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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, 2018

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) 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, 2018, the aggregate market value of the shares of common stock held by non-affiliates was approximately $424,418,326.

As of March 25, 2019, 95,717,052 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, 2018. 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 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: risks relating to interests of our largest stockholders that differ from our other stockholders; 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 lack of experience in manufacturing products and uncertainty about our resources and capabilities to do so on a clinical or commercial scale; risks relating to the commercialization, if any, of our products and proposed products (such as marketing, safety, regulatory, patent, product liability, supply, competition and other risks); our inability to predict when or if our product candidates will be approved for marketing by the China National Medical Products Administration authorities; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; the volatility in the market price of our common stock; 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; 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; and our dependence on third parties. 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, 2018 (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, which only speak as of the date made. 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. Additional information about the factors and risks that could affect our business, financial condition and results of operations, are contained in our filings with the U.S. Securities and Exchange Commission ("SEC"), which are available at www.sec.gov.

PART I

ITEM 1. BUSINESS.

OVERVIEW

CASI Pharmaceuticals, Inc. ("CASI", the "Company") (Nasdaq: CASI) is a U.S. pharmaceutical company with a platform to develop and accelerate the launch of pharmaceutical products and innovative therapeutics in China, U.S., and throughout the world. We are focused on acquiring, licensing, developing and commercializing products that address areas of unmet medical need. We intend to execute our plan to become a leading platform to launch medicines in the greater China market leveraging our China-based regulatory and commercial competencies and our global drug development expertise. We conduct substantially all of our operations through our wholly-owned subsidiary, CASI Pharmaceuticals (Beijing) Co., Ltd. ("CASI China"), which is headquartered in Beijing, China. CASI China has established China operations that are growing as we continue to further in-license or acquire products for our pipeline.

Our product pipeline features the following: (1) U.S. Food and Drug Administration (FDA) approved hematology oncology drugs in-licensed from Spectrum Pharmaceuticals, Inc. and certain of its affiliates ("Spectrum") for the greater China market, consisting of Melphalan Hydrochloride For Injection (EVOMELA®), Ibritumomab Tiuxetan (ZEVALIN®) and Vincristine Sulfate Liposome Injection (MARQIBO®), (2) a portfolio of 26 FDA-approved abbreviated new drug applications ("ANDAs"), including entecavir and tenofovir disoproxil fumarate (TDF) indicated for hepatitis B virus; and (3) four pipeline ANDAs that are pending FDA approval. We intend to prioritize a select subset of the ANDAs for product registration and commercialization in China. In addition to these advanced products, our pipeline includes a proprietary Phase 2 drug candidate, ENMD-2076, that we have previously determined not to pursue as a single agent, and instead we are exploring the feasibility of combination as a clinical strategy. We also have proprietary early-stage immune-oncological potential candidates in preclinical development.

We believe our product mix reflects a risk-balanced approach between products in various stages of development, between products that are branded and non-branded, and between products that are proprietary and generic. We intend to continue building a significant product pipeline of high quality pharmaceuticals, as well as innovative drug candidates for commercialization in China and for the rest of the world. For in-licensed products, 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 our drug development strategy. For our FDA-approved ANDAs, we intend to select and commercialize certain niche products from the portfolio that complement our therapeutic focus areas and which offer unique market and cost-effective manufacturing opportunities in China and/or in the U.S.

We believe the China operations offer a significant market and growth potential due to extraordinary increase in demand for high quality medicine coupled with regulatory reforms in China that make it easier for global pharmaceutical companies to introduce new pharmaceutical products into the country. We will continue to in-license clinical-stage and late-stage drug candidates, and leverage our platform and expertise, and hope to be the partner of choice to provide access to the China market. We expect the implementation of our plans will include leveraging our resources and expertise in both the U.S. and China so that we can maximize development and clinical strategies concurrently under U.S. FDA and China National Medical Products Administration (NMPA) regulatory regimes.

