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FORM 10-K

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF
THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017

Commission file number 0-20713

CASI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ___No X

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No ___

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

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☑
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of June 30, 2017, the aggregate market value of the shares of common stock held by non-affiliates was approximately $35,022,789.

As of March 28, 2018, 79,641,876 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, 2017. The proxy statement is incorporated herein by reference into the following parts of the Form 10-K:

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

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CASI PHARMACEUTICALS, INC.
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

Actual results could differ materially from those currently anticipated due to a number of factors, including: the risk that we may be unable to continue as a going concern as a result of our inability to raise sufficient capital for our operational needs; the possibility that we may be delisted from trading on the Nasdaq Capital Market; the volatility in the market price of our common stock; risks relating to interests of our largest stockholders that differ from our other stockholders; the risk of substantial dilution of existing stockholders in future stock issuances; the difficulty of executing our business strategy in China; the risk that we will not be able to effectively select, register and commercialize products from our recently acquired portfolio of Abbreviated New Drug Applications (ANDAs); our inability to predict when or if our product candidates will be approved for marketing by the China Food and Drug Administration authorities; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; risks relating to the need for additional capital and the uncertainty of securing additional funding on favorable terms; risks associated with our product candidates; risks associated with any early-stage products under development; the risk that results in preclinical and early clinical models are not necessarily indicative of later 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). Such factors, among others, could have a material adverse effect upon our business, results of operations and financial condition.

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, 2017 (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.

OVERVIEW

CASI Pharmaceuticals, Inc. ("CASI", the "Company") (Nasdaq: CASI) is a U.S. based biopharmaceutical company dedicated to bringing high quality, cost-effective pharmaceutical products and innovative oncology therapeutics to patients. We intend to execute our plan to become a leading pharmaceutical company with a substantial market share in China. We are headquartered in Rockville, Maryland with established China operations that are growing as we continue to further in-license or acquire products for our pipeline.

Our product pipeline features (1) EVOMELA®, MARQIBO®, and ZEVALIN®, all U.S. Food and Drug Administration ("FDA") approved drugs in-licensed from Spectrum Pharmaceuticals, Inc. for China regional rights, and currently in various stages in the regulatory process for market approval in China, (2) an acquired portfolio of 25 FDA-approved abbreviated new drug applications ("ANDAs") one ANDA that FDA tentatively approved, and three ANDAs that are pending FDA approval, from which we will prioritize a select subset for product registration and commercialization in China, (3) our proprietary drug candidate, ENMD-2076, currently in Phase 2 clinical development, and (4) CASI-001 and CASI-002, proprietary early-stage candidates in immuno-oncology in preclinical development. We believe our pipeline reflects a risk-balanced approach between products in various stages of development, and between products that we develop ourselves and those that we develop with our partners for the China regional market. We intend to continue building a significant product pipeline of high quality, cost-effective pharmaceuticals, as well as innovative drug candidates that we will commercialize alone in China and with partners for the rest of the world. For in-licensed products, the Company uses a market-oriented approach to identify pharmaceutical candidates that it believes have the potential for gaining widespread market acceptance, either globally or in China, and for which development can be accelerated under the Company's drug development strategy.

Our focus is to bring high quality, cost-effective pharmaceutical products and innovative oncology therapeutics to patients. 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 China-based 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 transition to a commercial enterprise.

IN-LICENSED PRODUCTS FOR THE CHINA REGIONAL MARKET

In September 2014, we acquired from Spectrum Pharmaceuticals, Inc. and certain of its affiliates (together referred to as "Spectrum") exclusive rights in greater China (including Taiwan, Hong Kong and Macau) to three in-licensed oncology products, including EVOMELA® (melphalan hydrochloride for injection) approved in the U.S. primarily for use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma, MARQIBO® (vinCRIStine sulfate LIPOSOME injection) approved in the U.S. for advanced adult Ph- acute lymphoblastic leukemia (ALL), and ZEVALIN® (ibritumomab tiuxetan) approved in the U.S. for advanced non-Hodgkin's lymphoma. A description of the products and their current status is below.

EVOMELA®

EVOMELA® is a new intravenous formulation of melphalan being investigated by Spectrum in the multiple myeloma transplant setting. The formulation avoids the use of propylene glycol, which is used as a co-solvent in the current formulation of melphalan and has been reported to cause renal and cardiac side-effects that limit the ability to deliver higher quantities of intended therapeutic compounds. The use of Captisol technology to reformulate melphalan is anticipated to allow for longer administration durations and slower infusion rates, potentially enabling clinicians to avoid reductions and safely achieve a higher dose intensity of pre-transplant chemotherapy. In March 2016, Spectrum received notification from the FDA of the grant of approval of its NDA for EVOMELA® (melphalan) for injection primarily for use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma. We have initiated the

regulatory and development process towards marketing approval for EVOMELA® in China. In December 2016, the China Food and Drug Administration ("CFDA") accepted for review our import drug registration application for EVOMELA® and in 2017 has granted priority review of the import drug registration clinical trial application (CTA), which has completed the quality testing phase of the regulatory process and is currently in technical review by Center for Drug Evaluation (CDE) of the CFDA as part of the regulatory process.

MARQIBO®

MARQIBO® is a novel, sphingomyelin/cholesterol liposome-encapsulated, formulation of vincristine sulfate, a microtubule inhibitor. MARQIBO® is approved by the FDA for the treatment of adult patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. We have initiated the regulatory and development process towards marketing approval for MARQIBO in China. In January 2016, the CFDA accepted for review our import drug registration application for MARQIBO® which currently is in the quality testing phase of the regulatory review.

ZEVALIN®

ZEVALIN® injection for intravenous use is a CD20-directed radiotherapeutic antibody. It is indicated for the treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL). ZEVALIN® is also indicated for the treatment of patients with previously untreated follicular non-Hodgkin's Lymphoma who achieve a partial or complete response to first-line chemotherapy. ZEVALIN® therapeutic regimen consists of two components: rituximab, and Yttrium-90 (Y-90) radiolabeled ZEVALIN® for therapy. ZEVALIN® builds on the combined effect of a targeted biologic monoclonal antibody augmented with the therapeutic effects of a beta-emitting radioisotope. Since ZEVALIN® is already approved in the U.S. and marketed by Spectrum, we expect that gaining approval from local regulatory authorities for commercialization in greater China will require a shorter timeframe compared to clinical-stage drugs. In 2017, the CFDA accepted for review our import drug registration for ZEVALIN® including both the antibody kit and the radioactive Yttrium-90 component.

U.S. FDA ANDAs

On January 26, 2018 the Company acquired a portfolio of 25 U.S. FDA-approved abbreviated new drug applications (ANDAs), one ANDA that FDA tentatively approved, and three ANDAs that are pending FDA approval. CASI intends to select and commercialize certain products from the portfolio that offer unique market and cost-effective manufacturing opportunities in China and/or in the U.S.

The portfolio consists of:

Product	Approved
Benazepril tablets	X
Bisoprolol fumarate tablets	X
Burprenorphine HCL Sublingual tablets	X
Cefprozil tablets	X
Cilostazol tablets – 50mg	X
Cilostazol tablets – 100mg	X
Desvenlafaxine ER tablets	X
Diclofenac potassium 50mg tablets	X

Diclofenac sodium DR 25mg, 50mg tablets	X
Diclofenac sodium DR 75mg tablets	X
Econazole nitrate cream	X
Entecavir tablets	X
Epinastine HCl Ophthalmic Solution	X
Heparin sodium for injection	X
Lisinopril tablets and Lisinopril BPP tablets	X
Methimazole tablets	X
Midodrine tablets	X
Nabumetone tablets	X
Naratriptan tablets	X
Ondansetron HCL tablets	X
Repaglinide tablets	X
Ribavirin capsules	X
Spironolactone tablets	X
Tizanidine tablets	X
Triamterene and hydrochlorothiazide combination tablets	X

Product	Pending
Aripiprazole tablets	X
Bepotastine Ophthalmic Solution	X
Bromfenac Ophthalmic Solution	X
Telmisartan and hydrochlorothiazide tablets	X

ENMD-2076

ENMD-2076, internally developed, is an orally-active, Aurora A/angiogenic kinase inhibitor with a unique kinase selectivity profile and multiple mechanisms of action. We are currently conducting multiple Phase 2 studies of ENMD-2076, the status of which is outlined below:

Disease Indication	***Status***		***Sites***
Advanced Fibrolamellar Carcinoma	U.S. sites:	Phase 2 trial enrollment completed	• Memorial Sloan-Kettering Cancer Center • University of Colorado Cancer Center • University of Texas Southwestern Medical Center • University of California at San Francisco • Dana-Farber Cancer Institute

	China sites:	Received CFDA approval to expand trial to China sites	• China site(s) to be determined
Triple-Negative Breast Cancer	U.S. sites:	Phase 2 trial enrollment completed; biomarker analysis ongoing	• University of Colorado • Indiana University
	China sites:	Phase 2a trial enrollment completed	• Cancer Hospital of Chinese Academy of Medical Sciences • Additional China site(s) to be determined

ENMD-2076 has received orphan drug designation from the FDA for the treatment of ovarian cancer, multiple myeloma, acute myeloid leukemia and hepatocellular carcinoma (HCC). In October 2015, the Company also received orphan drug designation from the European Medicines Agency (EMA) for the treatment of HCC including FLC. 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, such as a tax credit.

PRECLINICAL DEVELOPMENT

Our primary focus is on clinical-stage and late-stage drug candidates so that we can immediately employ our U.S. and China drug development model to accelerate clinical and regulatory progress. In addition to our clinical-and late-stage approach, we have two potential drug candidates in preclinical development that we will continue to evaluate in 2018.

MANAGEMENT

The current senior management team includes: Dr. Wei-Wu He, Executive Chairman, Dr. Ken K. Ren, Chief Executive Officer; Cynthia W. Hu, Chief Operating Officer, General Counsel & Secretary; Dr. Alexander A. Zukiwski, Chief Medical Officer, Sara B. Capitelli, Vice President, Finance & Principal Accounting Officer; and Dr. James E. Goldschmidt, Senior Vice President, Business Development. The Company, as part of its normal operations, also has consulting relationships with a core team of experts in clinical trial design, FDA and CFDA strategy, scientific research, manufacturing and formulation, among others.

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

BUSINESS DEVELOPMENT AND COMMERCIALIZATION STRATEGY

We intend to continue our path to become fully integrated with drug development and commercial operations. Our current external business development effort is concentrated on acquiring additional drug candidates through in-license and acquisitions to expand our pipeline. Our pipeline will reflect a diversified and risk-balanced set of assets that include (1) late-stage clinical drug candidates in-licensed for China regional rights, such as EVOMELA®, MARQIBO® and ZEVALIN®, (2) high quality generic pharmaceuticals, such as the portfolio of 29 ANDAs recently acquired, (3) proprietary innovative drug candidates, such as our ENMD-2076, and (4) new drug candidates under internal preclinical development. We use a market-oriented approach to identify pharmaceutical candidates that we believe have the potential for gaining widespread market acceptance, either globally or in China, and for which development can be accelerated under the Company's drug development strategy. Although oncology is our principal clinical and commercial focus, we will be opportunistic about other pharmaceuticals that can address unmet medical needs.

The Company's wholly-owned China-based subsidiary is executing the China portion of our drug development strategy, including conducting clinical trials in China, pursuing local funding opportunities and strategic collaborations, and implementing our plan for accelerated development and commercialization in the China market.

RELATIONSHIPS RELATING TO CLINICAL PROGRAMS

Contract Manufacturing. Clinical trial materials for EVOMELA®, MARQIBO®, and ZEVALIN® are supplied by our partner Spectrum and its contract manufacturers. We anticipate that the manufacturing for our newly acquired ANDA portfolio will be through new contract manufacturers located in China and outside of the U.S. after technology transfer. The manufacturing efforts for the production of our clinical trial materials for ENMD-2076 are performed by contract manufacturing organizations. Established relationships, coupled with supply agreements, have secured the necessary resources to supply clinical materials for our clinical development program. We believe that our current strategy of outsourcing manufacturing is cost-effective and allows for the flexibility we require.

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

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 regard to our in-licensed drug candidates (EVOMELA®, MARQIBO®, and ZEVALIN®), we have acquired exclusive licenses to intellectual property to enable us to develop and commercialize the drug candidates in our commercial markets.

With respect to ENMD-2076, we directly own 22 granted patents or allowed patent applications (including 2 granted United States patents, 1 granted Chinese patent, and 18 granted patents and 1 additional pending patent application in Brazil). 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. We also directly own two pending U.S. provisional applications directed to treatment methods using ENMD-2076.

We have pending trademark applications for CASI and CASI PHARMACEUTICALS.

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

GOVERNMENT REGULATION

U.S. Food and Drug Administration (FDA)

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

In the United States, the FDA regulates product candidates 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 the FFDCA, 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 must be obtained before clinical testing, and approvals must be obtained before marketing of biologics or drugs.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates or any future product candidates we may develop. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

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 study subjects 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. Generic drugs, which are therapeutic equivalents of existing brand name drugs, require the filing of an ANDA. An ANDA does not, for the most part, require clinical studies since safety and efficacy have already been demonstrated by the product originator. However, the ANDA must provide data to support the bioequivalence of the generic drug product. User fees must be paid with submission of applications for non-orphan products in order to support the cost of agency review. While such fees are not significant for ANDAs, an NDA for a non-orphan product requires a user fee of over $2.4 million.

