#### 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, 2013

Commission file number 0-20713

#### ENTREMED, 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 (Title of each class) The NASDAQ Stock Market LLC (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  $\underline{X}$ 

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  $\underline{X}$  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  $\underline{X}$  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  $\underline{X}$ 

As of June 30, 2013, the aggregate market value of the shares of common stock held by non-affiliates was approximately \$51,879,703.

As of March 14, 2014, 27,040,429 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, 2013. 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.

# ENTREMED, INC. FORM 10-K - FISCAL YEAR ENDED DECEMBER 31, 2013

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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 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 candidate 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; and risks relating to the commercialization, if any, of our proposed products (such as marketing, safety, regulatory, patent, product liability, supply, competition and other risks).

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, 2013 (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.

EntreMed, Inc. ("EntreMed" or "the Company") (Nasdaq: ENMD) is a clinical-stage pharmaceutical company employing a drug development strategy that leverages resources in both North America and in China to develop therapeutics for the treatment of cancer and other diseases. The Company is currently conducting activities in both China and North America in order to accelerate delivery of clinical data and to reduce costs of clinical trials. Our lead 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"). The Company's market focus includes developed countries, and also in particular, China, which has a pharmaceutical products market that we believe will continue to grow rapidly. Through partnerships, collaborations and strategic acquisitions, we intend to add additional drug candidates to our pipeline for development using the Company's US and China strategy. The Company intends to employ a market acceptance, either globally or in China, and for which development can be accelerated under the Company's US and China drug development strategy.

# ENMD-2076

ENMD-2076 is an orally-active, Aurora A/angiogenic kinase inhibitor with a unique kinase selectivity profile and multiple mechanisms of action. ENMD-2076 exerts its effects through multiple mechanisms of action, including anti-proliferative activity and the inhibition of angiogenesis. 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 also has shown promising activity in Phase 1 clinical trials in solid tumor cancers including ovarian, breast, liver, renal and sarcoma, as well as in leukemia and multiple myeloma. EntreMed is completing a Phase 2 trial of ENMD-2076 in ovarian cancer. In addition, EntreMed is currently conducting a dual-institutional Phase 2 study of ENMD-2076 in triple-negative breast cancer, a Phase 2 study in advanced/metastatic soft tissue sarcoma, and a Phase 2 study in advanced ovarian clear cell carcinoma. The status and development of ENMD-2076 is outlined below:

Disease Indication	<u>Status</u>	<u>Sites</u>
Advanced Solid tumors	Phase 1 trial completed	<ul><li>University of Colorado</li><li>Dana-Farber Cancer Institute</li></ul>
Leukemia	Phase 1 trial completed	Princess Margaret Hospital
Multiple Myeloma	Phase 1 trial completed	Indiana University Melvin & Bren Simon Cancer Center
Ovarian Cancer	Phase 2 trial being completed, enrollment closed	<ul> <li>Dana-Farber Cancer Institute</li> <li>University of Colorado</li> <li>Memorial Sloan-Kettering Cancer Center</li> <li>Indiana University Melvin &amp; Bren Simon Cancer Center</li> <li>University of Chicago Medical Center</li> <li>Princess Margaret Hospital</li> </ul>
Triple-Negative Breast Cancer	Phase 2 currently enrolling	University of Colorado     Indiana University

	New trial application accepted by CFDA, pending review and approval	• China site(s) to be determined
Advanced/Soft Tissue Sarcoma	Phase 2 currently enrolling	Princess Margaret Hospital
	New trial application accepted by CFDA, pending review and approval	• China site(s) to be determined
Healthy Volunteer	Phase 1 crossover bioequivalent trial being completed, enrollment closed	• Celerion, Inc.
Advanced Ovarian Clear Cell Carcinoma	Phase 2 currently enrolling	Princess Margaret Hospital
	New trial application accepted by CFDA, pending review and approval	• China site(s) to be determined

Clinical Phase 1 results were published (Clin Cancer Res 2011;17:849-860) and data from the leukemia and myeloma studies were presented during the American Society of Hematology meeting in December 2010. Anticancer activity was demonstrated with ENMD-2076 treatment in a variety of solid and hematological cancer patients. Also, as previously reported, at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2011, Phase 2 data in ovarian cancer patients was presented by the principal investigator conducting the Phase 2 ENMD-2076 study. The data demonstrated ENMD-2076 activity in a population of difficult to treat platinum resistant patients. In October 2011, we announced that the final data for the primary endpoint of progression free survival rate at 6 months was 22 percent. Phase 2 data in ovarian cancer were also published in the European Journal of Cancer in September 2012 in an article entitled "ENMD-2076, an Oral Inhibitor of Angiogenic and Proliferation Kinases, Has Activity in Recurrent, Platinum Resistant Ovarian Cancer." We believe that the data, together with the Phase 1 results, provide support for additional clinical studies in ovarian cancer and other forms of cancer. We continue to monitor patients who are receiving ENMD-2076, and are focused on collecting additional data on overall survival and other endpoints.

In July 2012, we commenced a dual-institutional Phase 2 study of ENMD-2076 in triple-negative breast cancer. The study is being conducted at the University of Colorado Cancer Center, with a second sited added in December 2012 at Indiana University Melvin & Bren Simon Cancer Center.

In November 2012, results of a preclinical study in triple-negative breast cancer (TNBC) of ENMD-2076 were published in the article, entitled "Predictive Biomarkers of Sensitivity to the Aurora and Angiogenic Kinase Inhibitor ENMD-2076 in Preclinical Breast Cancer Models." Through this study, ENMD-2076 shows activity against preclinical models of breast cancer with more robust activity against TNBC. We believe the study also supports further clinical investigation of ENMD-2076 in patients with metastatic TNBC with an emphasis on the continued development of p53-based predictive biomarkers. We also believe the study provides additional support for our ongoing Phase 2 TNBC trial.

In December 2012, to advance our global development strategy, we filed a new drug clinical trial application with the CFDA to conduct global clinical trials in triple-negative breast cancer patients using our proprietary drug candidate, ENMD-2076. 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 triple-negative breast cancer trial currently underway at the University of Colorado and Indiana University.

In January 2013, we commenced a single-center Phase 2 study of Oral ENMD-2076 administered to patients with advanced/metastatic soft tissue sarcoma. The study is being conducted at Princess Margaret Hospital in Toronto, Canada.

In June 2013, we filed a new drug global clinical trial application with the CFDA to expand our Phase 2 clinical trial of ENMD-2076 in advanced/metastatic sarcoma. 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 advanced/metastatic sarcoma trial currently underway at Princess Margaret Hospital.

In July 2013, we initiated a crossover bioavailability and food effect study of ENMD-2076. The study was to be a single-blind, randomized, single-dose, crossover study with a food effect arm to investigate the safety and relative bioavailability of two dosage forms of ENMD-2076 administered as escalating doses in two cohorts of healthy subjects. The study was expected to enroll approximately 29 healthy adult volunteers and be conducted in Tempe, Arizona by a clinical research organization. The pharmacokinetic data from the first cohort (compared the two dosage forms in fasted state), demonstrated ENMD-2076's relative bioavailability, and EntreMed took the position that continuing the study would be unnecessary. The data was submitted for review by the FDA, and the FDA gave EntreMed permission to stop the study after the first cohort. Cohort 1 involved 14 healthy volunteers that were dosed with the two dosage forms. The final clinical study report is expected to be completed in the second quarter of 2014.

In October 2013, we commenced a multi-center Phase 2 study of Oral ENMD-2076 administered to patients with ovarian clear cell carcinomas. The study is being conducted at Princess Margaret Hospital in Toronto, Canada with participation of up to seven additional cancer centers in Canada and the United States.

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.

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

We intend to advance clinical development of ENMD-2076, 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. The Chinese subsidiary 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 accelerated development and commercialization in the Chinese market.

#### **OTHER PRODUCT CANDIDATES**

ENMD-2076 is our only program currently under active clinical evaluation. Our other product candidates in the pipeline include (i) 2-methoxyestrdiol (2ME2) for autoimmune diseases for which we have an approved Investigational New Drug Application (IND) in rheumatoid arthritis treatment and (ii) MKC-1. We own or have exclusive license to these products.

2ME2 (2-methoxyestradiol) for Autoimmune Diseases. 2ME2 (2-methoxyestradiol) is 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 rheumatoid arthritis ("RA"). 2ME2 (2-methoxyestradiol) has potential as a single agent in RA based on its antiangiogenic, anti-inflammatory, and anti-osteoclastic (bone resorption) properties. Clinical trial activities have previously been conducted with 2ME2 in RA, but in an effort to focus on the development of ENMD-2076, no significant additional resources have been expended

on this program. In December 2012, preclinical results for 2ME2 were published online in the Early Edition of *Proceedings of the National Academy of Sciences* (PNAS). Together with our previous findings of its disease modifying activity in RA animal models, the study further extended 2ME2's therapeutic value to the management of multiple sclerosis, RA and possibly other autoimmune disorders. The Company is exploring multiple strategies for the development of 2ME2 including potential internal development and partnership opportunities.

