the year ended December 31, 2013. Interest income for the years ended December 31, 2014 and 2013 was $1,483 and $1,658, respectively.

Change in fair value of contingent rights. The Contingent Rights issued to Spectrum in connection with the license arrangements are considered derivative liabilities and were recorded initially at their estimated fair value, and are marked to market each reporting period until settlement. The change in fair value of the Contingent Rights for the year ended December 31, 2014 was $11,764.

LIQUIDITY AND CAPITAL RESOURCES

To date, we have been engaged primarily in research and development activities. As a result, we have incurred and expect to continue to incur operating losses in 2015 and the foreseeable future before we commercialize any products and penetrate significant markets such as China. Based on our current plans, we expect our current available cash and cash equivalents to meet our cash requirements for at least the twelve months subsequent to December 31, 2014.

We will require significant additional funding to fund operations until such time, if ever, we become profitable. We intend to augment our cash balances by pursuing other forms of capital infusion, including strategic alliances or collaborative development opportunities with organizations that have capabilities and/or products that are complementary to our capabilities and products in order to continue the development of our potential product candidates that we intend to pursue to commercialization. If we seek strategic alliances, licenses, or other alternative arrangements, such as arrangements with collaborative partners or others, to raise further financing, we may need to relinquish rights to certain of our existing product candidates, or products we would otherwise seek to develop or commercialize on our own, or to license the rights to our product candidates on terms that are not favorable to us.

We will continue to seek to raise additional capital to fund our research and development and advance the clinical development of ENMD-2076 and new product candidates, if any. We intend to explore one or more of the following alternatives to raise additional capital:

- selling additional equity securities;
- out-licensing product candidates to one or more corporate partners;
- completing an outright sale of non-priority assets; and/or
- engaging in one or more strategic transactions.

We also will continue to manage our cash resources prudently and cost-effectively.

There can be no assurance that adequate additional financing under such arrangements will be available to us on terms that we deem acceptable, if at all. If additional funds are raised by issuing equity securities, dilution to existing shareholders may result, or the equity securities may have rights, preferences, or privileges senior to those of the holders of our common stock. If we fail to obtain additional capital when needed, we may be required to delay or scale back our Phase 2 plans for ENMD-2076 or plans for other product candidates, if any.

At December 31, 2014, we had cash of $10,669,919, with working capital of $10,102,748.

FINANCING ACTIVITIES

On September 27, 2012, we filed a Form S-3 registration statement with the SEC utilizing a "shelf" registration process. On October 9, 2012, the Form S-3 registration statement was declared effective by the SEC. Pursuant to this shelf registration statement, we may sell debt or equity securities in one or more offerings up to a total public offering price of $30.0 million. We believe that this shelf registration statement currently provides us additional flexibility with regard to potential financings that we may undertake when market conditions permit or our financial condition may require. Our registered direct equity financing completed on March 14, 2013 (see below) was offered under the shelf registration statement.

On March 1, 2013, the Company entered into a definitive agreement with the 2013 Investors for a registered financing in the aggregate amount of approximately $10.8 million. In connection with the 2013 Financing, we entered into a Securities Purchase Agreement with the 2013 Investors pursuant to which the Company agreed to sell in a registered transaction 4,495,828 shares of the Company's common stock and warrants to purchase up to an aggregate of 2,247,912 shares of common stock. The 2013 Warrants cover a number of shares of common stock equal to 50% of the number of shares purchased by each 2013 Investor. The 2013 Warrants have an exercise price of $2.91 per share and are exercisable on September 4, 2013 and expire on September 4, 2016. The Company completed the closings on the 2013 Financing on March 14, 2013 and received net proceeds of approximately $10.3 million.

INFLATION AND INTEREST RATE CHANGES

Management does not believe that our working capital needs are sensitive to inflation and changes in interest rates.

TABLE OF CONTRACTUAL OBLIGATIONS

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

OFF-BALANCE-SHEET ARRANGEMENTS

We had no off-balance sheet arrangements during fiscal year 2014.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The response to this item is submitted in a separate section of this report. See Index to Consolidated Financial Statements on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

As of December 31, 2014, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Accounting Officer (our principal executive officer and principal financial officer, respectively) and our Chief Operating Officer & General Counsel, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e)). Our Chief Executive Officer, Principal Accounting Officer and Chief Operating Officer & General Counsel have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to our management (including our Chief Executive Officer, Principal Accounting Officer, and Chief Operating Officer & General Counsel) to allow timely decisions regarding required disclosures. Based on such evaluation, our Chief Executive Officer, Principal Accounting Officer, and Chief Operating Officer & General Counsel have concluded these disclosure controls are effective as of December 31, 2014.

Changes in Internal Control Over Financial Reporting

There have not been any changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2014 that have materially affected, or are 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 such term is defined in Securities Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is designed to provide reasonable assurance to our management and board of directors regarding the reliability of financial reporting and the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted accounting principles. Any internal control over financial reporting, no matter how well designed, has inherent limitations. As a result of these inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those internal controls determined to be effective can provide only reasonable assurance with respect to reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our management, including our Chief Executive Officer, Chief Operating Officer & General Counsel and Principal Accounting Officer, we conducted an assessment of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework*. Based on our assessment, we concluded that our internal control over financial reporting was effective as of December 31, 2014.

ITEM 9B. OTHER INFORMATION.

Our 2015 Annual Meeting of Stockholders will be held on June 8, 2015. Further information will be provided in our proxy statement that will be filed with the SEC and mailed to stockholders of record as soon as practicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2014.

We have adopted a Code of Ethics, as defined in applicable SEC rules, that applies to directors, officers and employees, including our principal executive officer and principal accounting officer. The Code of Ethics is available on the Company's website at *www.casipharmaceuticals.com*.

ITEM 11. EXECUTIVE COMPENSATION.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2014.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required under this item, with the exception of information relating to compensation plans under which equity securities of the Company are authorized for issue, which appears below, is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2014.

Options under Employee Benefit Plans

The following table discloses certain information about the options issued and available for issuance under all outstanding Company option plans, as of December 31, 2014.

	(a)	(b)	(c)
Plan category	***Number of securities to be issued upon exercise of outstanding options, warrants and rights***	***Weighted-average exercise price of outstanding options, warrants and rights***	***Number of securities remaining available for future issuance under equity compensation plans [excluding securities reflected in column (a)]***
Equity compensation plans approved by security holders	4,557,682	$2.40	1,615,752
Equity compensation plans not approved by security holders	0	$ 0.00	0
Total	4,557,682	$2.40	1,615,752

Warrants issued under the unauthorized plans represent compensation for consulting services rendered by the holders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2014.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2014.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) 1. FINANCIAL STATEMENTS - See index to Consolidated Financial Statements.

2. Schedules

All financial statement schedules are omitted because they are not applicable, not required under the instructions or all the information required is set forth in the financial statements or notes thereto.