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. The time required by the FDA to review and approve NDAs and ANDAs is variable and, to a large extent, beyond our control. Notwithstanding the submission of relevant data, the FDA may ultimately decide that an 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 current Good Manufacturing Practices, or cGMP, adverse event reporting, promotion and advertising, and other matters. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. 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.

The Generic Drug Enforcement Act of 1992 establishes penalties for wrongdoing in connection with the development or submission of an application. In general, the FDA is authorized to temporarily bar companies, or temporarily or permanently bar individuals, from submitting or assisting in the submission of applications to FDA, and to temporarily deny approval and suspend applications to market drugs under certain circumstances. In addition to debarment, the FDA has numerous discretionary disciplinary powers, including the authority to withdraw approval of an application or to approve an application under certain circumstances and to suspend the distribution of all drugs approved or developed in connection with certain wrongful conduct. The FDA may also withdraw product approval or take other corrective measures if ongoing regulatory requirements are not met or if safety or efficacy questions are raised after the product reaches the market.

Manufacturers and other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory requirements, and test each product batch or lot prior to its release. We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates and any future product candidates we may develop. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

Healthcare Regulation

Federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, also apply to our business. If we fail to comply with those laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. The laws that may affect our ability to operate include, but are not limited to: the federal Anti-Kickback Statute, which prohibits. among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; and federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent. Additionally, we are subject to state law equivalents of each of the above federal laws, which may be broader in scope and apply regardless of whether the payer is a federal healthcare program, and many of which differ from each other in significant ways and may not have the same effect, further complicate compliance efforts.

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who are expected to prescribe our products and from whom we obtain patient health information, are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology and

Clinical Health Act, or HIPAA. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we obtain and/or disclose individually identifiable health information from a HIPAA-covered entity, including healthcare providers, in a manner that is not authorized or permitted by HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business.

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the PPACA, created a federal requirement under the federal Open Payments program, that requires certain manufacturers to track and report to the Centers for Medicare and Medicaid Services, or CMS, annually certain payments and other transfers of value provided to physicians and teaching hospitals made in the previous calendar year. In addition, there are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

For those marketed products which are covered in the United States by the Medicaid programs, we have various obligations, including government price reporting and rebate requirements, which generally require products be offered at substantial rebates/discounts to Medicaid and certain purchasers (including "covered entities" purchasing under the 340B Drug Discount Program). We are also required to discount such products to authorized users of the Federal Supply Schedule of the General Services Administration, under which additional laws and requirements apply. These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate prices, or offer required discounts or rebates could subject us to substantial penalties.

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. For clinical-stage product candidates, our development activities in China can follow two purposes: (1) to obtain clinical data to support our global FDA-regulated trials as is the case for our proprietary ENMD-2076, and (2) to obtain clinical data to support local registration with the CFDA. For late-stage product candidates that we in-license for greater China rights, such as EVOMELA®, MARQIBO®, and ZEVALIN®, our development activities in China are to secure marketing approval from CFDA by conducting import drug registration. 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. For the registration of locally manufactured drugs, both drug substance and drug product need to be manufactured in China through either a self-owned facility or a contract manufacturing organization. The study drug to be used for clinical trials must be manufactured in compliance with CFDA Good Manufacturing Practice (GMP) guidelines. A domestic manufacturer of pharmaceutical products and active pharmaceutical ingredient (API) must obtain the drug manufacturing license and the GMP certification to produce pharmaceutical products and API 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. Both the drug manufacturing license and the GMP certificate is valid for five years, and 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.

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. For an investigational new drug application, a clinical trial approval issued from the CFDA is required to conduct clinical trials. Chemical generics, on the other hand, only need to undergo bioequivalent studies upon a filing for record with the CFDA. 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 Multi Regional Clinical Trials. CFDA regulations allow foreign drug developers to conduct import drug registration or multi regional clinical trials in China for a new drug as part of a global drug development program. An International Multicenter Clinical Trial (IMCCT) Application needs to be filed with the CFDA and approval is required prior to conducting the trials.

In October, 2017, the CFDA released the Decision on Adjusting Items concerning the Administration of Imported Drug Registration, which includes the following key points:

- If the International Multicenter Clinical Trial, or IMCCT, of a drug is conducted in China, the IMCCT drug does not need to be approved or entered into either a Phase II or III clinical trial in a foreign country, except for preventive biological products. Phase I IMCCT is permissible in China.

- If the IMCCT is conducted in China, the application for drug marketing authorization can be submitted directly after the completion of the IMCCT.

- With respect to clinical trial and market authorization applications for imported innovative chemical drugs and therapeutic biological products, the marketing authorization in the country or region where the foreign drug manufacturer is located will not be required.

- With respect to drug applications that have been accepted before the release of this Decision, if relevant requirements are met, importation permission can be granted if such applications request exemption of clinical trials for the imported drugs based on the data generated from IMCCT.

The CFDA Decision on IMCCT and the application for imported new drugs is expected to streamline and accelerate the applications for imported new drugs.

In order to apply for an IMCCT 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 IMCCT approval from the CFDA, clinical trials are conducted in compliance with the both FDA/ICH and CFDA Good Clinical Practice guidelines.

New Drug Registration and Application. After completion of the 3 phases of clinical trials demonstrating the safety and effectiveness of a pharmaceutical in its targeted indication, a New Drug Registration Application needs to be filled with the CFDA, which includes research data of chemistry, manufacturing and controls, pre-clinical studies and clinical trial report. For imported drugs, the New Drug Registration Application is also known as the Import Drug License Application.

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

Generic Quality Consistency Evaluation. The CFDA launched the generic quality consistency evaluation (GQCE) in August 2015, which requires generic drugs to conform to the quality standards of originator products. Except for immediate release oral solid dosage forms, manufacturers of generics need to conduct bioequivalent studies in order to establish equivalence to the originator products.

The first wave of GQCE focuses on 289 oral formulations of chemical drugs listed in China's Essential Drug List. The CFDA will revoke marketing authorizations of these generic drugs if their manufacturers fail to complete the GQCE by the end of 2018 (or the end of 2021 if bioequivalent studies are required). In addition, once one generic manufacturer successfully passes the GQCE, all of the other manufacturers producing the same generic drug must complete their GQCE within three years following the first successful GQCE. Otherwise, the CFDA will not renew their respective marketing authorizations.

The launch of GQCE will significantly enhance of the bar of entry of generic manufacturers. Generics that pass the GQCE will be on a preferred list at public hospital tenders and will be entitled to a more favorable reimbursement status. Public hospitals will only be allowed to purchase from the first three generic manufacturers who pass the GQCE.

COMPETITION

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

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

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

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

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

EMPLOYEES

Our work force, based in Rockville, Maryland and Beijing, China, currently consists of 49 full-time employees and 2 part-time employees. Certain of our activities, such as manufacturing and clinical trial operations, are outsourced at the present time. We may hire additional personnel, in addition to utilizing part-time or temporary consultants, on an as-needed basis. None of our employees are represented by a labor union, and we believe our relations with our employees are satisfactory.

CORPORATE HEADQUARTERS

We were incorporated under Delaware law in 1991. The Company was restructured in 2012 and implemented a name change in 2014 to "CASI Pharmaceuticals, Inc." 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 China-based subsidiary and an office in Beijing, and in 2014, established a R&D Center in Beijing. The Company also established a wholly-owned domestic China based subsidiary under which our preclinical activities are operated. Our staff in Beijing currently consists of 43 full-time employees and 1 part-time employee. Among its activities, our Beijing operations help to oversee the Company's local preclinical and clinical operation activities, as well as its CFDA regulatory activities. In addition, the Beijing operations provide support to our business development activities.

AVAILABLE INFORMATION

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

ITEM 1A. RISK FACTORS.

Risks Relating to our Financial Position and Need for Additional Capital

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

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

We have experienced losses in each year since inception. Through December 31, 2017, we had an accumulated deficit of approximately $452.7 million. We will seek to raise capital to continue our operations and although we have been successfully funded to date through the sales of our equity securities and through limited royalty payments, there is no assurance that our capital-raising efforts will be able to attract the funding needed to sustain our operations. If we are unable to obtain additional funding for operations, we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations. In any such event, investors may lose a portion or all of their investment.

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

Our Common Stock Could Be Delisted From The NASDAQ Capital Market, Which Could Affect Our Common Stock's Market Price and Liquidity.

Our listing on the NASDAQ Capital Market is contingent upon meeting all the continued listing requirements of the NASDAQ Capital Market. In the past, we have received written notices from NASDAQ for failing to maintain a minimum bid price of not less than $1.00 per share and a minimum of $2.5 million in stockholders' equity. Although we have regained compliance with NASDAQ'S continued listing standards, there can be no assurance that we will remain in compliance in the future.

If our common stock is delisted from the NASDAQ Capital Market, our ability to raise capital in the future may be limited. Delisting could also result in less liquidity for our stockholders and a lower stock price.

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

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

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

Access to capital markets is critical to our ability to operate. Traditionally, biopharmaceutical companies (such as we) have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets over the past few years have severely restricted raising new capital in amounts sufficient to conduct our current operations and have affected our ability to continue to expand or fund research and development efforts with our 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 2018. 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, 2017, we had cash and cash equivalents of approximately $43.5 million. We may continue to seek additional capital through public or private financing or collaborative agreements in 2018 and beyond. Our operations require significant amounts of cash. We may be required to seek additional capital for the future growth and development of our business. We can give no assurance as to the availability of such additional capital or, if available, whether it would be on terms acceptable to us. In addition, we may continue to seek capital through the public or private sale of securities, if market conditions are favorable for doing so. If we are successful in raising additional funds through the issuance of equity securities, stockholders will likely experience substantial dilution. If we are not successful in obtaining sufficient capital because we are unable to access the capital markets

on favorable terms, it could reduce our research and development efforts and materially adversely affect our future growth, results of operations and financial results.

Governmental control of currency conversion and payments of RMB out of mainland China may limit our ability to utilize our cash balances effectively and affect the value of your investment.

Our China subsidiary has assets that include approximately 79.4 million China Renminbi ("RMB"), valued at approximately $12.2 million in U.S. dollars. On a consolidated basis this balance accounts for approximately 28% of our total cash and cash equivalents. The Chinese government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of RMB out of mainland China. Control on payments out of mainland China may restrict the ability of our China subsidiary to remit RMB to us. Approval from China's State Administration of Foreign Exchange ("SAFE") and the People's Bank of China ("PBOC") may be required where RMB are to be converted into foreign currencies, including U.S. dollars, and approval from SAFE and the PBOC or their branches may be required where RMB are to be remitted out of mainland China. Specifically, under the existing restrictions, without a prior approval from SAFE and the PBOC, the cash balance of our China subsidiary is not available to us for activities outside of China including support of our in-licensing efforts. Furthermore, because repatriation of funds requires the prior approval of SAFE and PBOC, such repatriation could be delayed, restricted or limited.

Risks Relating to Our Business

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

We expect to continue to conduct clinical development related activities in China in 2018. To be successful in China we will need to: establish clinical trials; attract and retain qualified personnel to operate our China-based subsidiary; and attract and retain research and development employees. We cannot assure you that we will be able to do any of these. Employee turnover in China is high due to the intensely competitive and fluid market for skilled labor. Operations in China are subject to greater political, legal and economic risks than our operations in other countries. In particular, the political, legal and economic climate in China, both nationally and regionally, is fluid and unpredictable. Our ability to operate in China may be adversely affected by changes in Chinese laws and regulations such as those related to, among other things, taxation, import and export tariffs, environmental regulations, land use rights, intellectual property, employee benefits and other matters. In addition, we may not obtain or retain the requisite legal permits to operate in China, and costs or operational limitations may be imposed in connection with obtaining and complying with such permits. Any one of the factors cited above, or a combination of them, could result in unanticipated costs, which could materially and adversely affect our business and planned operations and development in China.

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

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

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

Development of Our Products is Uncertain

Our product candidates are 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. Any significant clinical setback or an unfavorable outcome in our clinical trials may require us to delay, reduce the scope of, or eliminate programs 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.

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

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

We have exclusive licenses to develop and commercialize EVOMELA® (melphalan hydrochloride) for injection MARQIBO® (vinCRIStine sulfate LIPOSOME injection) and ZEVALIN® (ibritumomab tiuxetan) in Greater China. In addition, on January 26, 2018 we acquired a portfolio of 25 U.S. FDA-approved ANDAs, one ANDA that FDA tentatively approved, and three ANDAs that are pending FDA approval. An ANDA contains data that is submitted to FDA for the review and potential approval of a generic drug product. Once approved, the applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand-name drug it references. We intend to select and commercialize certain products from our ANDA portfolio that offer unique market and cost-effective manufacturing opportunities in China and/or in the U.S.

Our success in commercializing these drugs may be inhibited by a number of factors, including:

- our inability to obtain regulatory approvals;
- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of our products;

- our lack of experience in manufacturing drugs for commercial sales;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

Developments By Competitors May Render Our Products Obsolete

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

In the generic products market, we face competition from other generic pharmaceutical companies, which may impact our selling price and revenues from such products. The FDA approval process often results in the FDA granting final approval to a number of ANDAs for a given product at the time a patent for a corresponding brand product or other market exclusivity expires. This may force us to face immediate competition when we seek to introduce a generic product into the market. If competition from other generic pharmaceutical companies intensifies, revenues may decline.

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.

Compliance with Ongoing Post-marketing Obligations for Our Approved ANDAs and NDAs May Uncover New Safety Information that Could Give Rise to a Product Recall, Updated Warnings, or Other Regulatory Actions that Could Have an Adverse Impact on Our Business.