*MKC-1 for Oncology.* MKC-1 is an orally-active, small molecule, cell cycle inhibitor with in vitro and in vivo efficacy against a broad range of human solid tumor cell lines, including multi-drug resistant cell lines. MKC-1 acts through multiple mechanisms of action, arresting cellular mitosis and inducing cell death (apoptosis) by binding to a number of different cellular proteins, including tubulin and members of the importin  $\beta$  family. MKC-1 has demonstrated broad antitumor effects in multiple preclinical models, including paclitaxel-resistant models, and was evaluated in several Phase 1 and 2 clinical studies prior to the licensing of the drug from Hoffman La Roche. Since acquired by EntreMed, MKC-1 has shown single agent antitumor activity in breast cancer patients and in combination with Alimta® in [non-small cell lung carcinoma] patients. MKC-1 has completed multiple Phase 2 clinical trials for cancer. MKC-1 is available to potential parties interested in partnering with the Company for further clinical evaluation.

### PRECLINICAL

Our focus is on clinical-stage or clinical-stage ready drug candidates so that we can immediately employ our US 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, 2013 and expect to continue to incur operating losses for the foreseeable future before commercialization of any products. We spent \$2,749,000 on research and development in 2013, as compared to \$2,375,000 in 2012. The increase in research and development spending relates to patients enrolling in and remaining on clinical trials during 2013, offset by a decrease in patent fees. 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. Dr. Wei-Wu He serves as our Chairman. 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.

# SCIENTIFIC FOUNDATION

We developed our product candidates based on comprehensive research into the relationship between malignancy and angiogenesis (the growth of new blood vessels). This research led to a focus on product candidates that act on the cellular pathways that affect biological processes important in multiple diseases, specifically angiogenesis and cell cycle regulation through the inhibition of key kinases. Our product candidate, ENMD-2076,

has potential applications in oncology and other diseases that are dependent on the regulation of these processes.

**Kinase Inhibition**. Kinases are enzymes that are primary regulators of many essential processes in living cells. There are approximately 500 different kinases encoded in the human genome, and these proteins act together in intricate communication networks and pathways to control virtually every aspect of cellular function. The reliance of a cell on kinases to regulate function can be disastrous when kinase signaling becomes aberrant. Many human diseases have been linked to these enzymes including all forms of cancer, arthritis, inflammation, diabetes, and cardiovascular disease. The inhibition of kinases as a targeted therapeutic approach has now been validated by several drugs that have advanced successfully through clinical trials to the marketplace. The integral role kinases play in angiogenesis and cell cycle regulation has led us to develop inhibitors to key kinases involved in these processes.

**Cell Cycle Regulation.** Precise regulation of the cell cycle is essential for healthy cell functions including the replication, growth, and differentiation. One specific aspect of cell cycle regulation is the programmed control of cell death (apoptosis). In certain diseases, such as cancer, the balance between cell proliferation and cell death is altered, resulting in inappropriate cell growth. Our compounds impact biochemical pathways in cells that result in their death via apoptosis. We believe that the selective induction of apoptosis through drugs that induce cell cycle arrest can either stabilize or cause the regression of cancer, inflammation and other disease processes characterized by inappropriate cell growth.

Angiogenesis. Angiogenesis is a multi-step process whereby new blood vessels are formed. This tightly regulated process involves the migration, proliferation and differentiation of endothelial cells. In normal physiology, angiogenesis is a necessary component of the menstrual cycle and wound healing, where the process is regulated through appropriate shifts in the balance of pro-angiogenic and anti-angiogenic signals. This tight regulation of angiogenesis in normal physiology is absent or aberrant in multiple disease settings that are characterized by persistent, inappropriate blood vessel development. Inappropriate angiogenesis occurs in more than 80 diseases, particularly in various cancers where the growth of new blood vessels is necessary to sustain tumor growth.

#### BUSINESS DEVELOPMENT AND COMMERCIALIZATION STRATEGY

Oncology is our principal clinical and commercial focus. Based on ENMD-2076's strong preclinical antitumor activity, favorable safety profile and bioavailability, we believe that it has significant therapeutic potential in a broad range of tumor types and will continue to invest behind ENMD-2076 as our lead program. We believe that ENMD-2076 represents a potential Phase 3 partnering opportunity for large biopharmaceutical companies or drug development companies for either global or other territory rights outside of China. As a result, our strategy is to pursue the development of ENMD-2076 for oncology, obtain additional clinical data while being selective and opportunistic in exploring strategic alliances for this and other future compounds in our pipeline. We intend to employ 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 US and China drug development strategy. We may pursue co-development program with complementary expertise. We can also provide our co-development partners with substantial know-how relating to small molecules that inhibit angiogenesis and inflammation, as well as regulate cell cycle pathways.

In 2012, we established a wholly-owned Chinese subsidiary that is executing the China portion of our drug development strategy, which will include 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 have entered 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 14, 2014, we are conducting clinical trials for ENMD-2076 at the following institutions:

Clinical Trial	Institution
Phase 2 Ovarian Cancer	<ul> <li>Princess Margaret Hospital, Toronto, Ontario</li> </ul>
(being completed; enrollment closed)	• Indiana University Melvin & Bren Simon Cancer Center, Indianapolis, IN
Phase 2 Triple-Negative Breast Cancer (currently enrolling)	<ul> <li>University of Colorado Cancer Center, Aurora, CO</li> <li>Indiana University Melvin &amp; Bren Simon Cancer Center, Indianapolis, IN</li> </ul>
Phase 2 Advanced/Soft Tissue Sarcoma (currently enrolling)	Princess Margaret Hospital, Toronto, Ontario
Phase 1 Crossover Bioavailability Equivalent (being completed; enrollment closed)	• Celerion, Inc., Tempe, AZ
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 lead drug candidate, ENMD-2076, we directly own 9 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 entire patent estate for all of our product candidates, we directly own 7 granted patents and pending patent applications in the United States, 20 foreign granted patents and pending patent applications, and in connection with MKC-1, we have exclusively in-licensed an extensive patent estate of granted patents and pending patent applications worldwide. We review and assess our portfolio on a regular basis to secure protection and to align our patent strategy with our overall business strategy.

We have trademark protection for the trademark ENTREMED.

# **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, preclinical 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, MD and Beijing, China, currently consists of 15 full-time employees and 1 part-time employee. 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 10 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.entremed.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.

# 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, 2013, we had an accumulated deficit of approximately \$399 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.

Losses have continued since December 31, 2013. 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 access to the capital markets, 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.

# IDG is Our Largest Holder Of Common Stock And May Have Different Interests Than Our Other Stockholders

IDG-Accel China and its affiliated entities (collectively, "IDG") hold approximately 20.2% of the outstanding shares of our common stock (excluding the shares issuable under the warrants held by IDG). IDG is permitted to have a 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 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.

# 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 of a substantial amount of the shares of common stock held by them.

# 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 2014. 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, 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.

# 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 2014. 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, 2013, we had cash of approximately \$15,132,000. 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 2014 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 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.

#### We Do Not Have Any Late Stage Product Candidates

We do not have any late stage clinical programs, and ENMD-2076 is in Phase 2 trials. There is no assurance that ENMD-2076 will progress to further Phase 2 trials or advance to a Phase 3 trial, or that we will be able to finance such clinical trials. Accordingly, we do not have any near-term prospects of generating revenues from the commercial sale of ENMD-2076 or any of our product candidates.

# 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 2013, our stock price ranged from \$1.38 to \$3.47. 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.

# **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.

#### **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.

# We May Engage in Strategic and Other Corporate Transactions, Which Could Negatively Affect Our Business and Earnings

In 2014, 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 earnings, 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.

# 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, 2013, we leased approximately 4,200 square feet of office space in Rockville, Maryland where our headquarters are located. In addition, as of December 31, 2013, we leased approximately 1,900 square feet of office space in Beijing, China where our China operations are based. Additionally, on February 1, 2014, we entered into a lease for approximately 2,600 square feet of lab 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.

EntreMed 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				
-	Н	IGH	Ι	.OW
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
2012:				
First Quarter	\$	1.00	\$	2.95
Second Quarter		1.59		2.16
Third Quarter		1.72		2.48
Fourth Quarter		1.26		1.94

On March 14, 2014, the closing price of our common stock, as reported by The NASDAQ Capital Market, was \$1.86 per share. As of March 14, 2014 there were approximately 581 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.

In connection with the Company's financing in 2012, Celgene Corporation ("Celgene") waived all accrued dividends on its Series A Preferred, and converted its shares of Series A Preferred to shares of common stock. Upon conversion, the liquidation preference on such shares of Series A Preferred was eliminated and the class of Series A Preferred has since been eliminated.