3. Exhibits

2.1	Agreement and Plan of Merger, dated as of December 22, 2005 among EntreMed, Inc., E.M.K. Sub, Inc., Miikana Therapeutics, Inc., and Andrew Schwab (incorporated by reference to Exhibit 2.1 of our Form 8-K filed with the Securities and Exchange Commission on December 29, 2005)
3.1	Amended and Restated Certificate of Incorporation of EntreMed, Inc. (incorporated by reference to Exhibit 3.1 of our Form 10-Q for the quarter ended June 30, 2006 filed with the Securities and Exchange Commission)
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on July 7, 2010)
3.3	Amended and Restated Bylaws of EntreMed, Inc. (incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on December 12, 2007)
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on June 13, 2014)
4.1	Certificate of Elimination of Series A Preferred Stock filed with the Secretary of State of Delaware on September 13, 2012. (Incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on September 20, 2012.)
4.2	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on January 26, 2012)
4. 3	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Form 8-K filed with the Securities and Exchange Commission on March 6, 2013)
4.4	Form of Agent's Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of our Form 8-K filed with the Securities and Exchange Commission on March 6, 2013)
4.5	Certificate of Designation of Series A Preferred Stock (incorporated by reference to Exhibit 4.1 of our Form 8-K filed with the Securities and Exchange Commission on September 19, 2014)
4.6	Secured Promissory Note, dated as of September 17, 2014, issued to Talon Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 of our Form 8-K filed with the Securities and Exchange Commission on September 19, 2014)
10.1	License Agreement between Celgene Corporation and EntreMed, Inc. signed December 9, 1998 regarding thalidomide intellectual property + (incorporated by reference to Exhibit 10.28 of our Form 10-K for the year ended December 31, 1998 filed with the Securities and Exchange Commission)

10.2	Lease Agreement between EntreMed, Inc. and Red Gate III Limited Partnership, dated June 10, 1998 (incorporated by reference to Exhibit 10.31 our Form 10-K for the year ended December 31, 1998 filed with the Securities and Exchange Commission)
10.3	EntreMed, Inc. 2001 Long-Term Incentive Plan* (incorporated by reference to Appendix A to our Definitive Proxy Statement filed with the Securities and Exchange Commission on May 12, 2006)
10.4.1	Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated June 15, 2001+ (incorporated by reference to Exhibit 10.39.1 of our Form 10-Q for the quarter ended June 30, 2001 filed with the Securities and Exchange Commission)
10.4.2	Amendment 1 to Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated July 13, 2001(incorporated by reference to Exhibit 10.39.2 of our Form 10-Q for the quarter ended June 30, 2001 filed with the Securities and Exchange Commission)
10.4.3	Amendment 2 to Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated July 30, 2001(incorporated by reference to Exhibit 10.39.3 of our Form 10-Q for the quarter ended June 30, 2001 filed with the Securities and Exchange Commission)
10.4.4	Amendment 3 to Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated August 3, 2001 (incorporated by reference to Exhibit 10.39.4 of our Form 10-Q for the quarter ended June 30, 2001 filed with the Securities and Exchange Commission)
10.5	EntreMed, Inc. 2001 Long Term Incentive Plan Non-Qualified Stock Option Grant Agreement (Director)* (incorporated by reference to Exhibit 10.7 of our Form 8-K filed with the Securities and Exchange Commission on April 17, 2007)
10.6	EntreMed, Inc. 2001 Long Term Incentive Plan Non-Qualified Stock Option Grant Agreement (Non-Director Employee)* (incorporated by reference to Exhibit 10.8 of our Form 8-K filed with the Securities and Exchange Commission on April 17, 2007)
10.7	Form of Change in Control Agreement* (incorporated by reference to Exhibit 19.1 of our Form 8-K filed with the Securities and Exchange Commission on April 17, 2007)
10.8	Employment Agreement by and between EntreMed and Cynthia W. Hu, dated as of June 1, 2006* (incorporated by reference to Exhibit 10.1 of Form 8-K filed with the Securities and Exchange Commission on June 6, 2006)
10.9	Amendment to Employment Agreement by and between the Company and Cynthia W. Hu, effective April 16, 2007* (incorporated by reference to Exhibit 10.5 of our Form 8-K filed with the Securities and Exchange Commission on April 17, 2007)
10.10	Form of Restricted Stock Award under EntreMed, Inc. 2001 Long Term Incentive Plan* (incorporated by reference to Exhibit 10.2 of our Form 8-K filed with the Securities and Exchange Commission on March 11, 2005)
10.11	License Agreement between EntreMed and Celgene Corporation signed March 23, 2005 regarding the development and commercialization of Celgene's small molecule tubulin inhibitor compounds for the treatment of cancer+ (incorporated by reference to Exhibit 10.25 of our Form 10-Q for the quarter ended March 31, 2005 filed with the Securities and Exchange Commission)
10.12	Securities Purchase Agreement, dated September 7, 2010 by and between EntreMed, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on September 10, 2010)

10.13	Employment Agreement, by and between EntreMed, Inc. and Sara Capitelli, dated as of January 10, 2011* (incorporated by reference to Exhibit 10.33 of our Form 10-K for the fiscal year ended December 31, 2010 filed with the Securities and Exchange Commission)
10.14	Convertible Note and Warrant Purchase Agreement, dated January 20, 2012, by and among EntreMed, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on January 26, 2012)
10.15	EntreMed, Inc. 2011 Long-Term Incentive Plan* (incorporated by reference to Appendix A of our Definitive Proxy Statement filed with the Securities and Exchange Commission on April 16, 2013)
10.16	Employment Agreement by and between EntreMed, Inc. and Ken K. Ren, dated as of March 30, 2012* (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on April 3, 2012)
10.17	Securities Purchase Agreement, dated March 1, 2013, by and among EntreMed, Inc. and the investors thereto (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on March 6, 2013)
10.18	Employment Agreement by and between EntreMed, Inc. and Ken K. Ren, dated as of April 2, 2013* (incorporated by reference to Exhibit 10.1 of our Form 10-Q filed with the Securities and Exchange Commission on May 15, 2013)
10.19	EntreMed, Inc. 2011 Long-Term Incentive Plan, as amended* (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 21, 2014)
10.20	Investment Agreement, dated as of September 17, 2014, by and between CASI Pharmaceuticals, Inc. and Spectrum Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on September 19, 2014)
10.21	Investment Agreement, dated as of September 17, 2014, by and between CASI Pharmaceuticals, Inc. the Company and Spectrum Pharmaceuticals Cayman, L.P (incorporated by reference to Exhibit 10.2 of our Form 8-K filed with the Securities and Exchange Commission on September 19, 2014)
10.22	License Agreement, dated as of September 17, 2014, by and between CASI Pharmaceuticals, Inc. and Spectrum Pharmaceuticals, Inc. + (incorporated by reference to Exhibit 10.3 of our Form 10-Q/A filed with the Securities and Exchange Commission on January 21, 2015)
10.23	License Agreement, dated as of September 17, 2014, by and between CASI Pharmaceuticals, Inc. and Spectrum Pharmaceuticals Cayman, L.P. + (incorporated by reference to Exhibit 10.4 of our Form 10-Q/A filed with the Securities and Exchange Commission on January 21, 2015)
10.24	License Agreement, dated as of September 17, 2014, by and between CASI Pharmaceuticals, Inc. and Talon Therapeutics, Inc. + (incorporated by reference to Exhibit 10.5 of our Form 10-Q/A filed with the Securities and Exchange Commission on January 21, 2015)
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a) Certification of Principal Accounting Officer
32.1	Rule 13a-14(b) Certification by Chief Executive Officer
32.2	Rule 13a-14(b) Certification by Principal Accounting Officer

101**	Interactive Data Files The following financial information from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2014 and 2013, (ii) Consolidated Statements of Operations for the years ended December 31, 2014 and 2013, (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2014 and 2013 (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2014 and 2013 and (v) Notes to Consolidated Financial Statements.

*	Management Contract or any compensatory plan, contract or arrangement.
+	Certain portions of this exhibit have been omitted based upon a request for confidential treatment. The omitted portions have been filed with the Commission pursuant to our application for confidential treatment.
**	Filed herewith

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.

Date: March 27, 2015

CASI Pharmaceuticals, Inc.