After the FDA approves a drug for marketing under an NDA or ANDA, the product's sponsor must comply

with several post-marketing obligations that continue until the product is discontinued. These post-marking obligations include the prompt reporting of serious adverse events to the agency, the submission of product-specific annual reports that include changes in the distribution, manufacturing, and labeling information, and notification when a drug product is found to have significant deviations from its approved manufacturing specifications (among others). Our ongoing compliance with these types of mandatory reporting requirements could result in additional requests for information from the FDA and, depending on the scope of a potential product issue that the FDA may decide to pursue, potentially also result in a request from the agency to conduct a product recall or to strengthen warnings and/or revise other label information about the product. Any of these post-marketing regulatory actions could materially affect our sales and, therefore, they have the potential to adversely affect our business, financial condition, results of operations and cash flows.

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 commercialization of our newly-acquired ANDA portfolio, development of our 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 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 our 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 are subject to certain U.S. healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.

We are subject to certain U.S. healthcare laws and regulations and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute (AKS), which governs our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities. The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. Remuneration is not defined in the AKS and has been broadly interpreted to include anything of value, including for example, gifts, discounts, coupons, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. This statute has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers and formulary managers, among others;

- the federal Food, Drug, and Cosmetic Act, or FDCA, and its regulations which prohibit, among other things, the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- federal and state government price reporting laws that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs (participation in these programs and

compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and could potentially affect our ability to offer certain marketplace discounts); and

- federal and state financial transparency laws, which generally require certain types of expenditures in the United States to be tracked and reported (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships with healthcare providers and healthcare entities, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities).

In addition, certain marketing practices, including off-label promotion, may also violate certain federal and state healthcare fraud and abuse laws, FDA rule and regulations, as well as false claims laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we, or our officers or employees, may be subject to penalties, including administrative civil and criminal penalties, damages, fines, withdrawal of regulatory approval, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to sell our products or operate our business and also adversely affect our financial results.

If we are unable to obtain both adequate coverage and adequate reimbursement from third-party payers for our products, our revenues and prospects for profitability will suffer.

Our ability to successfully commercialize our products is highly dependent on the extent to which coverage and reimbursement is, and will be, available from third-party payers, including governmental payers, such as Medicare and Medicaid, and private health insurers. Patients may not be capable of paying for our products themselves and may rely on third-party payers to pay for, or subsidize, the costs of their medications, among other medical costs. If third-party payers do not provide coverage or reimbursement for our products, our revenues and prospects for profitability will suffer. In addition, even if third-party payers provide some coverage or reimbursement for our products, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans often varies based on the type of contract or plan purchased.

Current healthcare laws and regulations and future legislative or regulatory reforms to the healthcare system may affect our ability to sell our products profitably.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

We expect that healthcare reform measures, including the potential repeal and replacement of PPACA, that may be adopted in the future, may have a significant impact on our business. Most recently, the Tax Cuts and Jobs Acts was enacted, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance. Additionally, all or a portion of PPACA and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business. If PPACA is repealed and replaced then it is unclear how the replacement statute may impact our business. If PPACA is not repealed or replaced then it will continue to impose requirements on our business.

Moreover, certain politicians, including the President, have announced intentions to propose initiatives to regulate the prices of pharmaceutical products. We cannot know what form any such legislation may take or the market's perception of how such legislation would affect us. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our current products and/or those for which we may receive regulatory approval in the future.

Risks Relating to Our Reliance on Third Parties

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.

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.

Risks Relating to Our Common Stock

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

Our common stock price has fluctuated from year-to-year and quarter-to-quarter and will likely continue to be volatile. During 2017, our stock price has ranged from $0.91 to $4.00. 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.

Our Largest Holders Of Common Stock May Have Different Interests Than Our Other Stockholders

A small number of our stockholders hold a significant amount of our outstanding common stock. These stockholders may have interests that are different from the interests of our other stockholders. We cannot assure that our largest stockholders will not seek to influence our business in a manner that is contrary to our goals or strategies or the interests of our other stockholders. In addition, the significant concentration of ownership in our common stock may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with significant stockholders. Our largest stockholders, if they acted together, could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. Our largest stockholders together may be able to determine all matters requiring stockholder approval.

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

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

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

We may issue additional shares of common stock or other securities that are convertible into or exercisable for common stock in connection with future acquisitions, future sales of our securities for capital raising purposes, future strategic relationships, or for other business purposes. The future issuance of any additional shares of our common stock may create downward pressure on the trading price of our common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in

conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock are then traded.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

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

ITEM 2. PROPERTIES.

As of December 31, 2017, we leased approximately 4,200 square feet of office space in Rockville, Maryland where our headquarters are located. In addition, as of December 31, 2017, we leased approximately 4,100 square feet of office space in Beijing, China where our China operations are based and approximately 11,000 square feet of laboratory space in Beijing, China. We believe that our facilities are adequate for current needs; however, the Company is in the process of expanding operations in China and, accordingly, intends to increase facilities to meet our foreseeable and long-term needs. We do not own any real property.

ITEM 3. LEGAL PROCEEDINGS.

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

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market for Common Equity

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

Closing Prices	HIGH	LOW
2017:		
First Quarter	$ 1.50	$ 1.20
Second Quarter	1.35	0.91
Third Quarter	1.91	0.95
Fourth Quarter	4.00	1.71
2016:		
First Quarter	$ 1.45	$ 0.68
Second Quarter	1.50	1.05
Third Quarter	1.22	0.84
Fourth Quarter	1.72	1.11

On March 26, 2018, the closing price of our common stock, as reported by The NASDAQ Capital Market, was $4.00 per share. As of March 26, 2018 there were approximately 315 holders of record of our common stock.

Dividend Policy

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

ITEM 6. SELECTED FINANCIAL DATA.

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

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

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

OVERVIEW

We are a U.S. based biopharmaceutical company dedicated to bringing high quality, cost-effective pharmaceutical products and innovative oncology therapeutics to patients. We intend to execute our plan to become a leading pharmaceutical company with a substantial market share in China. We are headquartered in Rockville, Maryland with established China operations that are expanding as we continue to further in-license or acquire products for our pipeline.

Our product pipeline features (1) EVOMELA®, MARQIBO®, and ZEVALIN®, all U.S. FDA approved drugs in-licensed from Spectrum Pharmaceuticals, Inc. for China regional rights, and currently in various stages in the regulatory process for market approval in China, (2) an acquired portfolio of 25 FDA-approved abbreviated new drug applications ("ANDAs"), one ANDA that FDA tentatively approved, and three ANDAs that are pending FDA approval, from which we will prioritize a select subset of product registration and commercialization in China, (3) our proprietary drug candidate, ENMD-2076, currently in Phase 2 clinical development, and (4) CASI-001 and CASI-002, proprietary early-stage candidates in immuno-oncology in preclinical development. We believe our pipeline reflects a risk-balanced approach between products in various stages of development, and between products that we develop ourselves and those that we develop with our partners for the China regional market. We intend to continue building a significant product pipeline of high quality, cost-effective pharmaceuticals, as well as innovative drug candidates that we will commercialize alone in China and with partners for the rest of the world. For in-licensed products, the Company uses a market-oriented approach to identify pharmaceutical candidates that it believes have the potential for gaining widespread market acceptance, either globally or in China, and for which development can be accelerated under the Company's drug development strategy. For our FDA-approved ANDAs, we intend to select and commercialize certain products from the portfolio that offer unique market and cost-effective manufacturing opportunities in China and/or in the U.S. For ENMD-2076, our current development is focused on niche and orphan indications.

Our focus is to bring high quality, cost-effective pharmaceutical products and innovative oncology therapeutics to patients. 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, we are doing business in China through our wholly-owned China-based subsidiary that will execute the China portion of our drug development strategy, including conducting clinical trials in China, pursuing local funding opportunities and strategic collaborations, and implementing our transition to a commercial enterprise.

Our primary focus is to acquire high quality, cost-effective medicines, as well as to in-license clinical-stage and late-stage drug candidates so that we can immediately employ our U.S. and China drug development model to accelerate commercialization, and clinical and regulatory progress. In addition to our high quality, cost-effective medicines, and our clinical-and late-stage approach for innovative products, we have other potential drug candidates in preclinical development which it will continue to evaluate in 2018.

Since inception, the Company has incurred significant losses from operations and has incurred an accumulated deficit of $452.7 million. The Company restructured its business in 2012 in connection with an investment led by one of the Company's largest stockholders, followed by implementation of a name change to reflect its core mission and business strategy. The Company expects to continue to incur operating losses for the foreseeable future due to, among other factors, its continuing clinical activities. In March 2018, the Company entered into securities purchase agreements pursuant to which the Company is issuing 15,432,091 shares of its

common stock with accompanying warrants to purchase 6,172,832 shares of its common stock in a $50 million private placement (the "2018 Strategic Financing"). To date, the Company has received gross proceeds of $29.3 million and expects to receive additional gross proceeds of $20.7 million in the near future. The 2018 Strategic Financing Closing included an investment from ETP Global Fund, L.P., a healthcare investment fund. The managing member of Emerging Technology Partners, LLC, which is the general partner of ETP Global Fund, L.P., is also the Executive Chairman of the Company. The 2018 Strategic Financing also included an investment from IDG-Accel China Growth Fund III L.P. ("IDG-Accel Growth") and IDG-Accel China III Investors L.P. ("IDG-Accel Investors"). A director and shareholder of IDG-Accel China Growth Fund GP III Associates Ltd., which is the ultimate general partner of IDG-Accel Growth and IDG-Accel Investors, is also a board member of the Company. In October 2017, the Company entered into securities purchase agreements for an approximately $23.8 million strategic financing. The Company held its initial closing on October 17, 2017, a second closing on October 23, 2017 and a final closing on November 20, 2017 and received approximately $23.4 million in net proceeds, (collectively, the "2017 Closings"). Net proceeds from the 2018 Strategic Financing and the 2017 Closings are being used to prepare for the anticipated launch of the Company's first commercial product in China, to support the Company's business development activities, to advance the development of the Company's pipeline, support its marketing and commercial planning activities, and for other general corporate purposes.

As a result of the 2018 Strategic Financing and the 2017 Closings, the Company believes that it has sufficient resources to fund its operations at least through March 29, 2019. As of December 31, 2017, approximately $12.2 million of the Company's cash balance was held by CASI China. We intend to continue to exercise tight controls over operating expenditures. In developing drug candidates, we intend to use and leverage resources available to us in both the United States and China. We intend to pursue additional financing opportunities as well as opportunities to raise capital through forms of non- or less- dilutive arrangements, such as partnerships and collaborations with organizations that have capabilities and/or products that are complementary to our capabilities and products in order to continue the development of our product candidates that we intend to pursue to commercialization.

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

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

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

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

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

- *Expenses for Clinical Trials* - Expenses for clinical trials are incurred from planning through patient enrollment to reporting of the data. We estimate expenses incurred for clinical trials that are in process based on patient enrollment and based on clinical data collection and management. Costs that are associated with patient enrollment are recognized as each patient in the clinical trial completes the enrollment process. Estimated clinical trial costs related to enrollment can vary based on numerous factors, including expected number of patients in trials, the number of patients that do not complete participation in a trial, and when a patient drops out of a trial. Costs that are based on clinical data collection and

management are recognized in the reporting period in which services are provided. In the event of early termination of a clinical trial, we accrue an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial.

- *Stock-Based Compensation* - All share-based payment transactions are recognized in the consolidated financial statements at their fair values. Compensation expense associated with service and performance 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. Share-based awards granted to employees with a performance condition are measured based on the probable outcome of that performance condition during the requisite service period. Such an award with a performance condition will be expensed if it is probable that a performance condition will be achieved. For the years ended December 31, 2017 and 2016, $30,500 and $10,100, respectively, was expensed for share awards with performance conditions that became probable during that period. Using the straight-line expense attribution method over the requisite service period, which is generally the option vesting term ranging from immediately to one to three years, share-based compensation expense recognized for the years ended December 31, 2017 and 2016 totaled approximately $650,000 and $2,995,000, respectively.

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

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

- *Fair Value Measurements* - At each reporting period, we perform a detailed analysis of our assets and liabilities that are measured at fair value. All assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3 in accordance with the hierarchy established by U.S. GAAP. As of December 31, 2017, the Contingent Rights had been fully settled resulting a zero balance at the end of 2017. In measuring the fair value of financial instruments at every balance sheet date, we used Level 3 unobservable inputs, including such inputs as our estimated borrowing rate and our future capital requirements, and the timing, probability, size and characteristics of those capital raises, among other inputs.

RESULTS OF OPERATIONS

Years Ended December 31, 2017 and 2016.

Revenues and Cost of Product Sales. There were no revenues recorded for the years ended December 31, 2017 and 2016.

Research and Development Expenses. Our 2017 research and development expenses totaled $7,595,000 as compared to $4,646,000 in 2016, a 63% increase. In 2017, our research and development expenses reflect direct project costs of $856,000 for ENMD-2076, $3,603,000 for drugs in-licensed from Spectrum, and $1,301,000 for preclinical development activities primarily in China. The 2016 amount reflects direct project costs for ENMD-2076 of $1,696,000, $547,000 for drugs in-licensed from Spectrum, and $862,000 for preclinical development activities primarily in China. The increase in 2017 research and development spending primarily reflects higher costs associated with the quality testing phase of the CFDA regulatory review of ZEVALIN® and EVOMELA® in 2017.