### 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 clinical-stage pharmaceutical company employing a drug development strategy that leverages resources in both North America and in China to develop therapeutics for the treatment of cancer and other diseases. We are currently conducting activities in both China and North America in order to accelerate delivery of clinical data and to reduce costs of clinical trials. Our lead drug candidate is ENMD-2076, a selective Aurora A and angiogenic kinase inhibitor for the treatment of cancer, which we will continue to develop under 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. Our market focus includes developed countries, and also in particular, China, which has a pharmaceutical products market that we believe will continue to grow rapidly. Through partnerships, collaborations, and strategic acquisitions, we intend to add additional drug candidates to our pipeline for development using our US and China strategy. We intend to employ 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 our US and China drug development strategy.

ENMD-2076 is an orally-active, Aurora A/angiogenic kinase inhibitor with a unique kinase selectivity profile and multiple mechanisms of action. ENMD-2076 exerts its effects through multiple mechanisms of action, including anti-proliferative activity and the inhibition of angiogenesis. 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 also has shown promising activity in Phase 1 clinical trials in solid tumor cancers including ovarian, breast, liver, renal and sarcoma, as well as in leukemia and multiple myeloma. EntreMed is completing a Phase 2 trial of ENMD-2076 in ovarian cancer. In addition, EntreMed is currently conducting a dual-institutional Phase 2 study of ENMD-2076 in triple-negative breast cancer, a Phase 2 study in advanced/metastatic soft tissue sarcoma, and a Phase 2 study in advanced ovarian clear cell carcinoma.

Clinical Phase 1 results were published (Clin Cancer Res 2011;17:849-860) and data from the leukemia and myeloma studies were presented during the American Society of Hematology meeting in December 2010. Anticancer activity was demonstrated with ENMD-2076 treatment in a variety of solid and hematological cancer patients. Also, as previously reported, at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2011, Phase 2 data in ovarian cancer patients was presented by the principal investigator conducting the Phase 2 ENMD-2076 study. The data demonstrated ENMD-2076 activity in a population of difficult to treat platinum resistant patients. In October 2011, we announced that the final data for the primary endpoint of progression free survival rate at 6 months was 22 percent. Phase 2 data in ovarian cancer were also published in the European Journal of Cancer in September 2012 in an article entitled "ENMD-2076, an Oral Inhibitor of Angiogenic and Proliferation Kinases, Has Activity in Recurrent, Platinum Resistant Ovarian Cancer." We believe that the data, together with the Phase 1 results, provide support for additional clinical studies in ovarian cancer and other forms of cancer. We continue to monitor patients who are receiving ENMD-2076, and are focused on collecting additional data on overall survival and other endpoints.

In July 2012, we commenced a dual-institutional Phase 2 study of ENMD-2076 in triple-negative breast cancer. The study is being conducted at the University of Colorado Cancer Center, with a second sited added in December 2012 at Indiana University Melvin & Bren Simon Cancer Center.

In November 2012, results of a preclinical study in triple-negative breast cancer (TNBC) of ENMD-2076 were published in the article, entitled "Predictive Biomarkers of Sensitivity to the Aurora and Angiogenic Kinase Inhibitor ENMD-2076 in Preclinical Breast Cancer Models." Through this study, ENMD-2076 shows activity against preclinical models of breast cancer with more robust activity against TNBC. The study also supports further clinical investigation of ENMD-2076 in patients with metastatic TNBC with an emphasis on the continued development of p53-based predictive biomarkers. It provides strong support for the rational of our ongoing Phase 2 TNBC trial.

In December 2012, to advance our global development strategy, we filed a new drug clinical trial application with the CFDA to conduct global clinical trials in triple-negative breast cancer patients using our proprietary drug candidate, ENMD-2076. 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 triple-negative breast cancer trial currently underway at the University of Colorado and Indiana University.

In January 2013, we commenced a single-center Phase 2 study of Oral ENMD-2076 administered to patients with advanced/metastatic soft tissue sarcoma. The study is being conducted at Princess Margaret Hospital in Toronto, Canada.

In June 2013, we filed a new drug global clinical trial application with the CFDA to expand our Phase 2 clinical trial of ENMD-2076 in advanced/metastatic sarcoma. 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 advanced/metastatic sarcoma trial currently underway at Princess Margaret Hospital.

In July 2013, we initiated a crossover bioavailability and food effect study of ENMD-2076. The study was to be a single-blind, randomized, single-dose, crossover study with a food effect arm to investigate the safety and relative bioavailability of two dosage forms of ENMD-2076 administered as escalating doses in two cohorts of healthy subjects. The study was expected to enroll approximately 29 healthy adult volunteers and be conducted in Tempe, Arizona by a clinical research organization. The pharmacokinetic data from the first cohort (compared the two dosage forms in fasted state), demonstrated ENMD-2076's relative bioavailability, and EntreMed took the position that continuing the study would be unnecessary. The data was submitted for review by the FDA, and the FDA gave EntreMed permission to stop the study after the first cohort. Cohort 1 involved 14 healthy volunteers that were dosed with the two dosage forms. The final clinical study report is expected to be completed in early 2014.

In October 2013, we commenced a multi-center Phase 2 study of Oral ENMD-2076 administered to patients with ovarian clear cell carcinomas. The study is being conducted at Princess Margaret Hospital in Toronto, Canada with participation of up to seven additional cancer centers in Canada and the United States.

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.

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

ENMD-2076 is our only program currently under active clinical evaluation. Our other product candidates in the pipeline include 2-methoxyestrdiol (2ME2) for autoimmune diseases, for which we have an approved IND in RA treatment, and MKC-1. We own or have exclusive licenses to these products.

We intend to advance clinical development of ENMD-2076, 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 accelerated development and commercialization in the Chinese market.

Since inception, we have incurred significant losses from operations and have incurred an accumulated deficit of \$399.1 million. We expect to continue to incur operating losses for the foreseeable future due to, among other factors, our continuing clinical activities. 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.

On January 20, 2012, we entered into a Convertible Note and Warrant Purchase Agreement (the "Purchase Agreement") with certain accredited investors (the "2012 Investors"), pursuant to which we issued and sold to the 2012 Investors, in a private placement, subordinated mandatorily convertible promissory notes (collectively, the "Notes") with an aggregate principal amount of \$10 million (the "2012 Financing"). We also issued warrants (the "2012 Warrants") to the Investors to purchase an aggregate of 1,739,132 shares of the Company's common stock. The 2012 Warrants cover a number of shares of common stock equal to 20% of the principal amount of the Notes purchased by each investor, divided by \$1.15. The 2012 Warrants have an exercise price of \$1.40 per share and were exercisable beginning on July 29, 2012 and expire on July 29, 2017.

The 2012 Financing was completed on February 2, 2012. We received net proceeds of approximately \$9.3 million. We received approval of the 2012 Financing from the Company's stockholders at the 2012 annual stockholders meeting held on April 30, 2012. On May 1, 2012, the Notes, including accrued interest of \$144,658, automatically and immediately converted into 8,821,431 shares of common stock and the 2012 Warrants became exercisable on July 29, 2012. The Notes bore an interest rate of 6% and converted at a conversion price of \$1.15 per share. The conversion price reflected the 10-day average closing sale price of our Common Stock ended on January 20, 2012.

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.

Royalty Revenue – Royalties from licenses are based on third-party sales and recorded as earned in accordance with contract terms, when third-party results are reliably measured and collectibility is reasonably assured. Our 2012 revenues were from royalties on the sale of Thalomid<sup>®</sup>. In 2004, certain provisions of a purchase agreement, dated June 14, 2001, by and between Bioventure Investments kft ("Bioventure") and the Company were satisfied and, as a result, beginning in 2005 we became entitled to share in the royalty payments received by Royalty Pharma Finance Trust, successor to Bioventure, on annual Thalomid<sup>®</sup> sales above a certain threshold. Based on the licensing agreement royalty formula, annual royalty sharing commences when net royalties received by Royalty Pharma exceeds \$15,375,000. We did not meet the threshold to earn any revenue from royalties on the sale of Thalomid<sup>®</sup> in 2013 and do not expect to meet the threshold in any subsequent year.

- We are also eligible to receive royalties from Oxford Biomedica, PLC based on a portion of the net sales of products developed for the treatment of ophthalmic (eye) diseases based in part on the Endostatin gene. We did not receive any payment from Oxford Biomedica, PLC in 2012 or 2013. We do not expect to receive payments from Oxford Biomedica, PLC in 2014.
- Royalty payments, if any, are recorded as revenue when received and/or when 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 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. As of December 31, 2013, no expense has been recorded for share awards with performance conditions. 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, 2013 and 2012 totaled \$2,044,000 and \$978,000, 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.