By: /s/Ken K. Ren
Ken K. Ren
Chief Executive Officer

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

SIGNATURE	TITLE	DATE
/s/Ken K. Ren Ken K. Ren	Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2015
/s/Sara B. Capitelli Sara B. Capitelli	Principal Accounting Officer	March 27, 2015
/s/Wei-Wu He Wei-Wu He	Chairman	March 27, 2015
/s/James Z. Huang James Z. Huang	Director	March 27, 2015
/s/Tak W. Mak Tak W. Mak	Director	March 27, 2015
/s/Franklin C. Salisbury Franklin C. Salisbury	Director	March 27, 2015
/s/Rajesh C. Shrotriya Rajesh C. Shrotriya	Director	March 27, 2015
/s/Y. Alexander Wu Y. Alexander Wu	Director	March 27, 2015

The following consolidated financial statements of CASI Pharmaceuticals, Inc. are included in Item 8:

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
CASI Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheets of CASI Pharmaceuticals, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for the years then ended. CASI Pharmaceuticals, Inc.'s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated 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 consolidated financial statements are free of material misstatement. The company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of CASI Pharmaceuticals, Inc. as of December 31, 2014 and 2013, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ CohnReznick LLP

Vienna, Virginia
March 27, 2015

CASI Pharmaceuticals, Inc.
Consolidated Balance Sheets

	DECEMBER 31, 2014	DECEMBER 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,669,919	$ 15,131,671
Accounts receivable, net of allowance for doubtful accounts of $12,536 at December 31, 2014 and 2013	23,727	-
Prepaid expenses and other	328,150	279,773
Total current assets	11,021,796	15,411,444
Property and equipment, net	261,781	78,142
Other assets	26,011	17,965
Total assets	$ 11,309,588	$ 15,507,551
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 754,628	$ 402,456
Accrued liabilities	164,420	162,710
Total current liabilities	919,048	565,166
Note payable, net of discount	1,390,015	-
Contingent rights derivative liability	9,422,735	-
Total liabilities	11,731,798	565,166
Commitments and contingencies	-	-
Stockholders' equity (deficit) :		
Convertible preferred stock, $1.00 par value; 5,000,000 shares authorized and 0 shares issued and outstanding at December 31, 2014 and 2013	-	-
Common stock, $.01 par value: 170,000,000 shares authorized at December 31, 2014 and 2013; 32,525,356 shares and 27,119,974 shares issued at December 31, 2014 and 2013, respectively	325,252	271,198
Additional paid-in capital	432,558,698	421,775,039
Treasury stock, at cost: 79,545 shares held at December 31, 2014 and December 31, 2013	(8,034,244)	(8,034,244)
Accumulated deficit	(425,271,916)	(399,069,608)
Total stockholders' equity (deficit)	(422,210)	14,942,385
Total liabilities and stockholders' equity (deficit)	$ 11,309,588	$ 15,507,551

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Operations

	YEAR ENDED DECEMBER 31,	
	2014	2013
Revenues:		
Product sales	$ 23,727	$ -
	23,727	-
Costs and expenses:		
Cost of product sales	7,467	-
Research and development	2,765,492	2,677,008
General and administrative	3,756,548	3,063,011
Acquired in-process research and development	19,681,711	-
	26,211,218	5,740,019
Interest (income) expense, net	26,581	(1,658)
Change in fair value of contingent rights	(11,764)	-
Net loss	$ (26,202,308)	$ (5,738,361)
Net loss per share (basic and diluted)	$ (0.92)	$ (0.22)
Weighted average number of shares outstanding (basic and diluted)	28,595,402	26,125,852

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
Years Ended December 31, 2014 and 2013

	Preferred Stock		Common Stock		Treasury	Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Stock	Capital	Deficit	Total
Balance at December 31, 2012	-	$ -	22,503,393	$ 225,828	$ (8,034,244)	$ 409,374,905	$ (393,331,247)	$ 8,235,242
Issuance of common stock for options exercised	-	-	3,817	38	-	7,152	-	7,190
Issuance of common stock for warrants exercised		-	37,391	374	-	51,973	-	52,347
Issuance of common stock pursuant to the 2013 Financing, net of stock issuance costs (Note 8)	-	-	4,495,828	44,958	-	6,607,297	-	6,652,255
Fair value of warrants issued pursuant to the 2013 Financing (Note 8)	-	-	-	-	-	3,689,330	-	3,689,330
Stock-based compensation expense, net of forfeitures	-	-	-	-	-	2,044,382	-	2,044,382
Net loss	-	-	-	-	-	-	(5,738,361)	(5,738,361)
Balance at December 31, 2013	-	-	27,040,429	271,198	(8,034,244)	421,775,039	(399,069,608)	14,942,385
Issuance of common stock pursuant to the Spectrum licensing transaction (Note 4)	-	-	5,405,382	54,054	-	8,594,557	-	8,648,611
Stock-based compensation expense, net of forfeitures	-	-	-	-	-	2,189,102	-	2,189,102
Net loss	-	-	-	-	-	-	(26,202,308)	(26,202,308)
Balance at December 31, 2014	-	$ -	32,445,811	$ 325,252	$ (8,034,244)	$ 432,558,698	$ (425,271,916)	$ (422,210)

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

	YEAR ENDED DECEMBER 31,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (26,202,308)	$ (5,738,361)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	48,179	17,389
Stock-based compensation expense	2,189,102	2,044,382
Acquired in-process research and development	19,681,711	-
Non-cash interest	25,922	-
Change in fair value of contingent rights	(11,764)	-
Changes in operating assets and liabilities:		
Accounts receivable	(23,727)	669,310
Prepaid expenses and other	(56,423)	(90,846)
Accounts payable	352,172	(102,395)
Payable to related party	-	(86,683)
Accrued liabilities	1,710	11,491
Net cash used in operating activities	(3,995,426)	(3,275,713)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of furniture and equipment	(231,818)	(42,975)
Cash paid for acquired in-process research and development	(234,508)	-
Net cash used in investing activities	(466,326)	(42,975)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock and warrants	-	10,789,987
Stock issuance costs	-	(448,402)
Proceeds from exercise of options and warrants	-	59,537
Net cash provided by financing activities	-	10,401,122
Net (decrease) increase in cash and cash equivalents	(4,461,752)	7,082,434
Cash and cash equivalents at beginning of year	15,131,671	8,049,237
Cash and cash equivalents at end of year	$ 10,669,919	$ 15,131,671
Supplemental disclosure of cash flow information:		
Non-cash financing activity:		
Common stock issued in connection with acquired in-process research and development	$ 8,648,611	$ -
Promissory note, net of discount, issued in connection with acquired in-process research and development	$ 1,364,093	$ -
Contingent rights issued in connection with acquired in-process research and development	$ 9,434,499	$ -
Warrant issued to placement agent	$ -	$ 115,150
Non-cash investing activity:		
Disposal of fully depreciated property and equipment, at cost	$ -	$ 123,980

See accompanying notes.

1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

CASI Pharmaceuticals, Inc. ("CASI" or "the Company") is a biopharmaceutical company focused on the acquisition, development and commercialization of innovative therapeutics addressing cancer and other unmet medical needs with a strategic commercial focus on the greater China market. The Company's mission is to deliver pharmaceutical drugs to patients with unmet medical needs directly in China, and in the rest of the world by establishing partnerships for global development and commercialization. The Company intends to become fully integrated with drug development and commercial operations.