At December 31, 2017, and, since acquired, accumulated direct project expenses for ENMD-2076 totaled $28,511,000, $4,536,000 for drugs in-licensed from Spectrum, and for preclinical development activities primarily

in China, accumulated project expenses totaled $3,356,000. Our research and development expenses also include non-cash stock-based compensation totaling $272,000 and $746,000, respectively, for 2017 and 2016. 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 2018 to be devoted to advancing our in-licensed products towards market approval in China, the technology transfer activities and regulatory support associated with our ANDA portfolio, and our early-stage candidates in preclinical development. We expect our expenses in 2018 to increase based on our commercial and clinical development plan. 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 $7,595,000 in 2017 from $4,646,000 in 2016.

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 $333,000 in 2017 and $302,000 in 2016. The increase in 2017 is primarily associated with higher costs associated with our pre-clinical activities.

- *Clinical Trial Costs* – Clinical trial costs, which include clinical site fees, monitoring costs and data management costs, decreased to $417,000 in 2017 from $1,219,000 in 2016. This decrease primarily relates to higher enrollment patient costs and clinical trial management costs associated with our Phase 2 clinical trial in advanced fibrolamellar carcinoma (FLC) during the 2016 period.

- *Lab Supplies* – Laboratory supplies associated with our pre-clinical activities increased to $294,000 in 2017 from $177,000 in 2016 due to the expansion of activities in our China research and development lab in 2017.

- *Contract Manufacturing Costs* – The costs of manufacturing or acquiring the material used in clinical trials for our product candidates is reflected in contract manufacturing. These costs include bulk manufacturing, encapsulation and fill and finish services, and product release costs. Contract manufacturing costs increased in 2017 to $2,987,000 from $229,000 in 2016. The increase in 2017 primarily reflects costs associated with the purchase of ZEVALIN® and EVOMELA® in 2017 from our partner Spectrum for CFDA quality testing purposes to support CASI's application for import drug registration during 2017.

- *Personnel Costs* – Personnel costs increased to $2,644,000 in 2017 from $1,960,000 in 2016. This variance is primarily attributed to increased salary and benefit costs associated with new employees in China and our new Chief Medical Officer in the U.S. in 2017, offset by a decrease in non-cash stock-based compensation expense totaling $474,000 in 2017 compared to 2016.
- Also reflected in our 2017 research and development expenses are outsourced consultant costs of $213,000 and facility and related expenses of $485,000. In 2016, these expenses totaled $300,000 and $328,000, respectively. The decrease in outsourced consultant costs reflects lower costs associated with clinical trial management and evaluation and regulatory activities in the U.S. The increase in facilities and related expenses is due to new leased lab space in China in 2017.

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 decreased to $3,156,000 in 2017 from $4,775,000 in 2016. This decrease is primarily related to a decrease of $1,871,000 in stock-based compensation expense, primarily related to stock options awarded in connection with the closings of the Company's strategic financing in 2016, offset by an increase in salary and benefits associated with U.S. employees, including new business development employees in 2017.

Interest (income) expense, net. Interest expense, net for the years ended December 31, 2017 and 2016 was $(1,009) and $26,090, respectively. This includes interest expense on our note payable of $7,500 for both years; non-cash interest expense of $7,476 and $26,308, respectively, representing the amortization of the debt discount; offset by interest income of $15,985 and $7,718, respectively.

Change in fair value of contingent rights. The Contingent Rights issued to Spectrum in connection with the license arrangements are considered derivative liabilities and were recorded initially at their estimated fair value, and are marked to market each reporting period until settlement. The change in fair value of the Contingent Rights for the years ended December 31, 2017 and 2016 was $19,891 and $6,788, respectively.

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 2018 and the foreseeable future before we commercialize any products and penetrate significant markets such as China. Based on our current plans, we expect our current available cash and cash equivalents to meet our cash requirements for at least through March 29, 2019.

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 commercialization efforts, research and development, and 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 commercialization efforts, our advancement of the Spectrum products, and our Phase 2 plans for ENMD-2076 or plans for other product candidates, if any.

At December 31, 2017, we had cash and cash equivalents of approximately $43.5 million, with working capital of approximately $38.8 million. As of December 31, 2017, approximately $12.2 million of the Company's cash balance was held by the Company's wholly-owned subsidiary in China. As previously disclosed, on January

26, 2018 the Company paid $18 million for a portfolio of 25 U.S. FDA-approved ANDAs, one ANDA that FDA tentatively approved, and three ANDAs that are pending FDA approval.

As a result of the Company's acquisition of a portfolio of ANDAs, we believe that this transaction provides significant and permanent changes to our operations in China, allowing our subsidiary in China to generate operating revenues from the China marketplace in the future and potentially to sustain their own operations without the necessity of parent support. Accordingly, effective January 1, 2018, the functional currency of the Company's subsidiary based in China has been changed to the local currency of the China RMB. The Company does not expect this change in functional currency will have a material impact on the consolidated financial statements.

FINANCING ACTIVITIES

"Shelf" Registration Statement

On December 13, 2017, we filed a Form S-3 registration statement with the SEC utilizing a "shelf" registration process. On December 22, 2017, 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 $100 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.

Securities Purchase Agreements

As discussed above, on March 19, 2018, the Company entered into securities purchase agreements (the "Securities Purchase Agreements") with certain institutional investors, accredited investors and current stockholders, pursuant to which the Company is issuing 15,432,091 shares of its common stock with accompanying warrants to purchase 6,172,832 shares of its common stock in a $50 million private placement. To date, the Company has received gross proceeds of $29.3 million and expects to receive additional gross proceeds of $20.7 million in the near future. The purchase price for each share of common stock and warrant was $3.24. The warrants will become exercisable 180 days after issuance at a $3.69 per share exercise price, and will expire five years from the date of issuance. The Securities Purchase Agreements and warrants each include additional customary representations, warranties and covenants. The Company also agreed to file a resale registration within 120 days following the closing covering the shares of common stock issued and the shares of common stock underlying the warrants.

Additionally, as discussed above, on October 13, 2017, the Company entered into securities purchase agreements with certain institutional investors, accredited investors and current stockholders pursuant to which the Company agreed to sell 7,951,865 shares of its common stock and warrants exercisable for up to 1,590,373 shares of its common stock (exclusive of the Agent Warrants described below) in a registered direct offering (the "2017 Offering") for gross proceeds of $23,855,595. As a result of the 2017 Closings related to the 2017 Offering, the Company received approximately $23.4 million after offering expenses and issued 7,951,865 shares of common stock. The shares and warrants were sold together, consisting of one share of common stock and a warrant to purchase 0.20 shares of common stock for each share of common stock purchased, at a combined offering price of $3.00. The warrants are exercisable beginning on April 17, 2018 and expire on April 17, 2020. The warrants have an exercise price of $3.75 per share. The fair value of the warrants issued is $1,558,566, calculated using the Black-Scholes-Merton valuation model value of $0.98 with a contractual life of 2.5 years, an assumed volatility of 85.4%, and a risk-free interest rate of 1.54%.

In connection with the 2017 Offering, the Company issued to its placement agent or its designees warrants to purchase 48,133 shares of common stock at an exercise price of $3.75 per share of common stock (the "Agent Warrants"), representing the number of warrants equal to an aggregate of 4% of the number of shares sold to investors placed by the placement agent in the 2017 Offering, excluding investments made by certain China-focused investors that were placed by the Company. The Agent Warrants are exercisable beginning on April 17, 2018 and expire on April 17, 2019. The fair value of the warrants issued is $28,880, calculated using the Black-Scholes-Merton valuation model value of $0.60 with a contractual life of 1.5 years, an assumed volatility of 77.8%, and a risk-free interest rate of 1.54%.

Common Stock Sales Agreement

On February 23, 2018, the Company entered into a Common Stock Sales Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("HCW"). Pursuant to the terms of the Sales Agreement, the Company may sell from time to time, at its option, shares of the Company's common stock, through HCW, as sales agent, with an aggregate sales price of up to $25 million (the "Shares").

Any sales of Shares pursuant to the Sales Agreement will be made under the Company's effective "shelf" registration statement (the "Registration Statement") on Form S-3 (File No. 333-222046) which became effective on December 22, 2017 and the related prospectus supplement and the accompanying prospectus, as filed with the Securities and Exchange Commission (the "SEC") on February 23, 2018.

Under the terms of the Sales Agreement, the Company may sell shares of its common stock through HCW by any method permitted that is deemed an "at the market offering" as defined in Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"). HCW will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). Actual sales will depend on a variety of factors to be determined by the Company from time to time, including (among others) market conditions, the trading price of the Company's common stock, capital needs and determinations by the Company of the appropriate sources of funding for the Company. The Company is not obligated to make any sales of common stock under the Sales Agreement and the Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. The Company will pay a commission rate of up to 3.0% of the gross sales price per share sold and agreed to reimburse HCW for certain specified expenses. The Company has also agreed pursuant to the Sales Agreement to provide HCW with customary indemnification and contribution rights.

The Company or HCW upon notice to the other, may suspend the offering of the Shares under the Sales Agreement at any time. The offering of the Shares pursuant to the Sales Agreement will terminate upon the sale of Shares in an aggregate offering amount equal to $25 million, or sooner if either the Company or HCW terminate the Sales Agreement pursuant to its terms.

Through March 2018, the Company issued 143,248 Shares under the Sales Agreement resulting in net proceeds to the Company of approximately $475,000.

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 2017.

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, 2017, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Accounting Officer (our principal executive officer and principal financial officer, respectively) and our Chief Operating Officer & General Counsel, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e)). Our Chief Executive Officer, Principal Accounting Officer and Chief Operating Officer & General Counsel have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to our management (including our Chief Executive Officer, Principal Accounting Officer, and Chief Operating Officer & General Counsel) to allow timely decisions regarding required disclosures. Based on such evaluation, our Chief Executive Officer, Principal Accounting Officer, and Chief Operating Officer & General Counsel have concluded these disclosure controls are effective as of December 31, 2017.

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, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is designed to provide reasonable assurance to our management and board of directors regarding the reliability of financial reporting and the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted accounting principles. Any internal control over financial reporting, no matter how well designed, has inherent limitations. As a result of these inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those internal controls determined to be effective can provide only reasonable assurance with respect to reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our management, including our Chief Executive Officer, Chief Operating Officer & General Counsel and Principal Accounting Officer, we conducted an assessment of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework 2013*. Based on our assessment, we concluded that our internal control over financial reporting was effective as of December 31, 2017.

ITEM 9B. OTHER INFORMATION.

Our 2018 Annual Meeting of Stockholders will be held on June 11, 2018. 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, 2017.

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

ITEM 11. EXECUTIVE COMPENSATION.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2017.

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, 2017.

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, 2017.

	(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	11,585,315	$1.42	2,852,234
Equity compensation plans not approved by security holders	0	$0.00	0
Total	11,585,315	$1.42	2,852,234

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, 2017.

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, 2017.

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

1.1	Engagement Letter, dated as of October 12, 2017, by and between CASI Pharmaceuticals, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.1 of our Form 8-K filed with the Securities and Exchange Commission on October 19, 2017)
2.1	Agreement and Plan of Merger, dated as of December 22, 2005 among EntreMed, Inc., E.M.K. Sub, Inc., Miikana Therapeutics, Inc., and Andrew Schwab (incorporated by reference to Exhibit 2.1 of our Form 8-K filed with the Securities and Exchange Commission on December 29, 2005)
3.1	Amended and Restated Certificate of Incorporation of EntreMed, Inc. (incorporated by reference to Exhibit 3.1 of our Form 10-Q for the quarter ended June 30, 2006 filed with the Securities and Exchange Commission)
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on July 7, 2010)
3.3	Amended and Restated Bylaws of EntreMed, Inc. (incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on December 12, 2007)
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on June 13, 2014)
4.1	Certificate of Elimination of Series A Preferred Stock filed with the Secretary of State of Delaware on September 13, 2012. (Incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on September 20, 2012.)
4.2	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on January 26, 2012)
4.3	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Form 8-K filed with the Securities and Exchange Commission on March 6, 2013)
4.4	Form of Agent's Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of our Form 8-K filed with the Securities and Exchange Commission on March 6, 2013)