# **RESULTS OF OPERATIONS**

Years Ended December 31, 2013 and 2012.

*Revenues.* There was no revenue recorded in 2013. Revenues were \$669,000 in 2012. Our revenues for 2012 reflect royalty revenues received from the sales of Thalomid<sup>®</sup>. The lack of revenue for 2013 was consistent with our expectations and results from decreased royalty revenue earned on sales of Thalomid<sup>®</sup> in the United States. Annual sales of Thalomid<sup>®</sup> in 2013 decreased to a level below the threshold amount to trigger a royalty payment to the Company. As a result we did not earn any royalty revenue in 2013 and do not expect to earn any in any subsequent year. Beginning in 2005, we became entitled to share in the royalty payments received by Royalty Pharma Finance Trust on annual Thalomid<sup>®</sup> sales when Royalty Pharma Finance Trust receives more than \$15,375,000 in royalties. Thalomid<sup>®</sup> sales in 2012 surpassed the annual revenue targets and we recorded royalty revenues of \$669,000.

*Research and Development Expenses.* Our 2013 research and development expenses totaled \$2,749,000 as compared to \$2,375,000 in 2012, a 16% increase. In 2013, our research and development expenses reflect direct project costs for ENMD-2076 of \$1,452,000 and \$64,000 for 2ME2. The 2012 amount reflects direct project costs for ENMD-2076 of \$1,312,000 and \$190,000 for 2ME2. The increase in 2013 research and development spending reflects increased costs associated with the clinical development of ENMD-2076 in the U.S. and China during 2013, as well as an increase in non-cash stock-based compensation expense, offset by lower patent costs and the absence of severance related costs in 2013.

At December 31, 2013, accumulated direct project expenses for 2ME2 were \$58,087,000 and, since acquired, accumulated direct project expenses for ENMD-2076 totaled \$23,440,000. Our research and development expenses also include non-cash stock-based compensation totaling \$763,000 and \$273,000, respectively, for 2013 and 2012. The increase in stock-based compensation expense is related to the increase in stock options granted in 2013. 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 2014 to be devoted to the development of our ENMD-2076 program. We expect our ENMD-2076 expenses in 2014 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 \$2,749,000 in 2013 from \$2,375,000 in 2012.

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 \$41,000 in 2013 and \$42,000 in 2012 on these activities associated with clinical trials for the development of the ENMD-2076.
- Clinical Trial Costs Clinical trial costs, which include clinical site fees, monitoring costs and data
  management costs, increased to \$647,000 in 2013, from \$227,000 in 2012. The increase in 2013 relates to
  costs associated with enrolling patients in Phase 2 clinical trials for TNBC and ovarian clear cell carcinoma
  during 2013 and increased costs associated with clinical research organization costs 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
  decreased in 2013 to \$212,000, from \$276,000 in 2012. The decrease in 2013 primarily reflects the timing
  of manufacturing costs incurred by our operations in China related to manufacturing of ENMD-2076.
- Personnel Costs Personnel costs increased to \$1,331,000 in 2013 from \$1,048,000 in 2012. This increase
  is attributed to an increase in non-cash stock-based compensation expense totaling \$490,000 during 2013
  and increased salary and benefit costs associated with new employees in China during 2013, offset by
  severance expense of \$286,000 in 2012.
- Also reflected in our 2013 research and development expenses are patent costs of \$72,000, and facility and related expenses of \$110,000. In 2012, these expenses totaled \$439,000 and \$70,000, respectively. The decrease in patent costs during 2013 reflects higher costs in 2012 associated with the execution of our intellectual property strategy, including maintaining our patent portfolio and expanding our patent protection internationally. The increase in expenses in facilities and related expenses in 2013 resulted from leased office 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 \$2,991,000 in 2013 from \$2,798,000 in 2012. This increase is primarily related to an increase of \$576,000 related to non-cash stock-based compensation in 2013 due to an increase in stock option awards during the year, offset by the reduction in personnel costs of \$275,000, a reduction in Board of Directors fees of \$60,000, as well as lower professional fees of \$71,000 compared to 2012.

*Interest Expense.* Interest expense for the year ended December 31, 2012 was \$10,041,000. All of the interest expense was non-cash interest (including \$684,000, related to amortization of deferred financing costs; \$2,156,000, related to amortization of debt discount; and \$145,000, related to accrued interest on our Notes payable which was converted to shares of common stock on May 1, 2012). Also included in the \$10 million non-cash

interest expense for the year ended December 31, 2012 was \$7,057,000, representing the value of the beneficial conversion feature associated with the Notes. There was no interest expense for the year ended December 31, 2013.

*Dividends on Series A Convertible Preferred Stock.* The Consolidated Statement of Operations for the year ended December 31, 2012 reflects accrued, but unpaid, dividends of \$335,000, related to Series A Convertible Preferred Stock held by Celgene pursuant to a Securities Purchase Agreement dated December 31, 2002. Celgene, the holder of Series A Preferred Stock accumulated dividends at a rate of 6% and participated in dividends declared and paid on the common stock, if any. In connection with the stockholder approval of the 2012 Financing on April 30, 2012, Celgene waived all accrued dividends on the Series A Preferred Stock, and is no longer entitled to any liquidation preference on its shares. There are no outstanding shares of Series A Convertible Preferred Stock and the Series A class of preferred stock has been eliminated.

# 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 2014 and the foreseeable future before we commercialize any products. Based on our current plans, we expect our current available cash and cash equivalents to meet our cash requirements for at least the next twelve months.

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, 2013, we had cash of \$15,131,671, with working capital of \$14,846,278.

# 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.

Prior to the 2013 Financing, on February 2, 2012, we completed a financing with the 2012 Investors, for an aggregate gross amount of \$10,000,000. In connection with the 2012 Financing, on January 20, 2012, we entered into the Purchase Agreement with the 2012 Investors, pursuant to which we issued and sold to the 2012 Investors, in a private placement, the Notes with an aggregate principal amount of \$10 million. We also issued warrants to the Investors to purchase an aggregate of 1,739,132 shares of the Company's common stock. The 2012 Warrants cover a number of shares of common stock equal to 20% of the principal amount of the Notes purchased by each Investor, divided by \$1.15. The 2012 Warrants have an exercise price of \$1.40 per share and are exercisable on or after July 29, 2012 and expire five years after the exercisable date. At the closing of the 2012 Financing, we received net proceeds of approximately \$9.3 million. We received approval of the 2012 Financing from the Company's stockholders at the 2012 annual stockholders meeting held on April 30, 2012. On May 1, 2012, the Notes, including accrued interest of \$144,658, automatically and immediately converted into 8,821,431 shares of common stock and the 2012 Warrants became exercisable on July 29, 2012. The Notes bore an interest rate of 6% and converted at a conversion price of \$1.15 per share. The conversion price reflects the 10-day average closing sale price of our common stock ending on January 20, 2012.

# 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 2013.

# 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, 2013, 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 Principal Accounting 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 & General Counsel) to allow timely decisions regarding required disclosures. Based on such evaluation, our Chief Executive Officer, Principal Accounting Officer, and Chief Operating Officer, and Chief Operating Officer, and Chief Operating Officer, and Chief Operating Officer, Principal Accounting Officer and counsel) to allow timely decisions regarding required disclosures. Based on such evaluation, our Chief Executive Officer, Principal Accounting Officer, and Chief Operating Officer as of December 31, 2013.

#### **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, 2013 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 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 reporting and the preparation of financial reporting 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, 2013.

#### **ITEM 9B. OTHER INFORMATION.**

Our 2014 Annual Meeting of Stockholders will be held on June 12, 2014. 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, 2013.

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.entremed.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, 2013.

### 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, 2013.

#### **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, 2013.

	(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	3,586,394	\$2.69	1,110,876
Equity compensation plans not approved by security holders	0	\$ 0.00	0
Total	3,586,394	\$2.69	1,110,876

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, 2013.