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 commercial launches. In December 2018, we received NMPA approval of Melphalan Hydrochloride For Injection (EVOMELA), for:

- use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma, and
- the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.

We intend to begin commercializing this drug through CASI China beginning in 2019 using EVOMELA supplied through Spectrum and its suppliers. All future needs will be sourced from Acrotech Biopharma L.L.C. ("Acrotech") and its suppliers.

The Company is building an internal commercial team to prepare for the launch of our first commercial product, Melphalan Hydrochloride for Injection (EVOMELA) in 2019. As part of the strategy to support our future clinical and commercial manufacturing needs and to manage our supply chain for certain products, on December 26, 2018, the Company established CASI Pharmaceuticals (Wuxi) Co., Ltd. ("CASI Wuxi") in China to construct a cGMP manufacturing facility in Wuxi, China. The site is currently in the design and engineering phase with construction expected to begin in 2019. Through CASI China, we will focus on China market devoting more resources and investment going forward.

HEMATOLOGY ONCOLOGY PRODUCTS FOR THE GREATER CHINA MARKET

In September 2014, we acquired from Spectrum exclusive rights in greater China (including Taiwan, Hong Kong and Macau) to three oncology products, including (1) Melphalan Hydrochloride for Injection (EVOMELA) 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, (2) Ibritumomab Tiuxetan (ZEVALIN) approved in the U.S. for advanced non-Hodgkin's lymphoma; and (3) Vincristine Sulfate Liposome Injection (MARQIBO) approved in the U.S. for advanced adult Ph- acute lymphoblastic leukemia (ALL). On March 1, 2019, Spectrum sold these products, along with the licenses and contracts relating thereto, to Acrotech. The Company does not expect any material adverse effect on its operations to result from the sale. A description of the products and their current status is below.

Melphalan Hydrochloride for Injection (EVOMELA)

Melphalan Hydrochloride For Injection (EVOMELA) is a new intravenous formulation of melphalan being investigated by Acrotech 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. In December 2016, the NMPA, formerly the China Food and Drug Administration, accepted for review our import drug registration application for Melphalan Hydrochloride For Injection (EVOMELA) and in 2017 has granted priority review of the import drug registration clinical trial application (CTA). On December 3, 2018, we received NMPA's approval for importation, marketing and sales in China. The Company has assembled an internal commercial team and a local distribution partner working together and currently preparing for the commercial launch of Melphalan Hydrochloride for Injection (EVOMELA) in 2019. The Company is also preparing for a post-marketing study.

Ibritumomab Tiuxetan (ZEVALIN)

Ibritumomab Tiuxetan (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 and marketed in the U.S., 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 NMPA accepted for review our import drug registration for Ibritumomab Tiuxetan (ZEVALIN) including both the antibody kit and the radioactive Yttrium-90 component. On February 12, 2019 the Company received NMPA's approval of the Company's

Clinical Trial Application (CTA) to allow for a confirmatory registration trial to evaluate the drug's efficacy and safety. We intend to advance Ibritumomab Tiuxetan (ZEVALIN).

Vincristine Sulfate Liposome Injection (MARQIBO)

Vincristine Sulfate Liposome Injection (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. In January 2016, the NMPA accepted for review our import drug registration application for and on March 4, 2019 the Company received NMPA's approval of the Company's Clinical Trial Application (CTA) to allow for a confirmatory registration trial to evaluate its efficacy and safety. We intend to advance Vincristine Sulfate Liposome Injection (MARQIBO).

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. We will 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. In October 2018, we acquired an additional U.S. FDA-approved abbreviated new drug application for tenofovir disoproxil fumarate (TDF ANDA), which is indicated for the treatment of hepatitis B virus.