The Company employs a diversified and risk-managed approach to its pipeline that includes (1) internal development of its lead proprietary drug candidate, ENMD-2076, leveraging resources and dual development in North America and China, (2) in-license or acquisition of late-stage clinical drug candidates, such as ZEVALIN®, MARQIBO®, and CE Melphalan, and (3) internal development of new drug candidates with clinically proven targets using the Company's proprietary new drug delivery technology platform. Through partnerships, collaborations and strategic acquisitions, the Company intends to add additional drug candidates to its pipeline. The Company uses a market-oriented approach to identify pharmaceutical candidates that it believes have the potential for gaining widespread market acceptance, either globally or in China, and for which development can be accelerated under the Company's drug development strategy.

The Company's lead internal drug candidate is ENMD-2076, a selective Aurora A and angiogenic kinase inhibitor for the treatment of cancer, which it will continue to develop with approval by the United States Food and Drug Administration (the "FDA"). In parallel, the Company will include ENMD-2076 in clinical sites in China as an import drug as well as develop ENMD-2076 in China locally under the China Food and Drug Administration ("CFDA"). In March 2015, the Company initiated a Phase 2 clinical trial of ENMD-2076 in triple-negative breast cancer ("TNBC") at the Cancer Hospital of Chinese Academy of Medical Sciences in Beijing, China, as part of the Company's ongoing trial in TNBC in the U.S.

ENMD-2076 has received orphan drug designation for the treatment of ovarian cancer, multiple myeloma, acute myeloid leukemia and hepatocellular carcinoma (HCC).

In September 2014, CASI filed an Investigational New Drug application (IND) with the FDA to conduct a Phase II trial in advanced fibrolamellar carcinoma (FLC). In February 2015, the Company conducted a meeting with the FDA and received formal guidance from the FDA regarding the clinical and regulatory path that may lead to market approval of ENMD-2076 for the treatment of FLC. CASI will also be conducting a food effect study of ENMD-2076 in healthy human subjects and intends to move forward and is working with its principal investigators and the FLC patient community to initiate a trial in 2015.

In September 2014, the Company acquired from Spectrum Pharmaceuticals, Inc. and certain of its affiliates (together referred to as "Spectrum") (see Note 4) exclusive rights in greater China (including Taiwan, Hong Kong and Macau) to three in-licensed oncology products, including ZEVALIN® (ibritumomab tiuxetan) approved in the U.S. for advanced non-Hodgkin's lymphoma, MARQIBO® (vinCRIStine sulfate LIPOSOME injection) approved in the U.S. for advanced adult Ph- acute lymphoblastic leukemia (ALL), as well as Captisol Enabled™ melphalan (CE melphalan), which is the subject of a New Drug Application filed with FDA by Spectrum in 2014. The Company has initiated the regulatory and development process to obtain marketing approval for ZEVALIN and MARQIBO in its territorial region, and will initiate commercial activities of ZEVALIN in Hong Kong. The Company will continue to seek to expand its pipeline by acquiring additional drug candidates through in-license and acquisitions.

The Company's pipeline also includes 2ME2 (2-methoxyestradial), an orally active compound that has antiproliferative, antiangiogenic and anti-inflammatory properties. The Company intends to advance 2ME2 to

clinical trials in using a new drug delivery form. Under the Company's new drug delivery technology platform, it intends to develop additional new drug candidates with clinically proven targets.

The accompanying consolidated financial statements include the accounts of CASI Pharmaceuticals, Inc. and its subsidiaries, Miikana Therapeutics, Inc. ("Miikana") and CASI Pharmaceuticals (Beijing) Co., Ltd. ("CASI China"). CASI China is a non-stock Chinese entity with 100% of its interest owned by CASI. CASI China received approval for a business license from the Beijing Industry and Commercial Administration in August 2012 and has operating facilities in Beijing. All inter-company balances and transactions have been eliminated in consolidation.

LIQUIDITY RISKS AND MANAGEMENT'S PLANS

Since inception, the Company has incurred significant losses from operations and has incurred an accumulated deficit of $425.3 million. The Company expects to continue to incur operating losses for the foreseeable future due to, among other factors, its continuing clinical activities. On March 14, 2013 (the "2013 Financing"), the Company closed on the sale of 4,495,828 shares of common stock and 2,247,912 warrants to certain investors for approximately $10.8 million (see Note 8). As a result of this transaction, along with on-going cost containment measures, the Company believes that it has sufficient resources to fund its operations for at least the twelve months subsequent to December 31, 2014. The Company will continue to exercise tight controls over operating expenditures and will continue to pursue opportunities, as required, to raise additional capital and will also actively pursue non- or less-dilutive capital raising arrangements in China to support the Company's dual-country approach to drug development.

The Company intends to advance clinical development of its drugs and drug candidates, and the implementation of the Company's plans will include leveraging its resources in both the United States and China. In order to capitalize on the drug development and capital resources available in China, the Company is doing business in China through its wholly-owned Chinese subsidiary that will execute the China portion of the Company's drug development strategy, including conducting clinical trials in China, pursuing local funding opportunities and strategic collaborations, and implementing the Company's plan for development and commercialization in the Chinese market.

The Company intends to pursue additional financing opportunities as well as opportunities to raise capital through forms of non- or less- dilutive arrangements, such as partnerships and collaborations with organizations that have capabilities and/or products that are complementary to the Company's capabilities and products in order to continue the development of the product candidate that the Company intends to pursue to commercialization.

RECLASSIFICATIONS

Certain prior period amounts were reclassified to conform to the current period presentation.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

SEGMENT INFORMATION

The Company currently operates in one business segment, which is the development of targeted therapeutics primarily for the treatment of cancer. The Company is managed and operated as one business. CASI's senior management team reports to the Board of Directors and is responsible for aligning the Company's business strategy with its core scientific strengths, while maintaining prudent resource management, fiscal responsibility and accountability. The Company employs a drug development strategy in the United States and China to develop targeted therapeutics for the global market and its current lead drug candidate is ENMD-2076, an Aurora A and angiogenic kinase inhibitor for the treatment of cancer.

The Company does not operate separate lines of business with respect to its product candidates. Accordingly, the Company does not have separately reportable segments as defined by authoritative guidance issued by the Financial Accounting Standards Board (FASB).

RESEARCH AND DEVELOPMENT

Research and development expenses consist primarily of compensation and other expenses related to research and development personnel, research collaborations, costs associated with pre-clinical correlative testing and clinical trials of the Company's drug candidates, including the costs of manufacturing drug substance and drug product, regulatory maintenance costs, and facilities expenses. Research and development costs are expensed as incurred.

PROPERTY AND EQUIPMENT

Furniture and equipment and leasehold improvements are stated at cost and are depreciated over their estimated useful lives of 3 to 5 years. Depreciation and amortization is determined on a straight-line basis. Depreciation and amortization expense was $48,179 and $17,389 in 2014 and 2013, respectively.

Property and equipment consists of the following:

	DECEMBER 31,	
	2014	2013
Furniture and equipment	$ 480,550	$ 248,732
Leasehold improvements	6,382	6,382
	486,932	255,114
Less: accumulated depreciation and amortization	(225,151)	(176,972)
	$ 261,781	$ 78,142

IMPAIRMENT OF LONG-LIVED ASSETS

In accordance with authoritative guidance issued by FASB, the Company periodically evaluates the value reflected in its consolidated balance sheets of long-lived assets, such as equipment, when events and circumstances indicate that the carrying amount of an asset may not be recovered. Such events and circumstances include the use of the asset in current research and development projects, any potential alternative uses of the asset in other research and development projects in the short to medium term and restructuring plans entered into by the Company. No impairment charges were recorded in 2014 and 2013.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents include cash and highly liquid investments with original maturities of less than 90 days. Substantially all of the Company's cash equivalents are held in short-term money market accounts.