### 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, 2013.

#### 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 from our Form 8-K previously 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 from our Form 10-Q for the quarter ended June 30, 2006 previously filed with the Securities and Exchange Commission)
- 3.2 Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on July 7, 2010)
- 3.3 Amended and Restated By-laws of EntreMed, Inc. (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on December 12, 2007)
- 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 previously filed with the Securities and Exchange Commission on September 20, 2012.)
- 4.2 Form of Common Stock Purchase Warrant, dated September 7, 2010 (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on September 10, 2010)
- 4.3 Form of Common Stock Purchase Warrant (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on January 26, 2012)
- 4.4 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)

- 4.5 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)
- 10.1 License Agreement between Children's Hospital Medical Center Corporation and EntreMed, Inc. signed December 20, 1996 regarding Estrogenic Compounds as Anti-Mitotic Agents (incorporated by reference from our Form 10-K for the year ended December 31, 1996 previously filed with the Securities and Exchange Commission)
- 10.2 License Agreement between Celgene Corporation and EntreMed, Inc. signed December 9, 1998 regarding thalidomide intellectual property + (incorporated by reference from our Form 10-K for the year ended December 31, 1998 previously filed with the Securities and Exchange Commission)
- 10.3 Lease Agreement between EntreMed, Inc. and Red Gate III Limited Partnership, dated June 10, 1998 (incorporated by reference from our Form 10-K for the year ended December 31, 1998 previously filed with the Securities and Exchange Commission)
- 10.4 EntreMed, Inc. 2001 Long-Term Incentive Plan\* (incorporated by reference from Appendix A to our Definitive Proxy Statement filed with the Securities and Exchange Commission on May 12, 2006)
- 10.5.1 Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated June 15, 2001+ (incorporated by reference from our Form 10-Q for the quarter ended June 30, 2001 previously filed with the Securities and Exchange Commission)
- 10.5.2 Amendment 1 to Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated July 13, 2001(incorporated by reference from our Form 10-Q for the quarter ended June 30, 2001 previously filed with the Securities and Exchange Commission)
- 10.5.3 Amendment 2 to Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated July 30, 2001(incorporated by reference from our Form 10-Q for the quarter ended June 30, 2001 previously filed with the Securities and Exchange Commission)
- 10.5.4 Amendment 3 to Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated August 3, 2001 (incorporated by reference from our Form 10-Q for the quarter ended June 30, 2001 previously filed with the Securities and Exchange Commission)
- 10.6 EntreMed, Inc. 2001 Long Term Incentive Plan Non-Qualified Stock Option Grant Agreement (Director)\* (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on April 17, 2007)
- 10.7 EntreMed, Inc. 2001 Long Term Incentive Plan Non-Qualified Stock Option Grant Agreement (Non-Director Employee)\* (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on April 17, 2007)
- 10.8 Form of Change in Control Agreement\* (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on April 17, 2007)
- 10.9 Employment Agreement by and between EntreMed and Cynthia W. Hu, dated as of June 1, 2006\* (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on June 6, 2006)
- 10.10 Amendment to Employment Agreement by and between the Company and Cynthia W. Hu, effective April 16, 2007\* (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on April 17, 2007)
- 10.11 Form of Restricted Stock Award under EntreMed, Inc. 2001 Long Term Incentive Plan\* (incorporated

by reference from our Form 8-K previously filed with the Securities and Exchange Commission on March 11, 2005.

- 10.12 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 from our Form 10-Q for the quarter ended March 31, 2005 previously filed with the Securities and Exchange Commission)
- 10.13 Securities Purchase Agreement, dated September 7, 2010 by and between EntreMed, Inc. and the investors party thereto (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on September 10, 2010)
- 10.14 Employment Agreement, by and between EntreMed, Inc. and Sara Capitelli, dated as of January 10, 2011\* (incorporated by reference from our Form 10-K for the fiscal year ended December 31, 2010, previously filed with the Securities and Exchange Commission)
- 10.15 Convertible Note and Warrant Purchase Agreement, dated January 20, 2012, by and among EntreMed, Inc. and the investors party thereto (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on January 26, 2012)
- 10.16 EntreMed, Inc. 2011 Long-Term Incentive Plan\* (incorporated by reference from Appendix A to our Definitive Proxy Statement previously filed with the Securities and Exchange Commission on April 16, 2013)
- 10.17 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)
- 10.18 Securities Purchase Agreement, dated March 1, 2013, by and among EntreMed, Inc. and the investors thereto (incorporated by reference from our Form 8-K previously filed with the Securities and Exchange Commission on March 6, 2013)
- 10.19 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)
- 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, 2013, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2013 and 2012, (ii) Consolidated Statements of Operations for the years ended December 31, 2013 and 2012, (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2013 and 2012 (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2013 and 2012 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.
- \*\* This exhibit is furnished and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (15 U.S.C. 78r), or otherwise subject to the liability of that section. Such exhibit will not be deemed to be incorporated by reference into any filing under the Securities Act or Securities Exchange Act, except to the extent that the Registrant specifically incorporates it by reference.

# **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 21, 2014

ENTREMED, INC.

By: <u>/s/Ken K. Ren</u> 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
<u>/s/Ken K. Ren</u> Ken K. Ren	Chief Executive Officer (Principal Executive Officer)	March 21, 2014
<u>/s/Sara B. Capitelli</u> Sara B. Capitelli	Principal Accounting Officer	March 21, 2014
<u>/s/Wei-Wu He</u> Wei-Wu He	Chairman	March 21, 2014
<u>/s/Tak W. Mak</u> Tak W. Mak	Director	March 21, 2014
<u>/s/James Z. Huang</u> James Z. Huang	Director	March 21, 2014
<u>/s/Jennie C. Hunter-Cevera</u> Jennie C. Hunter-Cevera	Director	March 21, 2014
<u>/s/Y. Alexander Wu</u> Y. Alexander Wu	Director	March 21, 2014

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

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2013 and 2012	F-3
Consolidated Statements of Operations for the years ended December 31, 2013 and 2012	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2013 and 2012	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2013 and 2012	F-6
Notes to Consolidated Financial Statements	F-7

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of EntreMed, Inc.:

We have audited the accompanying consolidated balance sheets of EntreMed, Inc. as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended. EntreMed, Inc.'s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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 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 consolidated financial position of EntreMed, Inc. as of December 31, 2013 and 2012, and the consolidated results of its operations and its 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 21, 2014

# EntreMed, Inc. Consolidated Balance Sheets

	DECEMBE 2013	ER 31, <u>2012</u>
ASSETS Current assets: Cash and cash equivalents Accounts receivable, net of allowance for doubtful accounts of \$12,536 at December 31, 2013 and 2012	\$ 15,131,671	\$ 8,049,237 669,310
Prepaid expenses and other Total current assets	<u> </u>	<u>189,465</u> 8,908,012
Property and equipment, net	78,142	52,556
Other assets Total assets	<u>17,965</u> <u>\$15,507,551</u>	<u> </u>
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities: Accounts payable Payable to related party Accrued liabilities Total current liabilities	\$ 402,456 <u>162,710</u> <u>565,166</u>	\$ 504,851 86,683 151,219 742,753
<ul> <li>Commitments and Contingencies</li> <li>Stockholders' equity:</li> <li>Convertible preferred stock, \$1.00 par value;</li> <li>5,000,000 shares authorized and 0 shares issued and outstanding at December 31, 2013 and 2012</li> <li>Common stock, \$.01 par value:</li> <li>170,000,000 shares authorized at December 31, 2013 and 2012;</li> <li>27,119,974 and 22,582,938 shares issued and outstanding at December 31, 2013 and 2012, respectively</li> </ul>	- - 271,198	- - 225,828
Additional paid-in capital Treasury stock, at cost: 79,545 shares held at December 31, 2013 and 2012 Accumulated deficit Total stockholders' equity Total liabilities and stockholders' equity	$\begin{array}{r} 421,775,039\\ (8,034,244)\\ \underline{ (399,069,608)}\\ 14,942,385\\ \underline{\$  15,507,551} \end{array}$	$\begin{array}{r} 409,374,905\\ (8,034,244)\\ \underline{(393,331,247)}\\ 8,235,242\\ \underline{\$ 8,977,995}\end{array}$

# EntreMed, Inc. Consolidated Statements of Operations

# YEAR ENDED DECEMBER 31,

	2013	2012
Revenues:		
Royalties	\$ -	<u>\$ 669,310</u>
		669,310
Costs and expenses:		
Research and development	2,749,430	2,375,339
General and administrative	2,990,589	2,797,971
	5,740,019	5,173,310
Interest (income) expense, net	(1,658)	10,041,224
Net loss	(5,738,361)	(14,545,224)
Dividends on Series A convertible preferred stock	<u> </u>	(335,000)
Net loss attributable to common shareholders	<u>\$ (5,738,361</u> )	<u>\$ (14,880,224</u> )
Net loss per share (basic and diluted)	<u>\$ (0.22</u> )	<u>\$ (0.78</u> )
Weighted average number of shares outstanding (basic		
and diluted)	26,125,852	19,055,064

EntreMed, Inc. Consolidated Statements of Stockholders' Equity Years Ended December 31, 2013 and 2012