Our portfolio consists of the following:

Approved Products	
Benazepril tablets	Heparin sodium for injection
Bisoprolol fumarate tablets	Lisinopril tablets and Lisinopril BPP tablets
Burprenorphine HCL Sublingual tablets	Methimazole tablets
Cefprozil tablets	Midodrine tablets
Cilostazol tablets – 50mg	Nabumetone tablets
Cilostazol tablets – 100mg	Naratriptan tablets
Desvenlafaxine ER tablets	Ondansetron HCL tablets
Diclofenac potassium 50mg tablets	Repaglinide tablets
Diclofenac sodium DR 25mg, 50mg tablets	Ribavirin capsules
Diclofenac sodium DR 75mg tablets	Spironolactone tablets
Econazole nitrate cream	Tenofovir disoproxil fumarate (TDF)
Entecavir tablets	Tizanidine tablets
Epinastine HCl Ophthalmic Solution	Triamterene and hydrochlorothiazide combination tablets

Products Pending FDA Approval	
Aripiprazole tablets	Bromfenac Ophthalmic Solution
Bepotastine Ophthalmic Solution	Telmisartan and hydrochlorothiazide tablets

OTHER ASSETS

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 have completed multiple Phase 2 studies in the U.S and one study in China and have determined not to pursue ENMD-2076 as a single agent and are exploring the feasibility of combination as a clinical strategy. We also have two proprietary early-stage immune-oncological potential candidates in preclinical development.

CASI WUXI

The Company is building an internal commercial team to prepare for the launch of our first commercial product, Melphalan Hydrochloride for Injection (EVOMELA) in 2019. As part of our strategy to support our future clinical and commercial manufacturing needs and to manage our supply chain, the Company has established CASI Wuxi to construct a cGMP manufacturing facility in Wuxi, China to support our future manufacturing needs. On November 16, 2018, the Company announced that it had entered into framework agreements to establish a joint venture to build and operate a manufacturing facility in the Wuxi Huishan Economic Development Zone in Jiangsu Province, China. We intend to invest, over time, $80 million in CASI Wuxi. Our investment will consist of (i) $21 million in cash within three months of the date of the establishment of CASI Wuxi, (ii) a transfer of selected ANDAs valued at $30 million, and (iii) an additional $29 million cash payment within three years from the date of establishment of CASI Wuxi. CASI Wuxi was established on December 26, 2018 and in February 2019, we funded our initial $21 million investment in CASI Wuxi. Additionally, Wuxi Jintou Huicun Investment Enterprise (Limited Partnership), a limited partnership organized under Chinese law, shall contribute the equivalent in RMB of USD $20 million in cash in CASI Wuxi. The site is currently in the design and engineering phase with construction expected to begin in 2019.

BUSINESS DEVELOPMENT

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. We intend for our pipeline to 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, ZEVALIN and MARQIBO; (2) high quality generic pharmaceuticals, such as the portfolio acquired from Sandoz in 2018 and tenofovir disoproxil fumarate (TDF) recently acquired from Laurus Labs, and (3) proprietary or licensed innovative drug candidates. 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 our global drug development strategy. Although oncology is our principal clinical and commercial focus, we are opportunistic about other therapeutic areas can address unmet medical needs.

RELATIONSHIPS RELATING TO PROGRAMS

Contract Manufacturing. Clinical trial materials for Melphalan Hydrochloride For Injection (EVOMELA), Ibritumomab Tiuxetan (ZEVALIN) and Vincristine Sulfate Liposome Injection (MARQIBO) are supplied by our partner Acrotech and its contract manufacturers.

On March 7, 2019, the Company entered into a three-year exclusive distribution agreement with China Resources Guokang Pharmaceuticals Co., Ltd ("CRGK") to appoint CRGK on an exclusive basis as its distributor to distribute Melphalan Hydrochloride for Injection (EVOMELA) in the territory of the People's Republic of China (excluding Hong Kong, Taiwan and Macau), subject to certain terms and conditions. The Company's internal

marketing and sales team will continue to be responsible for commercial activities, including, for example, direct interaction with KOLs, physicians, hospital centers and the generating of sales.