4.5	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 (included in Exhibit 10.1) of our Form 10-Q filed with the Securities and Exchange Commission on November 13, 2015)
4.6	Certificate of Designation of Series A Preferred Stock (incorporated by reference to Exhibit 4.1 of our Form 8-K filed with the Securities and Exchange Commission on September 19, 2014)
4.7	Secured Promissory Note, dated as of September 17, 2014, issued to Talon Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 of our Form 8-K filed with the Securities and Exchange Commission on September 19, 2014)
4.8	First Amendment to Secured Promissory Note, dated as of September 28, 2015, by and between CASI Pharmaceuticals, Inc. and Talon Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 of our Form 8-K filed with the Securities and Exchange Commission on October 1, 2015)
4.9	Second Amendment to Secured Promissory Note, dated as of December 13, 2016, by and between CASI Pharmaceuticals, Inc. and Talon Therapeutics, Inc. (incorporated by reference to Exhibit 4.3 of our Form 8-K filed with the Securities and Exchange Commission on December 16, 2016)
4.10	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 October 19, 2017)
4.11	Form of Wainwright Warrant (incorporated by reference to Exhibit 4.2 of our Form 8-K filed with the Securities and Exchange Commission on October 19, 2017)
4.12	Third Amendment to Secured Promissory Note, dated as of December 20, 2017, by and between CASI Pharmaceuticals, Inc. and Talon Therapeutics, Inc. (incorporated by reference to Exhibit 4.4 of our Form 8-K filed with the Securities and Exchange Commission on December 22, 2017)
4.13	Form of Warrant (incorporated by reference to Exhibit 4.1 of our Form 8-K filed with the Securities and Exchange Commission on March 23, 2018)
10.1	License Agreement between Celgene Corporation and EntreMed, Inc. signed December 9, 1998 regarding thalidomide intellectual property + (incorporated by reference to Exhibit 10.28 of our Form 10-K for the year ended December 31, 1998 filed with the Securities and Exchange Commission)
10.2	Lease Agreement between EntreMed, Inc. and Red Gate III Limited Partnership, dated June 10, 1998 (incorporated by reference to Exhibit 10.31 our Form 10-K for the year ended December 31, 1998 filed with the Securities and Exchange Commission)
10.3	EntreMed, Inc. 2001 Long-Term Incentive Plan* (incorporated by reference to Appendix A to our Definitive Proxy Statement filed with the Securities and Exchange Commission on May 12, 2006)
10.4.1	Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated June 15, 2001+ (incorporated by reference to Exhibit 10.39.1 of our Form 10-Q for the quarter ended June 30, 2001 filed with the Securities and Exchange Commission)
10.4.2	Amendment 1 to Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated July 13, 2001(incorporated by reference to Exhibit 10.39.2 of our Form 10-Q for the quarter ended June 30, 2001 filed with the Securities and Exchange Commission)
10.4.3	Amendment 2 to Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated July 30, 2001(incorporated by reference to Exhibit 10.39.3 of our Form 10-Q for the quarter ended June 30, 2001 filed with the Securities and Exchange Commission)
10.4.4	Amendment 3 to Purchase Agreement between Bioventure Investments kft and EntreMed, Inc., dated August 3, 2001 (incorporated by reference to Exhibit 10.39.4 of our Form 10-Q for the quarter ended

June 30, 2001 filed with the Securities and Exchange Commission)

10.5 EntreMed, Inc. 2001 Long Term Incentive Plan Non-Qualified Stock Option Grant Agreement (Director)* (incorporated by reference to Exhibit 10.7 of our Form 8-K filed with the Securities and Exchange Commission on April 17, 2007)

10.6 EntreMed, Inc. 2001 Long Term Incentive Plan Non-Qualified Stock Option Grant Agreement (Non-Director Employee)* (incorporated by reference to Exhibit 10.8 of our Form 8-K filed with the Securities and Exchange Commission on April 17, 2007)

10.7 Form of Change in Control Agreement* (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on April 17, 2007)

10.8 Employment Agreement by and between EntreMed and Cynthia W. Hu, dated as of June 1, 2006* (incorporated by reference to Exhibit 10.1 of Form 8-K filed with the Securities and Exchange Commission on June 6, 2006)

10.9 Amendment to Employment Agreement by and between the Company and Cynthia W. Hu, effective April 16, 2007* (incorporated by reference to Exhibit 10.5 of our Form 8-K filed with the Securities and Exchange Commission on April 17, 2007)

10.10 Form of Restricted Stock Award under EntreMed, Inc. 2001 Long Term Incentive Plan* (incorporated by reference to Exhibit 10.2 of our Form 8-K filed with the Securities and Exchange Commission on March 11, 2005)

10.11 License Agreement between EntreMed and Celgene Corporation signed March 23, 2005 regarding the development and commercialization of Celgene's small molecule tubulin inhibitor compounds for the treatment of cancer+ (incorporated by reference to Exhibit 10.25 of our Form 10-Q for the quarter ended March 31, 2005 filed with the Securities and Exchange Commission)

10.12 Securities Purchase Agreement, dated September 7, 2010 by and between EntreMed, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on September 10, 2010)

10.13 Employment Agreement, by and between EntreMed, Inc. and Sara Capitelli, dated as of January 10, 2011* (incorporated by reference to Exhibit 10.33 of our Form 10-K for the fiscal year ended December 31, 2010 filed with the Securities and Exchange Commission)

10.14 Convertible Note and Warrant Purchase Agreement, dated January 20, 2012, by and among EntreMed, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on January 26, 2012)

10.15 Securities Purchase Agreement, dated March 1, 2013, by and among EntreMed, Inc. and the investors thereto (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on March 6, 2013)

10.16 Employment Agreement by and between EntreMed, Inc. and Ken K. Ren, dated as of April 2, 2013* (incorporated by reference to Exhibit 10.1 of our Form 10-Q filed with the Securities and Exchange Commission on May 15, 2013)

10.17 Investment Agreement, dated as of September 17, 2014, by and between CASI Pharmaceuticals, Inc. and Spectrum Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on September 19, 2014)

10.18 Investment Agreement, dated as of September 17, 2014, by and between CASI Pharmaceuticals, Inc. the Company and Spectrum Pharmaceuticals Cayman, L.P (incorporated by reference to Exhibit 10.2 of our Form 8-K filed with the Securities and Exchange Commission on September 19, 2014)

10.19 License Agreement, dated as of September 17, 2014, by and between CASI Pharmaceuticals, Inc. and

	Spectrum Pharmaceuticals, Inc. + (incorporated by reference to Exhibit 10.3 of our Form 10-Q/A filed with the Securities and Exchange Commission on January 21, 2015)
10.20	License Agreement, dated as of September 17, 2014, by and between CASI Pharmaceuticals, Inc. and Spectrum Pharmaceuticals Cayman, L.P. + (incorporated by reference to Exhibit 10.4 of our Form 10-Q/A filed with the Securities and Exchange Commission on January 21, 2015)
10.21	License Agreement, dated as of September 17, 2014, by and between CASI Pharmaceuticals, Inc. and Talon Therapeutics, Inc. + (incorporated by reference to Exhibit 10.5 of our Form 10-Q/A filed with the Securities and Exchange Commission on January 21, 2015)
10.22	CASI Pharmaceuticals, Inc. 2011 Long-Term Incentive Plan, as amended* (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 14, 2017)
10.23	Form of Securities Purchase Agreement, dated September 20, 2015, by and among CASI Pharmaceuticals, Inc. and the investors thereto (incorporated by reference to Exhibit 10.1 of our Form 10-Q filed with the Securities and Exchange Commission on November 13, 2015)
10.24	Employment Agreement by and between CASI Pharmaceuticals, Inc. and Alex Zukiwski, dated as of April 3, 2017 * (incorporated by reference to Exhibit 10.1 of our Form 10-Q filed with the Securities and Exchange Commission on August 14, 2017)
10.25	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on October 19, 2017)
10.26	Asset Purchase Agreement, dated as of January 26, 2018, by and between CASI Pharmaceuticals, Inc. and Sandoz Inc. + **
10.27	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on March 23, 2018)
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, 2017, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2017 and 2016, (ii) Consolidated Statements of Operations for the years ended December 31, 2017 and 2016, (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2017 and 2016 (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2016 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 under 17 C.F.R. §§200.80(b)(4) and 230.406. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Commission pursuant to our confidential treatment request.
**	Filed herewith

SIGNATURES

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

Date: March 29, 2018

CASI Pharmaceuticals, Inc.

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

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

SIGNATURE	TITLE	DATE
/s/Ken K. Ren Ken K. Ren	Chief Executive Officer and Director (Principal Executive Officer)	March 29, 2018
/s/Sara B. Capitelli Sara B. Capitelli	Principal Accounting Officer	March 29, 2018
/s/Wei-Wu He Wei-Wu He	Executive Chairman	March 29, 2018
/s/James Z. Huang James Z. Huang	Director	March 29, 2018
/s/Franklin C. Salisbury Franklin C. Salisbury	Director	March 29, 2018
/s/Rajesh C. Shrotriya Rajesh C. Shrotriya	Director	March 29, 2018
/s/Y. Alexander Wu Y. Alexander Wu	Director	March 29, 2018
/s/ Quan Zhou Quan Zhou	Director	March 29, 2018

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

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
CASI Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CASI Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the 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.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. Federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to fraud or error. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purposes of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company's auditor since 2012.

Roseland, New Jersey
March 29, 2018

CASI Pharmaceuticals, Inc.
Consolidated Balance Sheets

	DECEMBER 31, 2017	DECEMBER 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 43,489,935	$ 27,092,928
Prepaid expenses and other	322,493	355,891
Total current assets	43,812,428	27,448,819
Property and equipment, net	1,046,514	229,591
Other assets	242,023	34,485
Total assets	$ 45,100,965	$ 27,712,895
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,087,770	$ 1,064,626
Payable to related party	2,228,366	-
Accrued liabilities	745,961	250,950
Total current liabilities	5,062,097	1,315,576
Note payable, net of discount	1,498,754	1,491,278
Contingent rights derivative liability	-	4,122,266
Total liabilities	6,560,851	6,929,120
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock, $1.00 par value; 5,000,000 shares authorized and 0 shares issued and outstanding at December 31, 2017 and 2016	-	-
Common stock, $.01 par value: 170,000,000 shares authorized at December 31, 2017 and 2016; 69,901,625 shares and 60,276,119 shares issued at December 31, 2017 and 2016, respectively	699,015	602,760
Additional paid-in capital	498,577,372	470,147,086
Treasury stock, at cost: 79,545 shares held at December 31, 2017 and 2016	(8,034,244)	(8,034,244)
Accumulated deficit	(452,702,029)	(441,931,827)
Total stockholders' equity	38,540,114	20,783,775
Total liabilities and stockholders' equity	$ 45,100,965	$ 27,712,895

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Operations

	YEAR ENDED DECEMBER 31,	
	2017	2016
Revenues:		
Product sales	$ -	$ -
	-	-
Costs and expenses:		
Research and development	7,595,182	4,645,560
General and administrative	3,156,138	4,775,050
	10,751,320	9,420,610
Interest (income) expense, net	(1,009)	26,090
Change in fair value of contingent rights	19,891	6,788
Net loss	$ (10,770,202)	$ (9,453,488)
Net loss per share (basic and diluted)	$ (0.18)	$ (0.17)
Weighted average number of shares outstanding (basic and diluted)	61,513,988	55,869,205

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity
Years Ended December 31, 2017 and 2016

	Preferred Stock		Common Stock		Treasury	Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Stock	Capital	Deficit	Total
Balance at December 31, 2015	-	$ -	32,445,811	$ 325,252	$ (8,034,244)	$ 434,099,890	$ (432,478,339)	$ (6,087,441)
Issuance of common stock and warrants pursuant to financing agreements	-	-	23,127,566	231,276	-	27,868,724	-	28,100,000
Issuance of common stock from exercise of contingent purchase right	-	-	4,623,197	46,232	-	-	-	46,232
Partial settlement of contingent purchase rights derivative	-	-	-	-	-	5,279,744	-	5,279,744
Stock issuance costs	-	-	-	-	-	(96,512)	-	(96,512)
Stock-based compensation expense, net of forfeitures	-	-	-	-	-	2,995,240	-	2,995,240
Net loss	-	-	-	-	-	-	(9,453,488)	(9,453,488)
Balance at December 31, 2016	-	-	60,196,574	602,760	(8,034,244)	470,147,086	(441,931,827)	20,783,775
Issuance of common stock and warrants pursuant to financing agreements	-	-	7,951,865	79,519	-	23,804,956	-	23,884,475
Issuance of common stock from exercise of contingent purchase right	-	-	1,519,096	15,191	-	-	-	15,191
Issuance of common stock for options exercised	-	-	154,545	1,545	-	324,454	-	325,999
Partial settlement of contingent purchase rights derivative	-	-	-	-	-	4,142,157	-	4,142,157
Stock issuance costs	-	-	-	-	-	(491,721)	-	(491,721)
Stock-based compensation expense, net of forfeitures	-	-	-	-	-	650,440	-	650,440
Net loss	-	-	-	-	-	-	(10,770,202)	(10,770,202)
Balance at December 31, 2017	-	$ -	69,822,080	$ 699,015	$ (8,034,244)	$ 498,577,372	$ (452,702,029)	$ 38,540,114

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

	YEAR ENDED DECEMBER 31,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (10,770,202)	$ (9,453,488)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	117,779	66,451
Net gain on disposal of assets	-	(12,459)
Stock-based compensation expense	650,440	2,995,240
Non-cash interest	7,476	26,308
Change in fair value of contingent rights	19,891	6,788
Changes in operating assets and liabilities:		
Prepaid expenses and other	(361)	86,029
Accounts payable	849,365	180,526
Payable to related party	2,228,366	-
Accrued liabilities	495,011	81,486
Net cash used in operating activities	(6,402,235)	(6,023,119)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(934,702)	(223,233)
Proceeds from sale of property and equipment	-	158,446
Net cash used in investing activities	(934,702)	(64,787)
CASH FLOWS FROM FINANCING ACTIVITIES		
Stock issuance costs	(462,841)	(96,512)
Proceeds from sale of common stock and warrants	23,870,786	28,146,232
Proceeds from exercise of stock options	325,999	-
Net cash provided by financing activities	23,733,944	28,049,720
Net increase in cash and cash equivalents	16,397,007	21,961,814
Cash and cash equivalents at beginning of year	27,092,928	5,131,114
Cash and cash equivalents at end of year	$ 43,489,935	$ 27,092,928
Supplemental disclosure of cash flow information:		
Non-cash financing activity:		
Warrant issued to placement agent	$ 28,880	$ -
Partial settlement of contingent rights derivative	$ 4,142,157	$ 5,279,744
Non-cash investing activity:		
Disposal of fully depreciated property and equipment, at cost	$ 7,523	$ 25,204

See accompanying notes.