	Preferre	Preferred Stock	Commo	Common Stock	Treasury	Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Stock	Capital	Deficit	Total
Balance at December 31, 2011	3,350,000	\$ 3,350,000	12,158,099	\$ 122,376	\$ (8,034,244)	\$ 385,879,634	\$ (378,786,023)	\$ 2,531,743
Issuance of common stock for ontions exercised		,	1.136	=		1 988	ı	1,999
Conversion of preferred stock into common stock	(3,350,000)	(3,350,000)	1,522,727	15,227		3,334,773		1
Issuance of common stock pursuant to the 2012 Financing,			а.	×.		х х		
net of stock issuance costs (Note 6)	ı		8,821,431	88,214		9,967,587		10,055,801
Fair value of warrants issued pursuant to the 2012								
Financing (Note 6)	ı	ı		ı		2,155,527		2,155,527
Fair value of beneficial conversion of notes pursuant to								
the 2012 Financing (Note 6)	ı	ı		ı		7,057,153		7,057,153
Stock-based compensation expense, net of forfeitures	ı	·		ı		978,243		978,243
Net loss				'			(14,545,224)	(14,545,224)
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	ı	ı	3,817	38	'	7,152		7,190
Issuance of common stock for warrants exercised		ı	37,391	374		51,973		52,347
Issuance of common stock pursuant to the 2013 Financing,								
net of stock issuance costs (Note 6)	ı	ı	4,495,828	44,958		6,607,297		6,652,255
Fair value of warrants issued pursuant to the 2013								
Financing (Note 6)	ı	ı		ı		3,689,330		3,689,330
Stock-based compensation expense, net of forfeitures	ı	ı		ı		2,044,382		2,044,382
Net loss	ı	ı	·	ı	ı		(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

# EntreMed, Inc. Consolidated Statements of Cash Flows

	YEAR ENDED	DECEMBER 31,
	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES Net loss Adjustments to reconcile net loss to net cash used in operating	\$ (5,738,361)	\$ (14,545,224)
activities: Depreciation and amortization Stock-based compensation expense Non-cash interest Changes in operating assets and liabilities:	17,389 2,044,382	20,457 978,243 10,041,292
Accounts receivable Prepaid expenses and other Accounts payable Payable to related party Accrued liabilities Net cash used in operating activities	669,310 (90,846) (102,395) (86,683) 11,491 (3,275,713)	1,263,432 (9,051) 51,522 86,683 (99,543) (2,212,189)
CASH FLOWS FROM INVESTING ACTIVITIES Purchases of furniture and equipment Net cash used in investing activities	<u>(42,975)</u> (42,975)	<u>(48,392)</u> (48,392)
CASH FLOWS FROM FINANCING ACTIVITIES Proceeds from issuance of convertible notes and warrants Debt issuance costs Proceeds from sale of common stock and warrants Stock issuance costs Proceeds from exercise of options and warrants Net cash provided by financing activities	10,789,987 (448,402) 59,537 10,401,122	10,000,000 (683,955) (88,856) <u>1,999</u> 9,229,188
Net increase in cash and cash equivalents Cash and cash equivalents at beginning of year Cash and cash equivalents at end of year	7,082,434 <u>8,049,237</u> <u>15,131,671</u>	6,968,607 <u>1,080,630</u> <u>\$ 8,049,237</u>
Supplemental disclosure of cash flow information:		
Non-cash financing activity: Common stock issued in connection with conversion of convertible notes and accrued interest	<u>\$</u>	<u>\$ 10,144,658</u>
Common stock issued in connection with conversion of preferred stock	<u>\$</u>	<u>\$_3,500,000</u>
Warrant issued to placement agent	<u>\$ 115,150</u>	<u>s                                    </u>
Non-cash investing activity: Disposal of fully depreciated property and equipment, at cost	<u>\$ 123,980</u>	<u>\$ 129,672</u>

#### EntreMed, Inc.

## Notes to Consolidated Financial Statements December 31, 2013

### 1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

EntreMed, Inc. and its subsidiaries ("EntreMed" or "the Company") (Nasdaq: ENMD) is a clinical-stage pharmaceutical company employing a drug development strategy that leverages resources in both North America and in China to develop therapeutics for the treatment of cancer and other diseases. The Company is currently conducting activities in both China and North America in order to accelerate delivery of clinical data and to reduce costs of clinical trials. The Company's lead drug candidate is ENMD-2076, a selective Aurora A and angiogenic kinase inhibitor for the treatment of cancer. ENMD-2076 has completed Phase 1 studies in patients with advanced solid tumors, multiple myeloma and leukemia and is currently completing data for a multi-center Phase 2 study in patients with platinum resistant ovarian cancer. In 2012, the Company initiated a dual-institutional Phase 2 study of ENMD-2076 in triple-negative breast cancer. Additionally, in January 2013, the Company initiated a Phase 2 trial in advanced ovarian clear cell carcinoma. The Company intends to pursue additional trials and is in various assessment and planning stages. The Company employs a market-oriented approach to identify pharmaceutical candidates that it believes has the potential for gaining widespread market acceptance either globally or in China and for which development can be accelerated under the Company's US and China drug development strategy.

ENMD-2076 is an orally-active, Aurora A/angiogenic kinase inhibitor with a unique kinase selectivity profile and multiple mechanisms of action. ENMD-2076 exerts its effects through multiple mechanisms of action, including anti-proliferative activity and the inhibition of angiogenesis. 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 also has shown promising activity in Phase 1 clinical trials in solid tumor cancers, including ovarian, breast, liver, renal and sarcoma, as well as in leukemia and multiple myeloma. The Company is completing a Phase 2 trial of ENMD-2076 in ovarian cancer. In addition, EntreMed is currently conducting a dual-institutional Phase 2 study of ENMD-2076 in triple-negative breast cancer, a Phase 2 study in advanced/metastatic soft tissue sarcoma, and a Phase 2 study in advanced ovarian clear cell carcinoma.

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

ENMD-2076 is the only program currently under active clinical evaluation. Other product candidates in the pipeline include 2-methoxyestrdiol (2ME2) for autoimmune diseases for which the Company has an approved Investigational New Drug Application in rheumatoid arthritis treatment and MKC-1. The Company owns or has exclusive license to these products.

The Company intends to advance clinical development of ENMD-2076 and the implementation of its plans will include leveraging 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. The Chinese subsidiary 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 accelerated 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 our capabilities and products in order to continue the development of the product candidate that the Company intends to pursue to commercialization.

The accompanying consolidated financial statements include the accounts of EntreMed, Inc. and its subsidiaries, Miikana Therapeutics, Inc. (Miikana) and EntreMed (Beijing) Co., Ltd. (EntreMed China). EntreMed China is a non-stock Chinese entity with 100% of its interest owned by EntreMed. EntreMed 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 \$399.1 million. The Company expects to continue to incur operating losses for the foreseeable future due to, among other factors, its continuing clinical activities. In February 2012 (the "2012 Financing"), the Company received the proceeds from a \$10 million convertible note financing. Upon approval by the Company's stockholders at the 2012 annual stockholders meeting, the convertible notes automatically converted into common stock on May 1, 2012 (see Note 6). In addition, 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 6). As a result of these transactions, along with on-going cost containment measures, the Company has sufficient resources to fund its operations for at least the next twelve months. 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 arrangements in China to support the Company's dual-country approach to drug development.

# 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. EntreMed'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 our drug candidate, including the costs of manufacturing drug substance and drug product, regulatory maintenance costs, and facilities expenses. Research and development costs are expensed as incurred, including costs incurred in filing, defending and maintaining patents.

# PROPERTY AND EQUIPMENT

Furniture and equipment and leasehold improvements are stated at cost and are depreciated over their estimated useful lives of 3 to 10 years. Depreciation and amortization is determined on a straight-line basis. Depreciation and amortization expense was \$17,389 and \$20,457 in 2013 and 2012, respectively.

Property and equipment consists of the following:

	DECEMB	ER 31,
	2013	2012
Furniture and equipment	\$ 248,732	\$ 235,093
Leasehold improvements	6,382	101,026
-	255,114	336,119
Less: accumulated depreciation		
and amortization	(176,972)	(283,563)
	<u>\$ 78,142</u>	<u>\$ 52,556</u>

#### **IMPAIRMENT OF LONG-LIVED ASSETS**

In accordance with authoritative guidance issued by FASB, the Company periodically evaluates the value reflected in its balance sheet 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 2013 and 2012.

## 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, 2013 and 2012.

As of December 31, 2012, one customer represented 100% of the total 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.

## **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, 2013 and 2012 was \$6,871 and \$2,029, respectively, and is included in accrued liabilities in the accompanying consolidated balance sheets.

# **DEBT ISSUANCE COST**

Amortization expense of debt issuance costs is calculated using the interest method over the term of the debt and is recorded in interest expense for 2012 in the accompanying consolidated statements of operations.

# CONVERTIBLE NOTES WITH DETACHABLE WARRANTS AND BENEFICIAL CONVERSION FEATURE

The Company accounts for the issuance of detachable stock purchase warrants in accordance with Accounting Standards Codification (ASC) Topic 470, whereby the proceeds received from convertible notes are allocated between the convertible notes and the detachable warrants based on the relative fair value of the convertible notes without the warrants and the warrants. The portion of the proceeds allocated to the warrants is recognized as additional paid-in capital and a debt discount. The debt discount related to warrants is accreted into interest expense through maturity of the notes.