We anticipate that the manufacturing for our newly acquired ANDA portfolio will be through multiple sources that may include our own facility in Wuxi, China (when constructed) and contract manufacturers located in China and outside of the U.S. after technology transfer. Established relationships, coupled with supply agreements, have secured the necessary resources to supply clinical materials for our clinical development program and to supply commercial inventory for Melphalan Hydrochloride For Injection (EVOMELA) and future product launches. We believe that our current strategy of in-house manufacturing for certain products and outsourcing manufacturing for other products is cost-effective and allows for the flexibility we require.

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 Melphalan Hydrochloride For Injection (EVOMELA), Ibritumomab Tiuxetan (ZEVALIN) and Vincristine Sulfate Liposome Injection (MARQIBO), 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 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.

National Medical Products Administration (NMPA, formerly the China Food and Drug Administration)

In the PRC, the newly-formed NMPA is the authority under the State Administration for Market Regulation (SAMR) that monitors and supervises the administration of pharmaceuticals products, medical appliances and equipment, and cosmetics. We are also subject to regulation and oversight by different levels of the food and drug administration in China. 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 NMPA. For late-stage product candidates that we in-license for greater China rights, such as Melphalan Hydrochloride For Injection (EVOMELA), Ibritumomab Tiuxetan (ZEVALIN) and Vincristine Sulfate Liposome Injection (MARQIBO), our development activities in China are to secure marketing approval from NMPA by conducting import drug registration. The "Law of the PRC on the Administration of Pharmaceuticals," as amended on May 24, 2015, 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 NMPA Good Manufacturing Practice (GMP) guidelines. A domestic manufacturer of pharmaceutical products and active pharmaceutical ingredient (API) must obtain the drug manufacturing license, the GMP certification and the drug/API registration approval 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 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 Administration of Market Regulation at the local level.

Preclinical Research and Clinical Trials. For an investigational new drug application, a clinical trial approval issued from the NMPA was historically required to conduct clinical trials. However, since July 24, 2018, the NMPA announced to adopt a negative notification system for clinical trial approvals. In particular, if the applicant does not receive negative comments within 60 days after the CDE accepts the clinical trial application, the applicant can proceed with the clinical trial immediately based on the protocol submitted without the need for obtaining a clinical trial approval. Chemical generics, on the other hand, only need to undergo bioequivalent studies upon a filing for record with the NMPA. 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 NMPA. In particular, safety evaluation research must be conducted in compliance with China's Good Laboratory Practice.

After completion of preclinical studies and obtaining permission to conduct the clinical trial from the NMPA, clinical trials are generally conducted in three sequential phases that may overlap or be combined, known as Phase 1, Phase 2, and Phase 3 clinical trials, in compliance with China's Good Clinical Practice:

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. NMPA 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 NMPA and approval is required prior to conducting the trials.

In October, 2017, the NMPA 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 NMPA 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 NMPA guidance.

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

Data derived from IMCCT can be used for the New Drug Registration Applications with the NMPA. When using IMCCT data to support New Drug Registration Applications in China, applicants shall submit completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with the ICH-CTD (International Conference on Harmonization-Common Technical Document) content and format requirements; subgroup research results summary and comparative analysis shall also be conducted concurrently.

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 NMPA, 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 NMPA has launched the generic quality consistency evaluation (GQCE) since 2013, which requires domestically-manufactured generic drugs to conform to the quality standards of originator products. In 2016, the Chinese regulatory authorities announced that imported generic drugs must also pass the GQCE in China. By way of background, the GQCE generally required the manufacturers of generics to conduct bioequivalent studies (or dissolution tests) of a generic drug against a qualified reference drug (typically the originator drug) in order to establish equivalence to the originator products. If there is no qualified reference drug, the generic manufacturer has to conduct a clinical efficacy trial.