1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

CASI Pharmaceuticals, Inc. ("CASI" or the "Company") is a U.S. based biopharmaceutical company dedicated to bringing high quality, cost-effective pharmaceutical products and innovative oncology therapeutics to patients. The Company intends to execute its plan to become a leading pharmaceutical company with a substantial market share in China. We are headquartered in Rockville, Maryland with established China operations that are expanding as we continue to further in-license or acquire products for our pipeline.

The Company's pipeline features (1) EVOMELA®, MARQIBO®, and ZEVALIN®, all U.S. Food and Drug Administration ("FDA") approved drugs in-licensed from Spectrum Pharmaceuticals, Inc. for China regional rights, and currently in various stages in the regulatory process for market approval in China, (2) an acquired portfolio (see Note 12) of 25 FDA-approved abbreviated new drug applications ("ANDAs"), one ANDA that FDA tentatively approved, and three ANDAs that are pending FDA approval, from which the Company intends to prioritize a select subset of product registration and commercialization in China, (3) our proprietary drug candidate, ENMD-2076, currently in Phase 2 clinical development, and (4) CASI-001 and CASI-002, proprietary early-stage candidates in immuno-oncology in preclinical development. The Company's pipeline reflects a risk-balanced approach between products in various stages of development, and between products that it develops and those that it develops with the Company's partners for the China regional market. The Company intends to continue building a significant product pipeline of high quality, cost-effective pharmaceuticals, as well as innovative drug candidates that it will commercialize alone in China and with partners for the rest of the world. For in-licensed products, the Company uses a market-oriented approach to identify pharmaceutical candidates that it believes have the potential for gaining widespread market acceptance, either globally or in China, and for which development can be accelerated under the Company's drug development strategy.

The Company's focus is to bring high quality, cost-effective pharmaceutical products and innovative oncology therapeutics to patients. The implementation of its plans will include leveraging the Company's 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 China-based 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 transition to a commercial enterprise.

In September 2014, the Company acquired from Spectrum Pharmaceuticals, Inc. and certain of its affiliates (together referred to as "Spectrum") exclusive rights in greater China (including Taiwan, Hong Kong and Macau) to three in-licensed oncology products, including EVOMELA™ (melphalan hydrochloride for injection) approved in the U.S. primarily for use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma, MARQIBO® (vinCRIStine sulfate LIPOSOME injection) approved in the U.S. for advanced adult Ph- acute lymphoblastic leukemia (ALL), and ZEVALIN® (ibritumomab tiuxetan) approved in the U.S. for advanced non-Hodgkin's lymphoma.

On January 26, 2018, the Company acquired a portfolio of 25 U.S. FDA-approved abbreviated new drug applications (ANDAs), one ANDA that FDA tentatively approved, and three ANDAs that are pending FDA approval. CASI intends to select and commercialize certain products from the portfolio that offer unique market and cost-effective manufacturing opportunities in China and/or in the U.S.

The Company's primary focus is to acquire high quality, cost-effective medicines, as well as to in-license clinical-stage and late-stage drug candidates so that it can immediately employ its U.S. and China drug development model to accelerate commercialization, and clinical and regulatory progress. In addition to its high quality, cost-

effective medicines, and clinical-and late-stage approach for innovative products, the Company has other potential drug candidates in preclinical development which it will continue to evaluate in 2018.

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

LIQUIDITY RISKS AND MANAGEMENT'S PLANS

Since inception, the Company has incurred significant losses from operations and has incurred an accumulated deficit of $452.7 million. The Company restructured its business in 2012 in connection with an investment led by one of the Company's largest stockholders, followed by implementation of a name change to reflect its core mission and business strategy. The Company expects to continue to incur operating losses for the foreseeable future due to, among other factors, its continuing clinical activities. In March 2018, the Company entered into securities purchase agreements pursuant to which the Company is issuing 15,432,091 shares of its common stock with accompanying warrants to purchase 6,172,832 shares of its common stock in a $50 million private placement (the "2018 Strategic Financing") (see Note 8). To date, the Company has received gross proceeds of $29.3 million and expects to receive additional gross proceeds of $20.7 million in the near future. The 2018 Strategic Financing Closing included an investment from ETP Global Fund, L.P., a healthcare investment fund. The managing member of Emerging Technology Partners, LLC, which is the general partner of ETP Global Fund, L.P., is also the Executive Chairman of the Company. The 2018 Strategic Financing also included an investment from IDG-Accel China Growth Fund III L.P. ("IDG-Accel Growth") and IDG-Accel China III Investors L.P. ("IDG-Accel Investors"). A director and shareholder of IDG-Accel China Growth Fund GP III Associates Ltd., which is the ultimate general partner of IDG-Accel Growth and IDG-Accel Investors, is also a board member of the Company. In October 2017, the Company entered into securities purchase agreements for an approximately $23.8 million strategic financing. The Company held its initial closing on October 17, 2017, a second closing on October 23, 2017 and a final closing on November 20, 2017 and received approximately $23.4 million in net proceeds, (collectively, the "2017 Closings") (see Note 8). Net proceeds from the 2018 Strategic Financing and 2017 Closings are being used to prepare for the anticipated launch of the Company's first commercial product in China, support the Company's business development activities, advance the development of the Company's pipeline, support its marketing and commercial planning activities, and for other general corporate purposes.

As a result of the 2018 Strategic Financing and 2017 Closings the Company believes that it has sufficient resources to fund its operations at least through March 29, 2019. As of December 31, 2017, approximately $12.2 million of the Company's cash balance was held by CASI China. The Company intends to continue to exercise tight controls over operating expenditures and will continue to pursue opportunities, as required, to raise additional capital and will also actively pursue non- or less-dilutive capital raising arrangements in China to support the Company's dual-country approach to drug development.

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 China-based subsidiary that will execute the China portion of the Company's drug development strategy, including commercialization and conducting clinical trials in China, pursuing local funding opportunities and strategic collaborations, and implementing the Company's plan for development and commercialization in the Chinese market.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

SEGMENT INFORMATION

The Company currently operates in one business segment, which is the development of innovative therapeutics addressing cancer and other unmet medical needs for the global market. The Company is managed and operated as one business. CASI's senior management team reports to the Board of Directors and is responsible for aligning the Company's business strategy with its core scientific strengths, while maintaining prudent resource management, fiscal responsibility and accountability. The Company employs a drug development strategy in the United States and China to develop targeted therapeutics for the global market that are potential first-in-class or market-leading compounds for treatment of cancer.

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

RESEARCH AND DEVELOPMENT

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

PROPERTY AND EQUIPMENT

Furniture and equipment and leasehold improvements are stated at cost and are depreciated or amortized over their estimated useful lives of 3 to 5 years. Depreciation and amortization is determined on a straight-line basis. Depreciation and amortization expense was $117,779 and $66,451 in 2017 and 2016, respectively.

Property and equipment consists of the following:

	DECEMBER 31,	
	2017	2016
Furniture and equipment	$ 1,150,052	$ 480,172
Leasehold improvements	268,734	11,435
	1,418,786	491,607
Less: accumulated depreciation and amortization	(372,272)	(262,016)
	$ 1,046,514	$ 229,591

IMPAIRMENT OF LONG-LIVED ASSETS

In accordance with authoritative guidance issued by the FASB, the Company periodically evaluates the value reflected in its consolidated balance sheets of long-lived assets, such as equipment, when events and circumstances indicate that the carrying amount of an asset may not be recovered. Such events and circumstances include the use of the asset in current research and development projects, any potential alternative uses of the asset in other research and development projects in the short to medium term and restructuring plans entered into by the Company. No impairment charges were recorded in 2017 and 2016.

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.

FOREIGN CURRENCY TRANSLATION

The U.S. dollar is the functional and reporting currency of the Company. Foreign currency denominated assets and liabilities of the Company and all of its subsidiaries are translated into U.S. dollars. Accordingly, monetary assets and liabilities are translated using the exchange rates in effect at the consolidated balance sheet date and revenues and expenses at the rates of exchange prevailing when the transactions occurred. Remeasurement adjustments are included in income (loss). As discussed in Note 12, on January 26, 2018 the Company acquired a portfolio of ANDAs. Management believes that this transaction provides significant and permanent changes to its operations in China, allowing its subsidiary in China to generate operating revenues from the China marketplace in the future and potentially to sustain their own operations without the necessity of parent support. Accordingly, effective January 1, 2018, the functional currency of the Company's subsidiary based in China has been changed to the local currency of the China Renminbi ("RMB").

EXPENSES FOR CLINICAL TRIALS

Expenses for clinical trials are incurred from planning through patient enrollment to reporting of the data. The Company estimates expenses incurred for clinical trials that are in process based on patient enrollment and based on clinical data collection and management. Costs that are associated with patient enrollment are recognized as each patient in the clinical trial completes the enrollment process. Estimated clinical trial costs related to enrollment can vary based on numerous factors, including expected number of patients in trials, the number of patients that do not complete participation in a trial, and the length of participation for each patient. Costs that are based on clinical data collection and management are recognized in the reporting period in which services are provided. In the event of early termination of a clinical trial, the Company accrues an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial. As of December 31, 2017 and 2016, clinical trial accruals were $402,773 and $499,028, 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 the FASB. Income tax expense has been provided using the asset and liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities as measured by the enacted tax rates that will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets if, based upon the available evidence, it is not more likely than not that the deferred tax assets will be realized.

The Company accounts for uncertain tax positions pursuant to the guidance of FASB Accounting Standards Codification Topic 740, *Income Taxes*. The Company recognizes interest and penalties related to uncertain tax positions, if any, in income tax expense. As of December 31, 2017 and 2016, the Company did not accrue any interest related to uncertain tax positions. To date, there have been no interest or penalties charged to the Company in relation to the underpayment of income taxes.

REVENUE RECOGNITION

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

NET LOSS PER SHARE

Net loss per share (basic and diluted) was computed by dividing net loss attributable to common shareholders by the weighted average number of shares of common stock outstanding. Outstanding options and warrants totaling 17,849,331 and 15,923,807 as of December 31, 2017 and 2016, 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 and performance 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. Share-based awards granted to employees with a performance condition are measured based on the probable outcome of that performance condition during the requisite service period. Awards with performance conditions will be expensed if it is probable that the performance condition will be achieved. During the years ended December 31, 2017 and 2016, $30,500 and $10,100, respectively, of stock compensation expense was recorded for share awards with performance conditions.

NEW ACCOUNTING PRONOUNCEMENTS

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

In January 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-01, *Financial Instruments–Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*. The accounting standard primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, it includes a clarification related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2017. The Company intends to adopt ASU 2016-01 in the first quarter of 2018 and does not expect that the adoption of this ASU will have a material effect on the consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. ASU 2016-02 supersedes existing lease guidance, including Accounting Standards Codification (ASC) 840 - *Leases*. Among other things, the new standard requires recognition of a right-of-use asset and liability for future lease payments for contracts that meet the definition of a lease. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Earlier application is permitted. The standard must be applied using a modified retrospective approach. The Company is currently evaluating the effect that the adoption of this ASU will have on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718) Scope of Modification Accounting.* ASU 2017-09 provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. This ASU does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. This ASU is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company intends to adopt ASU 2017-09 in the first quarter of 2018 and does not expect that the adoption of this ASU will have a material effect on the consolidated financial statements.

There are no other recently issued accounting pronouncements that are expected to have a material effect on the Company's financial position, results of operations or cash flows.

FAIR VALUE OF FINANCIAL INSTRUMENTS AND CONCENTRATIONS OF CREDIT RISK

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

USE OF ESTIMATES

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

DERIVATIVES

The Company entered into investment agreements with Spectrum (see Note 4) resulting in a purchase price derivative. In accordance with GAAP, derivative instruments are recognized as either assets or liabilities on the consolidated balance sheets and are measured at fair value with gains or losses recognized in earnings or other comprehensive income depending on the nature of the derivative. The Company determines the fair value of derivative instruments based on available market data using appropriate valuation models, giving consideration to all of the rights and obligations of each instrument. The derivative liability is re-measured at fair value at the end of each reporting period as long as it is outstanding. As of December 31, 2017, the derivative liability has been settled and is no longer outstanding.

3. RELATED PARTY TRANSACTIONS

In April, June 2017, and November 2017, under supply agreements with Spectrum, the Company received shipments of EVOMELA®, MARQIBO®, and ZEVALIN® respectively, in China for quality testing purposes to support CASI's application for import drug registration. In 2016, the Company also received shipments of MARQIBO® in China for quality testing purposes to support CASI's application for import drug registration. The former CEO of Spectrum and current board member of Spectrum is also a board member of CASI. The total cost of the materials was approximately $2,705,000 and $155,220 in 2017 and 2016, respectively, which is included in research and development expense for the respective years. As of December 31, 2017, the amount payable to Spectrum totaling $2,228,366 is reflected as a related party payable in the accompanying consolidated balance sheet.

4. LICENSE ARRANGEMENTS

The Company has certain product rights and perpetual exclusive licenses from Spectrum Pharmaceuticals, Inc. and certain of its affiliates (together referred to as "Spectrum") to develop and commercialize the following commercial oncology drugs and drug candidates in the greater China region (which includes China, Taiwan, Hong Kong and Macau) (the "Territories"):

- EVOMELA® (melphalan) for Injection ("Evomela");
- MARQIBO® (vinCRIStine sulfate LIPOSOME injection) ("Marqibo"); and
- ZEVALIN® (ibritumomab tiuxetan) ("Zevalin").

CASI is responsible for developing and commercializing these three drugs in the Territories, including the submission of import drug registration applications and conducting confirmatory clinical trials as needed.