ACCOUNTS RECEIVABLE

Accounts receivable are stated net of allowances for doubtful accounts. Allowances for doubtful accounts are determined on a specific item basis. Management reviews the credit worthiness of individual customers and past payment history to determine the allowance for doubtful accounts. There is an allowance for doubtful accounts of $12,536 at December 31, 2014 and 2013.

As of December 31, 2014, one customer represented 100% of revenue and net accounts receivable.

FOREIGN CURRENCY TRANSLATION

The U.S. dollar is the functional and reporting currency of the Company. Foreign currency denominated assets and liabilities of the Company and all of its subsidiaries are translated into U.S. dollars. Accordingly, monetary assets and liabilities are translated using the exchange rates in effect at the consolidated balance sheet date and revenues and expenses at the rates of exchange prevailing when the transactions occurred. Remeasurement adjustments are included in income (loss).

DEFERRED RENT

The Company accounts for rent expense related to operating leases by determining total minimum rent payments on the leases over their respective periods and recognizing the rent expense on a straight-line basis. The difference between the actual amount paid and the amount recorded as rent expense in each fiscal year is recorded as an adjustment to deferred rent. Deferred rent as of December 31, 2014 and 2013 was $9,593 and $6,871, respectively, and is included in accrued liabilities in the accompanying consolidated balance sheets.

EXPENSES FOR CLINICAL TRIALS

Expenses for clinical trials are incurred from planning through patient enrollment to reporting of the data. The Company estimates expenses incurred for clinical trials that are in process based on patient enrollment and based on clinical data collection and management. Costs that are associated with patient enrollment are recognized as each patient in the clinical trial completes the enrollment process. Estimated clinical trial costs related to enrollment can vary based on numerous factors, including expected number of patients in trials, the number of patients that do not complete participation in a trial, and the length of participation for each patient. Costs that are based on clinical data collection and management are recognized in the reporting period in which services are provided. In the event of early termination of a clinical trial, the Company accrues an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial. As of December 31, 2014 and 2013, clinical trial accruals were $262,997 and $244,192, respectively, and are included in accounts payable in the accompanying consolidated balance sheets.

INCOME TAXES

Income tax expense is accounted for in accordance with authoritative guidance issued by FASB. Income tax expense has been provided using the asset and liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities as measured by the enacted tax rates that will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets if, based upon the available evidence, it is not more likely than not that the deferred tax assets will be realized.

The Company accounts for uncertain tax positions pursuant to the guidance of FASB Accounting Standards Codification Topic 740, *Income Taxes*. The Company recognizes interest and penalties related to uncertain tax positions, if any, in income tax expense. As of December 31, 2014 and 2013, the Company did not accrue any interest related to uncertain tax positions. To date, there have been no interest or penalties charged to the Company in relation to the underpayment of income taxes.

REVENUE RECOGNITION

Revenue for product sales is not recognized until it is realized or realizable and earned. Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price to the buyer is fixed and determinable and collectibility is reasonably assured.

NET LOSS PER SHARE

Net loss per share (basic and diluted) was computed by dividing net loss attributable to common shareholders by the weighted average number of shares of common stock outstanding. Outstanding options and warrants totaling 8,568,585 and 7,907,959 as of December 31, 2014 and 2013, respectively, were anti-dilutive and, therefore, were not included in the computation of weighted average shares used in computing diluted loss per share.

SHARE-BASED COMPENSATION

The Company records compensation expense associated with service, performance, market condition based stock options and other equity-based compensation in accordance with provisions of authoritative guidance. The

fair value of awards whose fair values are calculated using the Black-Scholes option pricing model is generally being amortized on a straight-line basis over the requisite service period and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period. The fair value of awards with market conditions, which are valued using a binomial model, is being amortized based upon the derived service period. Share based awards granted to employees with a performance condition are measured based on the probable outcome of that performance condition during the requisite service period. Awards with performance conditions will be expensed if it is probable that the performance condition will be achieved. During the year ended December 31, 2014, $686,600 of stock compensation expense was recorded for share awards with performance conditions.

NEW ACCOUNTING PRONOUNCEMENTS

The Company has implemented all new accounting pronouncements that are in effect and that may impact the Company's consolidated financial statements.

In August 2014, the FASB issued Accounting Standard Update ("ASU") 2014-15, *Presentation of Financial Statements – Going Concern*. The new standard requires management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity's ability to continue as a going concern. The guidance 1) provides a definition for the term "substantial doubt," 2) requires an evaluation every reporting period, interim periods included, 3) provides principles for considering the mitigating effect of management's plans to alleviate the substantial doubt, 4) requires certain disclosures if the substantial doubt is alleviated as a result of management's plans, 5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and 6) requires an assessment period of one year from the date the financial statements are issued. The standard is effective for the Company's reporting year beginning January 1, 2017 and early adoption is not permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* which provides guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. The standard is effective for the Company's reporting year beginning January 1, 2017 and early adoption is not permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its consolidated financial statements.

FAIR VALUE OF FINANCIAL INSTRUMENTS AND CONCENTRATIONS OF CREDIT RISK

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. The Company maintains its cash in bank deposit accounts, which, at times, may exceed federally insured amounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents. The carrying amount of current assets and liabilities approximates their fair values due to their short-term maturities.

USE OF ESTIMATES

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company's most critical accounting estimates relate to accounting policies for derivatives, notes payable valuation, clinical trial accruals and share-based arrangements. Management bases its estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances. Actual results may differ from those estimates, and such differences may be material to the consolidated financial statements.

DERIVATIVES

The Company entered into investment agreements with Spectrum (see Note 4) resulting in a purchase price derivative. In accordance with GAAP, derivative instruments are recognized as either assets or liabilities on the consolidated balance sheets and are measured at fair value with gains or losses recognized in earnings or other comprehensive income depending on the nature of the derivative. The Company determines the fair value of derivative instrument based on available market data using appropriate valuation models, giving consideration to all of the rights and obligations of each instrument. The derivative liability is re-measured at fair value at the end of each reporting period as long as it is outstanding.

3. RELATED PARTY TRANSACTIONS

On October 31, 2012, CASI China obtained the necessary local regulatory approvals to establish a bank account in Beijing. Prior to establishing a bank account, CASI China incurred certain startup and initial operating expenses, which were advanced by the Company's Chief Executive Officer on behalf of CASI China, totaling $86,683. The full amount was repaid to the Company's Chief Executive Officer in February 2013.

4. LICENSE ARRANGEMENTS AND ACQUISITION OF IN-PROCESS RESEARCH AND DEVELOPMENT

In September 2014, the Company acquired certain product rights and perpetual exclusive licenses from Spectrum, to develop and commercialize the following commercial oncology drugs and drug candidates in China, Taiwan, Hong Kong and Macau (the "Territories"):

- Captisol-Enabled™ (propylene glycol-free) melphalan ("CE Melphalan");
- ZEVALIN® (ibritumomab tiuxetan) ("Zevalin"); and
- MARQIBO® (vinCRIStine sulfate LIPOSOME injection) ("Marqibo").

CE Melphalan is currently in Phase III clinical trials in the U.S. (with an NDA submission by Spectrum made in December 2014), whereas Zevalin and Marqibo are currently marketed in the U.S. CASI is responsible for developing and commercializing these three drugs in the Territories, including the submission of import drug registration applications and conducting confirmatory clinical trials.