In accordance with the provisions of ASC Topic 470, the Company allocated a portion of the proceeds received in connection with the 2012 Financing to the embedded beneficial conversion feature, based on the difference between the effective conversion price of the proceeds allocated to the convertible notes and the fair value of the underlying common stock on the date the convertible notes were issued. Since the convertible notes also had detachable stock purchase warrants, the Company first allocated the proceeds to the stock purchase warrants and the convertible notes proceeds between the beneficial conversion feature, which was accounted for as paid-in capital, and the initial carrying amount of the convertible notes. The discount resulting from the beneficial conversion feature is recorded as a debt discount.

# 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 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, 2013 and 2012, clinical trial accruals were \$244,192 and \$222,304, 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 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 ASC 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, 2013 and 2012, 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 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. Royalties from licenses are based on third-party sales and recorded as earned in accordance with contract terms, when third-party results are reliably measured and collectibility is reasonably assured.

All of the Company's 2012 revenues were from royalties based on the sale of Thalomid<sup>®</sup>, distributed by Celgene Corporation ("Celgene"). In 2004, certain provisions of a purchase agreement dated June 14, 2001 by and between Bioventure Investments kft ("Bioventure") and the Company were satisfied, and, as a result, in 2005 the Company became entitled to share in the royalty payments received by Royalty Pharma Finance Trust, successor to Bioventure, on annual Thalomid<sup>®</sup> sales above a certain threshold. Based on the licensing agreement royalty formula, the Company's right to share in the annual royalty commences when net royalties received by Royalty Pharma exceeds \$15,375,000. The Company did not recognize any royalty revenue in 2013, as it did not meet the threshold to earn royalties on the sale of Thalomid<sup>®</sup> in 2013. The Company does not expect to earn royalties from the sale of Thalomid<sup>®</sup> in any subsequent year.

## 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 7,907,959 and 3,686,338 for 2013 and 2012, 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. As of December 31, 2013, no expense has been recorded for share awards with performance conditions.

## NEW ACCOUNTING PRONOUNCEMENTS

EntreMed has implemented all new accounting pronouncements that are in effect and that may impact the Company's consolidated financial statements, and the Company does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its consolidated financial statements.

#### FAIR VALUE OF FINANCIAL INSTRUMENTS AND CONCENTRATIONS OF 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. Our most critical accounting estimates relate to accounting policies for 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.

#### 3. RELATED PARTY TRANSACTIONS

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

In connection with the successful completion of the 2012 Financing, as discussed in Note 6 below, and prior to his appointment to the Board of Directors, the Company paid a 6% advisory fee to Emerging Technology Partners LLC, of which the Company's Chairman is a general partner, for due diligence, its role in structuring and negotiating the transaction and as reimbursement for fees incurred. The 2012 Financing was approved by stockholders at the Company's annual meeting in 2012.

## 4. LICENSE AGREEMENTS

Pursuant to a purchase agreement dated June 14, 2001 by and between and the Company, as amended July 13, 2001, July 30, 2001 and August 3, 2001, Bioventure purchased all of the Company's right, title and interest to the net royalty payments payable by Celgene to the Company under the agreement dated as of December 9, 1998 by and between the Company and Celgene (the "Celgene Sublicense").

A provision of the Bioventure purchase agreement provided the potential for an adjustment in the purchase price if cumulative sales of Thalomid<sup>®</sup> exceeded \$800 million by December 31, 2004. Based on Thalomid<sup>®</sup> sales reported publicly by Celgene, the Company concluded that cumulative Thalomid<sup>®</sup> sales had reached this milestone by December 31, 2004, thus triggering a royalty sharing provision. Beginning the year after cumulative sales reach \$800 million, EntreMed is entitled to share in the royalty payments received by Royalty Pharma Finance Trust, successor to Bioventure, on annual Thalomid<sup>®</sup> sales above a certain threshold. The Company is entitled to receive these sub-royalty payments until the last relevant patent expires, as described under the agreement. In 2012 Thalomid<sup>®</sup> sales surpassed the royalty-sharing point and the Company recognized royalty revenues of \$669,310. The Company did not earn any royalties under the royalty sharing provision in 2013 and does not expect to earn any in the future.

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 NCD. Under the terms of the License Agreement, Elan is eligible to receive payments upon the achievement of certain clinical, manufacturing, and regulatory 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 EntreMed'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, 2013. The Company does not expect to achieve any milestones in 2014, as the Company does not expect to devote any significant resources to develop 2ME2 utilizing the NCD formulation.

#### 5. INCOME TAXES

The income tax provision is based on loss before income taxes of \$(5,314,629) in the U.S. and \$(423,732) in China. The Company has net operating loss carryforwards for income tax purposes of approximately \$343,555,000 at December 31, 2013 (\$339,553,000 at December 31, 2012) that expire in years 2018 through 2033. The Company also has research and development (R&D) tax credit carryforwards of approximately \$9,037,000 as of December 31, 2013 that expire in years 2018 through 2033. 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, 2013 and 2012 are as follows:

	DECEMBER 31,	
	2013	2012
Deferred income tax assets (liabilities):		
Net operating loss carryforwards	\$ 134,395,000	\$ 132,994,000
Research and development credit carryforward	9,037,000	9,019,000
Equity investment	72,000	72,000
Other	4,361,000	3,665,000
Depreciation	4,000	64,000
Valuation allowance for deferred income tax assets	<u>(147,869,000)</u>	(145,814,000)
Net deferred income tax assets	<u>\$</u>	<u>\$</u>

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

Tax benefit at statutory rate State taxes	$ \begin{array}{c}     2013 \\     (1,951,000) \\     (217,000) \\     (122,000) \end{array} $	$ \begin{array}{r}                                     $
Net R&D credit adjustment	(122,000)	(97,000)
Attribute expiration and other	8,000	4,068,000
Disallowed expenses	2,000	1,000
Change in valuation allowance	2,055,000	2,015,000
Other	231,000	67,000
Change in tax rates	(6,000)	(408,000)

The Company had \$3,006,000 of unrecognized tax benefits as of January 1, 2013 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, 2013, there were additional unrecognized tax benefits of \$33,000 related to R&D tax credits, and a reduction in unrecognized tax benefits of \$26,000 related to the remeasurement of certain prior year R&D credit carryforwards. The Company has a full valuation allowance at January 1, 2013 and at December 31, 2013 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:

	2013	2012
Unrecognized tax benefits balance at January 1	\$3,006,000	\$3,103,000
Reductions for Tax Positions of Prior Periods	(26,000)	(97,000)
Additions for Tax Positions of Current Period	33,000	
	¢2.012.000	<b>*2</b> 007 000
Unrecognized tax benefits balance at December 31	\$3,013,000	\$3,006,000

The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense. As of December 31, 2013 and 2012, 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, 2013. 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.

#### 6. STOCKHOLDERS' EQUITY

In 2002, the Company issued 3,350,000 shares of Series A Convertible Preferred Stock ("Series A Preferred Stock") to Celgene. The value of the common stock at the date the Series A Preferred Stock was issued was \$9.46. The Series A Preferred Stock was convertible, at the option of Celgene, at any time, into common stock at an initial per common share conversion price of \$11.00 (1 share of preferred converts into .45 shares of common). The conversion price was subject to change for certain dilutive events, as defined. The Series A Preferred Stock accrued and accumulated dividends at a rate of 6% and participated in dividends declared and paid on the common stock, if any. In connection with the 2012 Financing, as described below, and upon stockholder approval of the 2012 Financing at the 2012 annual meeting on April 30, 2012, Celgene converted all of its preferred stock to an aggregate of 1,522,727 shares of common stock, pursuant to the terms and conditions of the Series A Preferred Stock outstanding. As of April 30, 2012, cumulative unpaid preferred stock dividends totaled \$9,380,000, or \$2.80 per share. In connection with the stockholder approval of the 2012 Financing, Celgene waived all accrued dividends on the Series A Preferred Stock, and Celgene is no longer entitled to any liquidation preference on its shares.

## **2013 FINANCING**

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, 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%.

# **2012 FINANCING**

As described in Note 1 and in connection with the 2012 Financing, on January 20, 2012, the Company entered into a Convertible Note and Warrant Purchase Agreement (the "Purchase Agreement") with certain strategic accredited investors (the "Investors"), pursuant to which the Company issued and sold to the Investors, in a private placement, subordinated mandatorily convertible promissory notes (collectively, the "Notes") with an aggregate principal amount of \$10 million. The Company also issued warrants (the "2012 Warrants") to the Investors to purchase an aggregate of 1,739,132 shares of the Company's common stock, par value \$0.01 per share. The 2012 Warrants cover a number of shares of common stock equal to 20% of the principal amount of the Notes purchased by each Investor, divided by \$1.15. The 2012 Warrants have an exercise price of \$1.40 per share and became exercisable on July 29, 2012 and expire on July 29, 2017. The relative fair value of the 2012 Warrants issued was \$2,155,527, calculated using the Black-Scholes-Merton valuation model value of \$1.58 with an expected and contractual life of 5.5 years, an assumed volatility of 103%, and a risk-free interest rate of 0.71%. The 2012 Warrants were recorded as additional paid-in-capital and a discount on the Notes of \$2,155,527 was fully amortized as non-cash interest expense during the year ended December 31, 2012 as a result of the conversion of the Notes.