The Company is in various stages of the regulatory and development process to obtain marketing approval for EVOMELA®, MARQIBO®, and ZEVALIN® in its territorial region, with ZEVALIN® commercially available in Hong Kong. In January 2016, the China Food and Drug Administration (CFDA) accepted for review the Company's import drug registration application for MARQIBO® and currently is in the quality testing phase of the regulatory process. On March 10, 2016, Spectrum received notification from the U.S. Food and Drug Administration (FDA) of the grant of approval of its New Drug Application (NDA) for EVOMELA® primarily for use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma. In December 2016, the CFDA accepted for review the Company's import drug registration application for EVOMELA® and in 2017 has granted priority review of the import drug registration clinical trial application (CTA),

which has completed the quality testing phase of the regulatory process and is currently in technical review by Center for Drug Evaluation (CDE) of the CFDA as part of the regulatory process. In 2017, the CFDA accepted for review the Company's import drug registration for ZEVALIN® including both the antibody kit and the radioactive Yttrium-90 component.

As consideration for the acquisition from Spectrum, the Company issued a total 5,405,382 shares of its common stock, a $1.5 million 0.5% secured promissory note originally due in March 2016, and certain contingent rights ("Contingent Rights") to purchase additional shares of its common stock, which Contingent Rights expire upon the occurrence of certain events. The note has been subsequently amended to extend the due date to September 17, 2019 (see Note 5). The Company accounted for the acquisition of the product rights and licenses as an asset acquisition and, accordingly, recorded the acquired product rights and licenses at their estimated fair values based on the fair value of the consideration exchanged (including transaction costs) of approximately $19.7 million.

The fair value of the common stock issued was based on the closing market price of the Company's common stock on the acquisition date. The fair value of the promissory note was measured using Level 3 unobservable inputs (see Note 6) including primarily the Company's estimated incremental borrowing rate as provided by a commercial lending institution.

The Contingent Rights provide Spectrum with the option to acquire, at a strike price of par value, a variable number of additional shares of common stock that allows Spectrum to maintain its fully-diluted ownership percentage for a certain time period and under certain terms and conditions. These Contingent Rights will expire on the earlier of raising an aggregate of $50 million or September 17, 2019 (subject to possible extension only for certain outstanding derivative securities). Based on the terms and conditions of the Contingent Rights, the Company has determined that the Contingent Rights are a derivative financial instrument that is not indexed to its common stock and therefore is required to be accounted for at fair value, initially and on a recurring basis. The fair value of the Contingent Rights was measured using Level 3 unobservable inputs; the unobservable inputs include estimates of the Company's future capital requirements, and the timing, probability, size and characteristics of those capital raises, among other inputs. The total estimated fair value of the Contingent Rights was $0 and $4,122,266 as of December 31, 2017 and 2016, respectively; the change in fair value (see Note 6) is reflected as change in fair value of contingent rights in the accompanying consolidated statements of operations.

As a result of the 2017 Closings that occurred during 2017 (see Note 8), Spectrum exercised its Contingent Rights and the Company issued Spectrum 1,519,096 shares of common stock during 2017. This exercise resulted in the full settlement of the contingent rights derivative liability reducing the value to $0 as of December 31, 2017. The Company recorded a reduction to the contingent rights derivative liability and an increase to additional paid-in capital of $4,142,157 in 2017 related to the partial settlement of the contingent rights derivative as a result of the 2017 Closings, which is reflected in the accompanying consolidated balance sheet as of December 31, 2017. As a result of the 2016 Closings and the October 2016 Offering that occurred during 2016 (see Note 8), Spectrum exercised its Contingent Rights and the Company issued 4,623,197 shares of common stock during 2016. The Company recorded a reduction to the contingent rights derivative liability and an increase to additional paid-in capital of $5,279,744 in 2016 related to the partial settlement of the contingent rights derivative as a result of the 2016 Closings and the October 2016 Offering, which is reflected in the accompanying consolidated balance sheet as of December 31, 2016.

5. NOTE PAYABLE

As part of the license arrangements with Spectrum (see Note 4), the Company issued to Spectrum a $1.5 million 0.5% secured promissory note originally due March 17, 2016. The promissory note was recorded initially at its fair value, giving rise to a discount of approximately $136,000; the promissory note is presented as note payable, net of discount in the accompanying consolidated balance sheets. For the years ended December 31, 2017 and 2016, the Company recognized approximately $7,000 and $26,000 of non-cash interest expense, respectively, related to the amortization of the debt discount, using the effective interest rate method. On September 28, 2015, the Company entered into a First Amendment to Secured Promissory Note (the "Amendment") with Spectrum. Pursuant to the Amendment, the Company and Spectrum agreed to extend the maturity date of the note to March 17, 2017. On December 13, 2016, the Company entered into a Second Amendment to Secured Promissory Note (the "Second Amendment") with Spectrum to extend the maturity date of the Note to March 17, 2018. On December 20, 2017, the

Company entered into a Third Amendment to Secured Promissory Note (the "Third Amendment") with Spectrum to extend the maturity date of the Note to September 17, 2019. All other terms remain the same.

6. FAIR VALUE MEASUREMENTS

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

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

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

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

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

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

The following table presents the Company's financial liabilities accounted for at fair value on a recurring basis as of December 31, 2016 by level within the fair value hierarchy. The Contingent Rights were fully settled during 2017 resulting in a $0 fair value as of December 31, 2017.

	As of December 31, 2016			
	Level 1	Level 2	Level 3	Total
Liabilities - Contingent Rights	$ -	$ -	$ 4,122,266	$ 4,122,266

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

	2017	2016
Balance at beginning of year	$ 4,122,266	$9,395,222
Partial settlement of Contingent Rights	(4,142,157)	(5,279,744)
Change in fair value of Contingent Rights	19,891	6,788
Balance at end of year	$ -	$4,122,266

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

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

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

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

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

The Company measures its long-lived assets, including property and equipment, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be impaired. No such fair value impairment was recognized for the years ended December 31, 2017 and 2016.

7. INCOME TAXES

The income tax provision is based on loss before income taxes of $(8,658,120) in the U.S. and $(2,112,082) in China. The Company has net operating loss (NOL) carryforwards for income tax purposes of approximately $368,134,000 at December 31, 2017 that expire in years 2018 through 2038. The Company also has research and development ("R&D") tax credit carryforwards of approximately $9,593,000 as of December 31, 2017 that expire in years 2018 through 2038. Under the provisions of the Internal Revenue Code, the NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, respectively, as well as similar state tax provisions. This could limit the amount of tax attributes that the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. 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.

For financial reporting purposes, loss before taxes includes the following components:

	2017	2016
United States	$ (8,658,120)	$(7,375,974)
Foreign	(2,112,082)	(2,077,514)
Total	$(10,770,202)	$(9,453,488)

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, 2017 and 2016 are as follows:

	DECEMBER 31,	
	2017	2016
Deferred income tax assets:		
Net operating loss carryforwards	$ 96,786,000	$ 140,468,000
Research and development credit carryforward	9,592,000	9,399,000
Intangible assets	4,184,000	6,913,000
Equity-based compensation	3,812,000	5,578,000
Other	164,000	297,000
Valuation allowance for deferred income tax assets	(114,538,000)	(162,655,000)
Net deferred income tax assets	$ -	$ -

On December 22, 2017, H.R.1, known as the "Tax Act," was signed into law and makes broad and complex changes to the U.S. tax code, including, but not limited to, (1) reducing the U.S. federal corporate tax rate to a flat rate of 21% for periods after December 31, 2017 and (2) requiring a one-time transition tax on certain un-repatriated earnings of foreign subsidiaries that is payable over eight years. As a result of the reduction of the corporate tax rate to 21%, U.S. generally accepted accounting principles require companies to re-value their deferred tax assets and liabilities as of the date of enactment, with resulting tax effects accounted for in the reporting period of enactment. As a result of this revaluation, the Company has reduced its pre-valuation allowance deferred tax asset by $52,258,000 in the year ended December 31, 2017, with a corresponding decrease in the valuation allowance on its net deferred tax assets. The Company has no unrepatriated earnings in any of its foreign subsidiaries as they incurred losses since inception.

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

	2017	2016
Tax benefit at statutory rate	$ (3,662,000)	$ (3,214,000)
Effect of tax law change	52,258,000	-
State taxes	(290,000)	(232,000)
Net R&D credit adjustment	(185,000)	(105,000)
Attribute expiration	50,000	-
Nondeductible expenses	6,000	4,000
Change in valuation allowance	(48,117,000)	3,461,000
Other	125,000	177,000
Changes in applicable tax rates	(185,000)	(91,000)
	$ -	$ -

The Company had $3,133,000 of unrecognized tax benefits as of December 31, 2016 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, 2017, there were net additional unrecognized tax benefits of $65,000 related to R&D tax credits. The Company has a full valuation allowance at December 31, 2017 and 2016 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:

	2017	2016
Unrecognized tax benefits balance at January 1	$3,133,000	$3,097,000
Additions for Tax Positions of Prior Periods	3,000	1,000
Additions for Tax Positions of Current Period	62,000	35,000
Unrecognized tax benefits balance at December 31	$3,198,000	$3,133,000

The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense. As of December 31, 2017 and 2016, the Company had no accrued interest or penalties related to uncertain tax positions.

The tax returns for all years in the Company's major tax jurisdictions are not settled as of December 31, 2017. Due to the existence of tax attribute carryforwards (which are currently offset by a full valuation allowance), the Company treats all years' tax positions as unsettled due to the taxing authorities' ability to modify these attributes.

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

8. STOCKHOLDERS' EQUITY

SECURITIES PURCHASE AGREEMENTS

As described in Note 1, on March 19, 2018, the Company entered into securities purchase agreements (the "Securities Purchase Agreements") with certain institutional investors, accredited investors and current stockholders, pursuant to which the Company is issuing 15,432,091 shares of its common stock with accompanying warrants to purchase 6,172,832 shares of its common stock in a $50 million private placement. To date, the Company has received

gross proceeds of $29.3 million and expects to receive additional gross proceeds of $20.7 million in the near future. The purchase price for each share of common stock and warrant was $3.24. The warrants will become exercisable 180 days after issuance at a $3.69 per share exercise price, and will expire five years from the date of issuance. The Securities Purchase Agreements and warrants each include additional customary representations, warranties and covenants. The Company also agreed to file a resale registration within 120 days following the closing covering the shares of common stock issued and the shares of common stock underlying the warrants.

As described in Note 1, on October 13, 2017, the Company entered into securities purchase agreements with certain institutional investors, accredited investors and current stockholders pursuant to which the Company agreed to sell 7,951,865 shares of its common stock and warrants exercisable for up to 1,590,373 shares of its common stock (exclusive of the Agent Warrants described below) in a registered direct offering (the "2017 Offering") for gross proceeds of $23,855,595. As a result of the 2017 Closings related to the Offering, the Company received approximately $23.4 million after offering expenses and issued 7,951,865 shares of common stock. The shares and warrants were sold together, consisting of one share of common stock and a warrant to purchase 0.20 shares of common stock for each share of common stock purchased, at a combined offering price of $3.00. The warrants are exercisable beginning on April 17, 2018 and expire on April 17, 2020. The warrants have an exercise price of $3.75 per share. The fair value of the warrants issued is $1,558,566, calculated using the Black-Scholes-Merton valuation model value of $0.98 with a contractual life of 2.5 years, an assumed volatility of 85.4%, and a risk-free interest rate of 1.54%.

In connection with the 2017 Offering, the Company issued to its placement agent or its designees warrants to purchase 48,133 shares of common stock at an exercise price of $3.75 per share of common stock (the "Agent Warrants"), representing the number of warrants equal to an aggregate of 4% of the number of shares sold to investors placed by the placement agent in the 2017 Offering, excluding investments made by certain China-focused investors that were placed by the Company. The Agent Warrants are exercisable beginning on April 17, 2018 and expire on April 17, 2019. The fair value of the warrants issued is $28,880, calculated using the Black-Scholes-Merton valuation model value of $0.60 with a contractual life of 1.5 years, an assumed volatility of 77.8%, and a risk-free interest rate of 1.54%.

On September 20, 2015, the Company entered into stock purchase agreements with certain institutional and accredited investors for a $25.1 million financing. Pursuant to these agreements, the Company agreed to sell to the investors in a private placement an aggregate of 20,658,434 shares of the Company's common stock, at $1.19 per share, based on the closing bid price of the Company's common stock on the Nasdaq Capital Market on September 18, 2015, and a total of 4,131,686 warrants, representing a 20% warrant coverage, with a purchase price of $0.125 per whole warrant share. The warrants became exercisable three months after issuance at $1.69 per share exercise price, and expire three years from the date the warrants become exercisable. The offering closed after satisfaction of certain regulatory and customary closing conditions, with the net proceeds subject to payment of offering expenses, including fees and expenses.

On January 15, 2016, the Company completed the first closing and received approximately $10.3 million and yielded approximately $10.2 million after offering expenses (the "First Closing"). The First Closing resulted in the issuance of 8,448,613 shares of Common Stock, priced at $1.19 per share, and 1,689,722 warrants, with a purchase price of $0.125 per warrant. The warrants became exercisable on April 15, 2016 at $1.69 per share exercise price, and will expire on April 15, 2019. The fair value of the warrants issued is $321,047, calculated using the Black-Scholes-Merton valuation model value of $0.19 with a contractual life of 3.25 years, an assumed volatility of 70.1%, and a risk-free interest rate of 1.08%.