As consideration for the acquisition, the Company issued a total 5,405,382 shares of its common stock, a $1.5 million 0.5% secured promissory note due in March 2016, and certain contingent rights ("Contingent Rights") to purchase additional shares of its common stock. The Company accounted for the acquisition of the product rights and licenses as an asset acquisition and, accordingly, recorded the acquired product rights and licenses at their estimated fair values based on the fair value of the consideration exchanged (including transaction costs) of approximately $19.7 million. Because the products underlying the acquired product rights and licenses have not reached technological feasibility and have no alternative uses, they are considered "in-process research and development" costs; as such, the Company expensed the total purchase price at the acquisition date as acquired in-process research and development in the accompanying consolidated statements of operations.

The fair value of the common stock issued was based on the closing market price of the Company's common stock on the acquisition date. The fair value of the promissory note was measured using Level 3 unobservable inputs including primarily the Company's estimated incremental borrowing rate as provided by a commercial lending institution.

The Contingent Rights provide Spectrum with the option to acquire, at a strike price of par value, a variable number of additional shares of common stock that allows Spectrum to maintain its fully-diluted ownership percentage for a certain time period and under certain terms and conditions. Based on the terms and conditions of the Contingent Rights, the Company has determined that the Contingent Rights are a derivative financial instrument that is not indexed to its common stock and therefore is required to be accounted for at fair value, initially and on a recurring basis. The fair value of the Contingent Rights was measured using Level 3 unobservable inputs; the unobservable inputs include estimates of the Company's future capital requirements, and the timing, probability,

size and characteristics of those capital raises, among other inputs. The total estimated fair value of the Contingent Rights was $9,434,499 at the acquisition date and was $9,422,735 as of December 31, 2014; the change in fair value is reflected as change in fair value of contingent rights in the accompanying consolidated statements of operations.

5. NOTE PAYABLE

As part of the license arrangements with Spectrum (see Note 4), the Company issued to Spectrum a $1.5 million 0.5% secured promissory note due in March 2016. The promissory note was recorded initially at its fair value, giving rise to a discount of approximately $136,000; the promissory note is presented as note payable, net of discount in the accompanying consolidated balance sheets. For the year ended December 31, 2014, the Company recognized approximately $26,000 of non-cash interest expense related to the amortization of the debt discount, using the effective interest rate method.

6. FAIR VALUE MEASUREMENTS

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value. These tiers include:

- Level 1, defined as observable inputs such as quoted prices in active markets for identical assets;
- Level 2, defined as observable inputs other than Level 1 prices such as quoted prices for similar assets; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

An asset's or liability's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company performs a detailed analysis of its assets and liabilities that are measured at fair value. All assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of the Company's funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current assets and liabilities) approximate their carrying values because of their short-term nature.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis:

The Contingent Rights issued to Spectrum in connection with the license arrangements (see Note 4) are considered derivative liabilities and were recorded initially at their estimated fair value, and are marked to market each reporting period until settlement. The fair value of the Contingent Rights was measured using Level 3 unobservable inputs; the unobservable inputs include estimates of the Company's future capital requirements, and the timing, probability, size and characteristics of those capital raises, among other inputs. Generally, if the estimates of the size and probability of the Company's future capital requirements increase, the fair value of the Contingent Rights will also increase.

The following table presents the Company's financial liabilities accounted for at fair value on a recurring basis as of December 31, 2014 (none at December 31, 2013) by level within the fair value hierarchy:

	As of December 31, 2014			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities - Contingent Rights	$ -	$ -	$ 9,422,735	$ 9,422,735

The following table presents the changes in the Company's financial liabilities accounted for at fair value on a recurring basis using Level 3 unobservable inputs:

December 31, 2013	$ -
Issuance of Contingent Rights	9,434,499
Change in fair value of Contingent Rights	(11,764)
Balance at December 31, 2014	**$ 9,422,735**

Financial Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis:

The promissory note issued to Spectrum in connection with the license arrangements (see Note 4) was initially recorded at its fair value using Level 3 unobservable inputs including primarily the Company's estimated incremental borrowing rate as provided by a commercial lending institution.

Non-Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis:

The Company does not have any non-financial assets and liabilities that are measured at fair value on a recurring basis.

Non-Financial Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis:

The Company measures its long-lived assets, including property and equipment, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be impaired. No such fair value impairment was recognized for the years ended December 31, 2014 and 2013.

7. INCOME TAXES

The income tax provision is based on loss before income taxes of $(26,202,308). The Company has net operating loss carryforwards for income tax purposes of approximately $347,558,000 at December 31, 2014 ($343,101,000 at December 31, 2013) that expire in years 2018 through 2034. The Company also has research and development ("R&D") tax credit carryforwards of approximately $9,201,000 as of December 31, 2014 that expire in years 2018 through 2034. These net operating loss carryforwards include approximately $20,000,000, related to exercises of stock options for which the income tax benefit, if realized, would increase additional paid-in capital. The utilization of the net operating loss and research and development carryforwards may be limited in future years due to changes in ownership of the Company pursuant to Internal Revenue Code Section 382. For financial reporting purposes, a valuation allowance has been recognized to reduce the net deferred tax assets to zero due to uncertainties with respect to the Company's ability to generate taxable income in the future sufficient to realize the benefit of deferred income tax assets.

Deferred income taxes reflect the net effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred income tax assets and liabilities as of December 31, 2014 and 2013 are as follows:

	DECEMBER 31,	
	2014	2013
Deferred income tax assets (liabilities):		
Net operating loss carryforwards	$ 135,607,000	$ 134,395,000
Research and development credit carryforward	9,201,000	9,037,000
Intangible assets	8,079,000	625,000
Equity based compensation	4,316,000	3,489,000
Other	297,000	322,000
Valuation allowance for deferred income tax assets	(157,500,000)	(147,868,000)
Net deferred income tax assets	$ -	$ -

A reconciliation of the provision for income taxes to the federal statutory rate is as follows:

	2014	2013
Tax benefit at statutory rate	$ (8,909,000)	$ (1,951,000)
State taxes	(1,273,000)	(217,000)
Net R&D credit adjustment	(104,000)	(122,000)
Attribute expiration and other	8,000	8,000
Nondeductible expenses	4,000	2,000
Change in valuation allowance	9,631,000	2,055,000
Other	(38,000)	231,000
Change in tax rates	681,000	(6,000)
	$ -	$ -

The Company had $3,013,000 of unrecognized tax benefits as of January 1, 2014 related to net R&D tax credit carryforwards. The Company had a full valuation allowance on the net deferred tax asset recognized in the consolidated financial statements. For the year ended December 31, 2014, there were additional unrecognized tax benefits of $54,000 related to R&D tax credits. The Company has a full valuation allowance at January 1, 2014 and at December 31, 2014 against the full amount of its net deferred tax assets and therefore, there was no impact on the Company’s financial position.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	2014	2013
Unrecognized tax benefits balance at January 1	$3,013,000	$3,006,000
Additions for Tax Positions of Prior Periods	20,000	-
Reductions for Tax Positions of Prior Periods	-	(26,000)
Additions for Tax Positions of Current Period	34,000	33,000
Unrecognized tax benefits balance at December 31	$3,067,000	$3,013,000

The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense. As of December 31, 2014 and 2013, the Company had no accrued interest or penalties related to uncertain tax positions, respectively.

The tax returns for all years in the Company’s major tax jurisdictions are not settled as of December 31, 2014. Due to the existence of tax attribute carryforwards (which are currently offset by a full valuation allowance), the Company treats all years’ tax positions as unsettled due to the taxing authorities’ ability to modify these attributes.

The Company believes that the total unrecognized tax benefit, if recognized, would impact the effective rate, however, such reversal may be offset by a corresponding adjustment to the valuation allowance.