The 2012 Financing was completed on February 2, 2012. The Company received net proceeds of approximately \$9.3 million. The Company paid one of the investors, in a related-party transaction, a fee in the amount of 6% of the aggregate amount raised in the 2012 Financing. In connection with the 2012 Financing, the Company incurred a total of \$683,955 of debt issuance costs. All debt issuance costs were fully amortized and recorded as interest expense upon conversion of the Notes in the second quarter of 2012.

The Company received approval of the 2012 Financing from the Company's stockholders at the 2012 annual stockholders meeting held on April 30, 2012. On May 1, 2012, the Notes, including accrued interest of \$144,658, automatically and immediately converted into 8,821,431 shares of common stock and the 2012 Warrants became exercisable as of July 29, 2012. The Notes bore an interest rate of 6% and converted at a conversion price of \$1.15 per share. The conversion price reflected the 10-day average closing sale price of the Company's common stock ended on January 20, 2012.

The Notes were not convertible, and the 2012 Warrants were not exercisable, prior to receiving stockholder approval. The Notes contained a contingent beneficial conversion feature as the conversion price of the shares was less than the share price on the date of the Notes issuance. The beneficial conversion feature was valued at \$7,057,153 and was recorded as non-cash interest expense and additional paid-in-capital in the second quarter of 2012, upon removal of the contingency and conversion of the Notes on May 1, 2012.

## 7. 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 May 2013, the Company's shareholders approved an amendment to the 2011 Long-Term Incentive Plan, increasing the number of shares reserved for issuance from 1,730,000 to 4,230,000 shares of common stock to be available for grants and awards. In April 2012, 150,000 options were granted to the Company's Chief Executive Officer outside of the Company's 2011 Long-Term Incentive Plan, as an inducement award material to his employment, in accordance NASDAQ Listing Rule 5635(c)(4). As of December 31, 2013, there are 3,586,394 shares issuable under options previously granted and currently outstanding, with exercise prices ranging from \$1.59 to \$34.10. 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, 2013, 1,110,876 shares remained available for grant under the Company's 2011 Long-Term Incentive Plan.

The Company's net loss for the years ended December 31, 2013 and 2012 includes \$2,044,382 and \$978,243, 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:

	2013	2012
Research and development	\$ 763,470	\$ 273,204
General and administrative	1,280,912	705,039
Share-based compensation expense	\$ <u>2,044,382</u>	\$ <u>978,243</u>
Net share-based compensation expense, per common share:		
Basic and diluted	\$ <u>0.078</u>	\$ <u>0.051</u>

### 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. EntreMed 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. EntreMed 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—EntreMed 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, 2013 and 2012:

	Years ended December 31,	
	2013	2012
Expected volatility	105.30%	101.67%
Risk free interest rate	1.03%	0.94%
Expected term of option	5.77 years	5.74 years
Forfeiture rate	*5.00%	*5.00%
Expected dividend yield	-	-

\*-Throughout 2013 and 2012, forfeitures were estimated at 5%; the actual forfeiture rate was 0% and 6.4% for 2013 and 2012, respectively. The Company adjusted stock compensation expense for 2013 and 2012 based on the actual forfeiture rate.

The weighted average fair value of stock options granted was \$1.42 and \$1.59 in 2013 and 2012, 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, 2013 and 2012 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term In years	Aggregate Intrinsic Value
Outstanding at December 31, 2011	621,889	\$ 16.23		
Exercised	(1,136)	\$ 1.76		
Granted	1,249,000	\$ 2.04		
Expired	(197,833)	\$ 21.13		
Forfeited	(35,376)	\$ 4.69		
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	<u>_</u>	\$ -		
Outstanding at December 31, 2013	3,586,394	\$ 2.69	8.64	\$ -
Vested and expected to vest at				
December 31, 2013	3,512,769	\$ 2.71	8.48	\$ -
Exercisable at December 31, 2013	2,113,901	\$ 3.26	8.24	\$ -

The aggregate intrinsic value is calculated as the difference between (i) the closing price of the common stock at December 31, 2013 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 2013. The total intrinsic value of options exercised during the years ended December 31, 2013 and 2012 totaled approximately \$2,500 and \$400, respectively.

Cash received from option exercises under all share-based payment arrangements for the years ended December 31, 2013 and 2012 was \$7,190 and \$1,999, respectively. 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, 2013 and 2012.

The following summarizes information about stock options granted to employees and directors outstanding at December 31, 2013:

,	Options Outstanding		Options Exercisable		
		Weighted Average	Weighted		Weighted
	Number	Remaining	Average	Number	Average
Range of	Outstanding at	Contractual	Exercise	Exercisable at	Exercise
Exercise Prices	December 31, 2013	Life in Years	Price	December 31, 2013	Price
\$0.00 - \$3.00	3,305,701	9.0	\$ 1.88	1,844,333	\$ 1.92
\$3.01 - \$10.00	178,040	6.6	\$ 6.55	166,915	\$ 6.58
\$10.01 - \$20.00	61,070	3.0	\$ 17.28	61,070	\$ 17.28
\$20.01 - \$30.00	20,814	0.5	\$ 23.72	20,814	\$ 23.72
\$30.01 - \$40.00	20,769	1.6	\$ 34.09	20,769	\$ 34.09
	2 586 204	9 <i>C</i>	¢ 260	2 112 001	\$ 2.26
	3,586,394	8.6	<u>\$ 2.69</u>	2,113,901	<u>\$ 3.26</u>

As of December 31, 2013, there was approximately \$1,911,000 of total unrecognized compensation cost related to non-vested stock options. That cost is expected to be recognized over a weighted-average period of 1.5 years.

## Warrants

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

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2011	333,387	\$ 4.13
Granted	1,739,132	\$ 1.40
Exercised	-	\$ -
Expired	(22,725)	\$ 22.00
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
Exercisable at December 31, 2013	4,321,565	\$ 2.31

## 8. 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, EntreMed 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, 2013, a \$4 million potential milestone payment remains, payable in cash or shares of stock at our option, related to the ENMD-2076 program and the dosing of the first patient in a phase 3 pivotal trial.

*MKC-1.* Through the acquisition, 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 2014. 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.

2ME2 NCD (2-methoxyestradiol, NanoCrystal Dispersion, 2ME2 NCD) for Oncology. In January 2006, the Company entered into a License Agreement with 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 NCD. Under the terms of the License Agreement, Elan is eligible to receive payments upon the achievement of certain clinical, manufacturing, and regulatory 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 EntreMed'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, 2013. The Company has discontinued clinical development of 2ME2 NCD for oncology.

*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 our 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. There was no royalty payment received in 2013 or 2012. 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 2014 or beyond.

2ME2 (2-methoxyestradiol, 2ME2) for Oncology. The Company entered into a license agreement with CMCC for the exclusive, world-wide, royalty-bearing license to 2ME2, an inhibitor of angiogenesis. In consideration for retaining the 2ME2 rights, the Company must pay a royalty on any sublicensing fees, as defined in the agreement, to Children's Hospital, Boston. The agreement obligates the Company to pay up to \$1,000,000 "upon the attainment of certain milestones." As of December 31, 2013, the Company has paid \$500,000 under this

agreement for the milestones that have been achieved to date. The Company has discontinued research and development of 2ME2 for oncology and currently is evaluating 2ME2 for possible other indications.

ENMD-2076 is the only program currently under active clinical evaluation by the Company. 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 next 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 any of the other product candidates will reach additional developmental milestones in 2014 and accordingly does not anticipate any future milestone payments for these programs.

As of December 31, 2013, the Company also has purchase obligation commitments, in the normal course of business, for clinical trial contracts totaling \$395,000.

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, 2014, the Company entered into a one year lease in China for lab space. Rent expense is recognized under the straight-line method.

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

2014	\$ 233,040
2015	163,309
2016	161,338
2017	39,214
Thereafter	
Total minimum	
payments	<u>\$ 596,901</u>

Rental expense for the years ended December 31, 2013 and 2012 was \$175,000 and \$152,000, respectively.

## CONTINGENCIES

EntreMed 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.

# 9. EMPLOYEE RETIREMENT PLAN

The Company sponsors the EntreMed, 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 \$21,614 and \$26,500 in 2013 and 2012, respectively.