On June 24, 2016, the Company completed the second closing and received approximately $6.0 million (the "Second Closing"). The Second Closing resulted in the issuance of 4,906,118 shares of Common Stock, priced at $1.19 per share, and 981,223 warrants, with a purchase price of $0.125 per warrant. The warrants became exercisable on September 23, 2016 at $1.69 per share exercise price, and will expire on September 23, 2019. The fair value of the warrants issued is $431,738, calculated using the Black-Scholes-Merton valuation model value of $0.44 with a contractual life of 3.25 years, an assumed volatility of 70.4%, and a risk-free interest rate of 0.76%.

On July 5, 2016, the Company completed the third closing and received $1.0 million (the "Third Closing"). The Third Closing resulted in the issuance of 823,045 shares of Common Stock, priced at $1.19 per share, and 164,609

warrants, with a purchase price of $0.125 per warrant. The warrants became exercisable on October 4, 2016 at $1.69 per share exercise price, and will expire on October 4, 2019. The fair value of the warrants issued is $67,490, calculated using the Black-Scholes-Merton valuation model value of $0.41 with a contractual life of 3.25 years, an assumed volatility of 70.6%, and a risk-free interest rate of 0.66%.

On October 3, 2016, the Company completed the final closing and received $7.8 million (the "Final Closing"). The Final Closing resulted in the issuance of 6,480,655 shares of Common Stock, priced at $1.19 per share, and 1,296,129 warrants, with a purchase price of $0.125 per warrant. The warrants became exercisable on January 2, 2017 at $1.69 per share exercise price, and will expire on January 2, 2020. The fair value of the warrants issued is $544,374, calculated using the Black-Scholes-Merton valuation model value of $0.42 with a contractual life of 3.25 years, an assumed volatility of 71.4%, and a risk-free interest rate of 0.91%. The Final Closing included an investment from ETP Global Fund, L.P., a healthcare investment fund. The managing member of Emerging Technology Partners, LLC, which is the general partner of ETP Global Fund, L.P., is also the Executive Chairman of the Company.

On October 24, 2016, the Company entered into and closed on a stock purchase agreement with an accredited investor, pursuant to which the Company agreed to sell to the investor in a private placement an aggregate of 2,469,135 shares of the Company's Common Stock, priced at $1.190 per share, and 493,827 warrants, representing a 20% warrant coverage, with a purchase price of $0.125 per whole warrant share, for aggregate gross proceeds to the Company of $3.0 million (the "October 2016 Offering"). The warrants became exercisable on January 23, 2017 at $1.69 per share exercise price, and will expire on January 23, 2020. The fair value of the warrants issued in the October 2016 Offering is $306,173, calculated using the Black-Scholes-Merton valuation model value of $0.62 with a contractual life of 3.25 years, an assumed volatility of 72.2%, and a risk-free interest rate of 1.00%.

The Company granted registration rights to all of the investors and filed a resale registration statement covering the shares of common stock and the shares of common stock underlying the warrants on December 2, 2016. The registration statement was declared effective by the SEC on December 21, 2016.

COMMON STOCK SALES AGREEMENT

On February 23, 2018, the Company entered into a Common Stock Sales Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("HCW"). Pursuant to the terms of the Sales Agreement, the Company may sell from time to time, at its option, shares of the Company's common stock through HCW, as sales agent, with an aggregate sales price of up to $25 million (the "Shares").

Any sales of Shares pursuant to the Sales Agreement will be made under the Company's effective "shelf" registration statement (the "Registration Statement") on Form S-3 (File No. 333-222046) which became effective on December 22, 2017 and the related prospectus supplement and the accompanying prospectus, as filed with the Securities and Exchange Commission (the "SEC") on February 23, 2018.

Under the terms of the Sales Agreement, the Company may sell shares of its common stock through HCW by any method permitted that is deemed an "at the market offering" as defined in Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"). HCW will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). Actual sales will depend on a variety of factors to be determined by the Company from time to time, including (among others) market conditions, the trading price of the Company's common stock, capital needs and determinations by the Company of the appropriate sources of funding for the Company. The Company is not obligated to make any sales of common stock under the Sales Agreement and the Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. The Company will pay a commission rate of up to 3.0% of the gross sales price per share sold and agreed to reimburse HCW for certain specified expenses. The Company has also agreed pursuant to the Sales Agreement to provide HCW with customary indemnification and contribution rights.

The Company or HCW upon notice to the other, may suspend the offering of the Shares under the Sales Agreement at any time. The offering of the Shares pursuant to the Sales Agreement will terminate upon the sale of Shares in an aggregate offering amount equal to $25 million, or sooner if either the Company or HCW terminate the Sales Agreement pursuant to its terms.

Through March 2018, the Company issued 143,248 Shares under the Sales Agreement resulting in net proceeds to the Company of approximately $475,000.

9. SHARE-BASED COMPENSATION AND WARRANTS

The Company has adopted incentive and nonqualified stock option plans for executive, scientific and administrative personnel of the Company as well as outside directors and consultants. In June 2017, the Company's shareholders approved an amendment to the 2011 Long-Term Incentive Plan, increasing the number of shares reserved for issuance from 11,230,000 to 14,230,000 shares of common stock to be available for grants and awards. As of December 31, 2017, there are 11,585,315 shares issuable under options previously granted and currently outstanding, with exercise prices ranging from $0.86 to $7.37. In 2017, the Company awarded options to employees, covering up to 2,225,000 shares, in which vesting is subject to achievement of certain performance milestones. 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, 2017, 2,852,234 shares remained available for grant under the Company's 2011 Long-Term Incentive Plan. On March 13, 2018, upon the recommendation of the Compensation Committee of the Board of Directors (the "Board"), the Board approved a grant of stock options to the Company's Executive Chairman exercisable for 1 million shares of common stock that will vest and become exercisable on the first anniversary date of the grant. In addition, the Board approved the grant of a performance-based option covering 4 million shares of common stock that will vest if, within 18 months of the date of grant, specific operational and strategic milestones are achieved. Both grants are conditioned upon stockholder approval at the 2018 Annual Meeting of Stockholders.

The Company records compensation expense associated with stock options and other equity-based compensation in accordance with provisions of authoritative guidance. Compensation costs are recognized over the requisite service period, which is generally the option vesting term of up to three years. Awards with performance conditions will be expensed if it is probable that the performance condition will be achieved. For the years ended December 31, 2017 and 2016, $30,500 and $10,100, respectively was expensed for share awards with performance conditions that became probable during that period.

The Company's net loss for the years ended December 31, 2017 and 2016 includes $650,440 and $2,995,240, 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:

	2017	2016
Research and development	$ 271,733	$ 746,027
General and administrative	378,707	2,249,213
Share-based compensation expense	$ 650,440	$ 2,995,240
Net share-based compensation expense, per common share:		
Basic and diluted	$ 0.01	$ 0.05

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. Option valuation models, including Black-Scholes-Merton, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk free rate of interest, expected dividend yield, expected volatility, and the expected life of the award.

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

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

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

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

Forfeiture Rate—This is the estimated percentage of options granted that are expected to be forfeited or cancelled on an annual basis before becoming fully vested. The Company estimated the forfeiture rate for 2016 based on historical forfeiture experience for similar levels of employees to whom options were granted. Beginning in 2017, in accordance with authoritative guidance, forfeitures were no longer required to be estimated.

Following are the weighted-average assumptions used in valuing the stock options granted to employees during the years ended December 31, 2017 and 2016:

	Years ended December 31,	
	2017	2016
Expected volatility	78.88%	82.12%
Risk free interest rate	1.96%	1.29%
Expected term of option	6.29 years	5.33 years
Forfeiture rate	-	*3.00%
Expected dividend yield	-	-

*- In 2016, authoritative guidance required forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Throughout 2016, forfeitures were estimated at 3% and the actual forfeiture rate was 6% for 2016. The Company adjusted stock compensation expense for 2016 based on the actual forfeiture rate.

The weighted average fair value of stock options granted was $0.73 and $0.75 in 2017 and 2016, 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, 2017 and 2016 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
			In Years	
Outstanding at December 31, 2015	6,694,744	$ 1.99		
Exercised	-	$ -		
Granted	4,213,518	$ 1.00		
Expired	(856,512)	$ 2.24		
Forfeited	(516,444)	$ 1.14		
Outstanding at December 31, 2016	9,535,306	$ 1.57		
Exercised	(154,545)	$ 2.11		
Granted	3,199,500	$ 1.05		
Expired	(978,070)	$ 1.64		
Forfeited	(16,876)	$ 0.92		
Outstanding at December 31, 2017	11,585,315	$ 1.42	7.46	$21,730,182
Exercisable at December 31, 2017	8,468,971	$ 1.57	6.78	$14,781,148

The aggregate intrinsic value is calculated as the difference between (i) the closing price of the common stock at December 31, 2017 and (ii) the exercise price of the underlying awards, multiplied by the number of options that had an exercise price less than the closing price on the last trading day of the year. The intrinsic value of options exercised during the year ended December 31, 2017 totaled approximately $168,000. Cash received from option exercises under all share-based payment arrangements for the year ended December 31, 2017 was approximately $326,000. There were no options exercised in 2016.

The following summarizes information about stock options granted to employees and directors outstanding at December 31, 2017:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31, 2017	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable at December 31, 2017	Weighted Average Exercise Price
$0.00 - $1.00	3,950,656	8.9	$ 0.93	1,538,965	$ 0.87
$1.01 - $2.00	7,083,119	7.0	$ 1.53	6,378,466	$ 1.57
$2.01 - $3.00	375,000	4.2	$ 2.24	375,000	$ 2.24
$3.01 - $7.00	122,000	3.0	$ 6.24	122,000	$ 6.24
$7.01 - $8.00	54,540	1.5	$ 7.26	54,540	$ 7.26
	11,585,315	7.5	$ 1.42	8,468,971	$ 1.57

As of December 31, 2017, there was approximately $544,000 of total unrecognized compensation cost related to non-vested stock options. That cost is expected to be recognized over a weighted-average period of 1.8 years.

Warrants

Warrants issued generally expire after 2-5 years from the date of issuance. Stock warrant activity is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2015	4,010,903	$ 2.27
Issued	4,625,510	$ 1.69
Exercised	-	$ -
Expired	(2,247,912)	$ 2.91
Outstanding at December 31, 2016	6,388,501	$ 1.60
Issued	1,638,506	$ 3.75
Exercised	-	$ -
Expired	(1,762,991)	$ 1.46
Outstanding at December 31, 2017	6,264,016	$ 2.23
Exercisable at December 31, 2017	4,625,510	$ 1.69

10. COMMITMENTS AND CONTINGENCIES

COMMITMENTS

ENMD-2076. In January 2006, the Company acquired Miikana, a private biotechnology company. Pursuant to the Merger Agreement, the Company acquired all of the outstanding capital stock of Miikana Therapeutics, Inc. In 2008, the Company initiated a Phase 1 clinical trial with its Aurora A and angiogenic kinase inhibitor, ENMD-2076, in patients with solid tumors. A dosing of the first patient with ENMD-2076 triggered a purchase price adjustment milestone of $2 million, which the Company opted to pay in stock. As ENMD-2076 successfully completed Phase 1 clinical trials and advanced to Phase 2, the dosing of the first patient in 2010 triggered an additional purchase price adjustment milestone of $3 million, which was paid in 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. As of December 31, 2017, the $4 million potential milestone payment remains, payable in cash or shares of stock at the Company's option, related to the ENMD-2076 program and the dosing of the first patient in a Phase 3 pivotal trial.

With respect to the Company's in-licensed drug candidates for the Greater China market, the Company does not have to pay any milestone payments or royalties to Spectrum; however, CASI is responsible for paying royalties or milestones, if and when applicable, owed by Spectrum to upstream licensors that licensed related technology to Spectrum in accordance with the terms of the relevant upstream licenses, and only to the extent of the Greater China portion of such upstream royalties or milestones. The Company's sales of Zevalin in Hong Kong are subject to royalties. The Company does not expect to pay royalties for ZEVALIN® in China and Taiwan until commercial activities begin which will not occur until after ZEVALIN® receives marketing approval from the regulatory agencies and which is not expected to occur in 2018. The Company does not anticipate any payment obligations for the EVOMELA® and MARQIBO® programs in 2018.

As of December 31, 2017, the Company also has purchase obligation commitments, in the normal course of business, for clinical trial contracts totaling approximately $300,000. In March 2018, the Company committed to a purchase obligation of EVOMELA® from Spectrum for approximately $5.5 million.

The Company leases its principal executive offices in Rockville, MD under a lease agreement that continues through December 31, 2019. The Company leases office space in China under a lease agreement that continues through June 2018. The Company also leases lab space in China that continues through May 2022.

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

2018	$ 337,030
2019	259,459
2020	183,378
2021	191,691
2022	44,172
Thereafter	-
Total minimum payments	$1,015,730

Rental expense for the years ended December 31, 2017 and 2016 was approximately $440,000 and $328,000, respectively.

CONTINGENCIES

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

11. EMPLOYEE RETIREMENT PLAN

The Company sponsors the CASI Pharmaceuticals, Inc. 401(k) Plan 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 $70,167 and $30,300 in 2017 and 2016, respectively.

12. SUBSEQUENT EVENT

On January 26, 2018, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") by and between the Company and Sandoz Inc. ("Sandoz"), pursuant to which the Company acquired a portfolio of 25 U.S. FDA-approved ANDAs, 1 ANDA that FDA tentatively approved, 3 ANDAs that are pending FDA approval, and manufacturing and other information related to the products (the "Assets"). The purchase of the Assets closed simultaneously with the execution of the Asset Purchase Agreement. Pursuant to the Asset Purchase Agreement, the purchase price for the Assets was $18 million in cash paid at closing.