8. STOCKHOLDERS' EQUITY

As described in Note 1 and in connection with the 2013 Financing, on March 1, 2013, the Company entered into a definitive agreement with certain investors (collectively, the "2013 Investors") for a financing in the aggregate amount of approximately $10.8 million. In connection with the 2013 Financing, the Company entered into a Securities Purchase Agreement with the 2013 Investors pursuant to which the Company agreed to sell in a transaction registered under the Securities Act of 1933, as amended, 4,495,828 shares of the Company's common stock and warrants to purchase up to an aggregate of 2,247,912 shares of common stock (the "2013 Warrants"). The 2013 Warrants cover a number of shares of common stock equal to 50% of the number of shares purchased by each 2013 Investor. The 2013 Warrants have an exercise price of $2.91 per share and became exercisable on September 4, 2013 and expire on September 4, 2016. The fair value of the 2013 Warrants issued is $3,574,180, calculated using the Black-Scholes-Merton valuation model value of $1.59 with an expected and contractual life of 3.5 years, an assumed volatility of 102.3%, and a risk-free interest rate of 0.40%. The Company completed the closings on the 2013 Financing on March 14, 2013 and received net proceeds of approximately $10.3 million.

In connection with the 2013 Financing, the Company also issued a warrant to its placement agent to purchase up to 61,250 shares of common stock at an exercise price of $3.00 per share of common stock (the "Agent's Warrant"). The Agent's Warrant became exercisable on September 4, 2013 and will expire on October 9, 2017. The fair value of the Agent's Warrant issued is $115,150, calculated using the Black-Scholes-Merton valuation model value of $1.88 with an expected and contractual life of 4.6 years, an assumed volatility of 111.9%, and a risk-free interest rate of 0.85%.

9. SHARE-BASED COMPENSATION

The Company has adopted incentive and nonqualified stock option plans for executive, scientific and administrative personnel of the Company as well as outside directors and consultants. In June 2014, the Company's shareholders approved an amendment to the 2011 Long-Term Incentive Plan, increasing the number of shares reserved for issuance from 4,230,000 to 5,730,000 shares of common stock to be available for grants and awards. As of December 31, 2014, there are 4,557,682 shares issuable under options previously granted and currently outstanding, with exercise prices ranging from $1.59 to $34.10. In 2014, the Company awarded options to two officers and two board members, covering up to 400,000 shares, in which vesting is subject to achievement of certain performance milestone conditions. In 2012, the Company awarded options to two officers, a portion of which is subject to certain performance conditions and market conditions. Options granted under the plans generally vest over periods varying from immediately to one to three years, are not transferable and generally expire ten years from the date of grant. As of December 31, 2014, 1,615,752 shares remained available for grant under the Company's 2011 Long-Term Incentive Plan.

On September 17, 2014, the vesting of all of the performance condition options became probable as a result of the Spectrum transaction discussed in Note 4. Therefore, for the year ended December 31, 2014, non-cash compensation expense of $686,600 has been recorded for share awards with performance conditions.

The Company's net loss for the years ended December 31, 2014 and 2013 includes $2,189,102 and $2,044,382, respectively, of non-cash compensation expense related to the Company's share-based compensation awards. The compensation expense related to the Company's share-based compensation arrangements is recorded as components of general and administrative expense and research and development expense, as follows:

	2014	2013
Research and development	$ 690,409	$ 763,470
General and administrative	1,498,693	1,280,912
Share-based compensation expense	$ 2,189,102	$ 2,044,382
Net share-based compensation expense, per common share:		
Basic and diluted	$ 0.08	$ 0.08

Stock Options

The Company uses the Black-Scholes-Merton valuation model to estimate the fair value of service based and performance based stock options granted to employees. For market condition based options, the Company uses a binomial model to estimate fair value. These option valuation models require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk free rate of interest, expected dividend yield, expected volatility, and the expected life of the award.

Expected Volatility—Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company uses the historical volatility based on the daily price observations of its common stock during the period immediately preceding the share-based award grant that is equal in length to the award's expected term. The Company believes that historical volatility represents the best estimate of future long term volatility.

Risk-Free Interest Rate—This is the average interest rate consistent with the yield available on a U.S. Treasury note (with a term equal to the expected term of the underlying grants) at the date the option was granted.

Expected Term of Options—This is the period of time that the options granted are expected to remain outstanding. The Company uses a simplified method for estimating the expected term of service based awards granted. For performance based and market based awards, the expected term of service is based on the derived service period.

Expected Dividend Yield—The Company has never declared or paid dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. As such, the dividend yield percentage is assumed to be zero.

Forfeiture Rate—This is the estimated percentage of options granted that are expected to be forfeited or cancelled on an annual basis before becoming fully vested. The Company estimates the forfeiture rate based on historical forfeiture experience for similar levels of employees to whom options were granted.

Following are the weighted-average assumptions used in valuing the stock options granted to employees during the years ended December 31, 2014 and 2013:

	Years ended December 31,	
	2014	2013
Expected volatility	102.41%	105.30%
Risk free interest rate	1.78%	1.03%
Expected term of option	5.63 years	5.77 years
Forfeiture rate	*3.00%	*5.00%
Expected dividend yield	-	-

*-Throughout 2014 and 2013, forfeitures were estimated at 3% and 5%, respectively; the actual forfeiture rate was 1% and 0% for 2014 and 2013, respectively. The Company adjusted stock compensation expense for 2014 and 2013 based on the actual forfeiture rate.

The weighted average fair value of stock options granted was $1.44 and $1.42 in 2014 and 2013, respectively.

Share-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest, net of estimated forfeitures. The authoritative guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

A summary of the Company's stock option plans and of changes in options outstanding under the plans during the years ended December 31, 2014 and 2013 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term In years	Aggregate Intrinsic Value
Outstanding at December 31, 2012	1,636,544	$ 5.07		
Exercised	(3,817)	$ 1.88		
Granted	2,034,500	$ 1.78		
Expired	(80,833)	$ 27.37		
Forfeited	-	$ -		
Outstanding at December 31, 2013	3,586,394	$ 2.69		
Exercised	-	$ -		
Granted	1,090,000	$ 1.83		
Expired	(107,168)	$ 6.21		
Forfeited	(11,544)	$ 1.78		
Outstanding at December 31, 2014	4,557,682	$ 2.40	8.05	$ -
Vested and expected to vest at December 31, 2014	4,525,364	$ 2.40	7.99	$ -
Exercisable at December 31, 2014	3,480,426	$ 2.58	7.87	$ -

The aggregate intrinsic value is calculated as the difference between (i) the closing price of the common stock at December 31, 2014 and (ii) the weighted average exercise price of the underlying awards, multiplied by the number of options that had an exercise price less than the closing price on the last trading day of the year. The total intrinsic value of options exercised during the year ended December 31, 2013 totaled approximately $2,500. Cash received from option exercises under all share-based payment arrangements for the year ended December 31, 2013 was $7,190. There were no options exercised in 2014. Due to the availability of net operating loss carryforwards and research tax credits, tax deductions for option exercises were not recognized in the years ended December 31, 2014 and 2013.

The following summarizes information about stock options granted to employees and directors outstanding at December 31, 2014:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31, 2014	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable at December 31, 2014	Weighted Average Exercise Price
$0.00 - $2.00	3,824,802	8.4	$ 1.82	2,747,546	$ 1.82
$2.01 - $4.00	475,000	7.2	$ 2.26	475,000	$ 2.26
$4.01 - $10.00	176,540	5.6	$ 6.56	176,540	$ 6.56
$10.01 - $15.00	5,268	3.0	$ 13.75	5,268	$ 13.75
$15.01 - $20.00	55,258	1.9	$ 17.64	55,258	$ 17.64
$20.01 - $30.00	363	1.0	$ 21.34	363	$ 21.34
$30.01 - $35.00	20,451	0.6	$ 34.10	20,451	$ 34.10
	4,557,682	8.1	$ 2.40	3,480,426	$ 2.58

As of December 31, 2014, there was approximately $1,309,000 of total unrecognized compensation cost related to non-vested stock options. That cost is expected to be recognized over a weighted-average period of 1.3 years.

Warrants

Warrants granted generally expire after 3-5 years from the date of grant. Stock warrant activity to non-employees is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2012	2,049,794	$ 1.62
Granted	2,309,162	$ 2.91
Exercised	(37,391)	$ 1.40
Expired	-	$ -
Outstanding at December 31, 2013	4,321,565	$ 2.31
Granted	-	$ -
Exercised	-	$ -
Expired	310,662	$ 2.83
Outstanding at December 31, 2014	4,010,903	$ 2.27
Exercisable at December 31, 2014	4,010,903	$ 2.27

10. COMMITMENTS AND CONTINGENCIES

COMMITMENTS

ENMD-2076. In January 2006, the Company acquired Miikana, a private biotechnology company. Pursuant to the Merger Agreement, the Company acquired all of the outstanding capital stock of Miikana Therapeutics, Inc. In 2008, the Company initiated a Phase 1 clinical trial with its Aurora A and angiogenic kinase inhibitor, ENMD-2076, in patients with solid tumors. A dosing of the first patient with ENMD-2076 triggered a purchase price adjustment milestone of $2 million, which the Company opted to pay in stock. As ENMD-2076 successfully completed Phase 1 clinical trials and advanced to Phase 2, the dosing of the first patient in 2010 triggered an additional purchase price adjustment milestone of $3 million, which was paid stock in 2010. Under the terms of the merger agreement, the former Miikana stockholders may earn up to an additional $4 million of potential payments upon the satisfaction of additional clinical and regulatory milestones for ENMD-2076 and up to the $9 million of potential milestone payments that pertain to a preclinical program that the Company has discontinued. As of December 31, 2014, a $4 million potential milestone payment remains, payable in cash or shares of stock at the Company's option, related to the ENMD-2076 program and the dosing of the first patient in a Phase 3 pivotal trial.

MKC-1. The Company acquired rights to MKC-1, a Phase 2 clinical candidate licensed from Hoffman-LaRoche, Inc. ("Roche") by Miikana in April 2005. Under the terms of the agreement, Roche may be entitled to receive future payments upon successful completion of Phase 3 developmental milestones. The Company does not anticipate reaching any of these milestones in 2015. Roche is also eligible to receive royalties on sales and certain one-time payments based on attainment of annual sales milestones. The Company is also obligated to make certain "success fee" payments to ProPharma based on successful completion of developmental milestones under the Roche license agreement. MKC-1 is currently not under active clinical evaluation and the Company has no plans to advance the program.

2ME2 NCD (2-methoxyestradiol, NanoCrystal Dispersion, 2ME2 NCD) for Oncology. In January 2006, the Company entered into a License Agreement with Elan Corporation, plc ("Elan") in which the Company has been granted rights to utilize Elan's proprietary NanoCrystal Technology in connection with the development of the oncology product candidate, 2ME2 using its nanocrystal dispersion formulation. Under the terms of the License Agreement, Elan is eligible to receive payments upon the achievement of certain milestones and to receive royalty payments based on sales of 2ME2 NCD. Additionally, under the agreement and the corresponding Services Agreement, Elan has the right to manufacture the Company's 2ME2 NCD. Milestones related to the initiation of Phase 2 clinical trials for 2ME2 NCD have been paid and there are no additional milestones achieved as of December 31, 2014. The Company has discontinued clinical development of the NCD formulation of 2ME2.

Endostatin and Angiostatin for Eye Diseases. The Company is a party to a February 2004 agreement with Children's Medical Center Corporation ("CMCC") and Alchemgen Therapeutics pertaining to Endostatin and Angiostatin proteins, programs which have been discontinued by the Company, and pursuant to which Alchemgen received rights to market Endostatin and Angiostatin in Asia. In April 2008, the Company was advised that

Alchemgen Therapeutics ceased operations, therefore eliminating the Company's ability to receive any royalties from Alchemgen under the agreement. However, the Company is a party to a sublicense agreement with Oxford BioMedica PLC ("Oxford") to develop and market Endostatin and Angiostatin for ophthalmologic (eye) diseases. Pursuant to this sublicense, the Company is eligible to receive a portion of upfront payments and royalties from Oxford based on a portion of the payments received and net sales of gene products of Endostatin and Angiostatin and certain development milestone payments. There was no royalty payment received in 2014 or 2013. The Company does not control the drug development efforts of Oxford and has no information or control over when or whether any milestones will be reached that would result in additional payments to the Company in 2015 or beyond.

Pursuant to the Company's commitments for ENMD-2076, it could potentially pay $4 million, in stock or cash at the Company's election, when the pivotal trial development milestone is reached. With respect to the Company's other product candidates, which are not actively pursued or have been discontinued pursuant to the commitments detailed above, in aggregate, the Company could potentially pay up to $41 million if each licensed product candidate is fully developed and approved for commercial use in all of the major territories of the world. In this event, the Company would also be obligated to pay annual sales-based royalties under the license agreements. However, the Company does not expect that these other product candidates will reach additional developmental milestones in 2015 and accordingly does not anticipate any future milestone payments for these programs.

With respect to the Company's in-licensed drug candidates for the Greater China market, the Company does not have to pay any milestone payments or royalties to Spectrum; however, CASI is responsible for paying royalties or milestones, if and when applicable, owed by Spectrum to upstream licensors that licensed related technology to Spectrum in accordance with the terms of the relevant upstream licenses, and only to the extent of the Greater China portion of such upstream royalties or milestones. The Company's sales of Zevalin in Hong Kong are subject to royalties and accordingly we expect to pay royalties for such sales in 2015. The Company does not expect to pay royalties for ZEVALIN in China and Taiwan until commercial activities begin which will not occur until after ZEVALIN receives marketing approval from the regulatory agencies and which is not expected to occur in 2015. The Company does not expect to have sales of MARQIBO and CE Melphalan in 2015 as these products are not yet approved for marketing in the Greater China market, and accordingly the Company does not anticipate any payment obligations for these programs in 2015.

As of December 31, 2014, the Company also has purchase obligation commitments, in the normal course of business, for clinical trial contracts totaling approximately $278,000.

The Company leases its principal executive offices in Rockville, MD under a lease agreement that continues through December 31, 2016. The Company leases office space in China under a lease agreement that continues through June 2017. Effective February 1, 2015, the Company renewed a one year lease in China for lab space.

The future minimum payments under its facilities leases are as follows:

2015	243,196
2016	168,573
2017	39,214
Thereafter	-
Total minimum payments	$ 450,983

Rental expense for the years ended December 31, 2014 and 2013 was approximately $240,000 and $175,000, respectively.

CONTINGENCIES

The Company is subject in the normal course of business to various legal proceedings in which claims for monetary or other damages may be asserted. Management does not believe such legal proceedings, unless otherwise disclosed herein, are material.

11. EMPLOYEE RETIREMENT PLAN

The Company sponsors the CASI Pharmaceuticals, Inc. 401(k) and Trust. The plan covers substantially all employees and enables participants to contribute a portion of salary and wages on a tax-deferred basis. Contributions to the plan by the Company are discretionary. Contributions by the Company totaled approximately $28,400 and $21,600 in 2014 and 2013, respectively.

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