The first wave of GQCE focuses on 289 oral formulations of chemical drugs listed in China's Essential Drug List. The NMPA will reject to renew the 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 clinical efficacy trials are required). If the manufacturers can prove that the generics are products in shortage and clinically essential, they can apply for an extension up to 5 years in order to pass the GQCE. 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 NMPA 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. At the end of 2018, a pilot project concerning centralized procurement of 31 types of drugs covering 11 major Chinese cities directed hospitals to purchase generics that have passed the GQCE, which resulted in dramatic prices cuts for generics that won the tenders.

Pricing. Instead of direct government-set pricing which were historically used in China but abolished in June 2015, the government regulates prices for pharmaceuticals (except for narcotic and Type 1 psychotropic drugs) mainly by establishing a price negotiation, consolidated procurement mechanism, and revising medical insurance reimbursement standards. The Chinese government has initiated several rounds of price negotiations with manufacturers of patented drugs, drugs with an exclusive source of supply, and oncology drugs since 2016. The average percentage of price reduction has been over 50%. Once the government agreed with the drug manufacturers on the supply prices, the drugs would be automatically listed in the National Reimbursement Drug List (NRDL) and qualified for public hospital purchase.

Reimbursement. China is a single-payor market with near universal healthcare provided by the government. Up to 99% of the population receives healthcare coverage at various levels of reimbursement. Commercial insurance is available but is minimally adopted, and is seen as a supplement above and beyond government reimbursement. To obtain government reimbursement for a drug, the government must agree to add it to the NRDL or the provincial reimbursement drug lists at a negotiated price (at times at a significant discount). Prior to this time, the market is self-pay, where patients will be responsible for 100% of the launch price determined by the company. We believe the self-pay market in China is expanding, given the rise in personal income levels in the country. The government has committed to updating the NRDL in 2019. Previous updates to the NRDL occurred in 2017 and 2009. In addition, there were also NRDL price negotiations in 2018 for oncology drugs. Admission to the NRDL depends on a number of factors, including on-market experience, scale of patient adoption, physician endorsement, cost effectiveness and budget impact. Provincial governments have some discretion to add additional drugs not listed in the NDRL to provincial reimbursement drug lists.

Hospital Listing. Government hospitals currently represent over 90% of the pharmaceutical market in China. In order for a new drug to be prescribed at a government hospital, it has to be listed in the hospital formulary. The process of entry into the formulary is commonly referred to as "hospital listing", and typically requires a long lead time. These decisions are made on a hospital-by-hospital basis with timing that can range from every six months to every five years. Some hospitals also have temporary listing procedures that can accelerate timing. Private hospital and non-hospital pharmacies, which represent less than 10% of the drug market in China, do not require a formulary process to sell a drug.

Centralized Procurement and Tenders. Provincial and municipal government agencies will establish a provincial drug procurement agency to operate a mandatory collective tender process for purchases by government hospitals of a medicine included in provincial or local medicine procurement catalogs. The provincial or local medicine procurement catalogs are determined by the provincial drug procurement agency based on the National Essential Drugs List, the NDRL, local hospital formularies, etc. If a new drug has been included in a government hospital formulary, the NDRL or the provincial reimbursement drug list, the relevant hospitals must participate in collective tender processes for the purchase of such new drug. During the collective tender process, the provincial drug procurement agency will establish a committee consisting of recognized pharmaceutical experts. The committee will assess the bids submitted by the various participating pharmaceutical manufacturers, taking into consideration, among other things, the quality and price of the drug product and the service and reputation of the manufacturer. Only drug products that have been selected in the collective tender processes may be purchased by participating hospitals.

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 currently consists of 124 full-time employees and 1 part-time employee, the majority of which are located in China. 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. In 2012, we refocused our clinical and regulatory strategy to leverage resources in China and implemented a name change in 2014 to "CASI Pharmaceuticals, Inc." Our offices are located at 9620 Medical Center Drive, Suite 300, Rockville, Maryland 20850, and our telephone number is (240) 864-2600. Our wholly-owned subsidiary, CASI China, is headquartered in Beijing, China. We conduct substantially all of our operations through CASI China, CASI China's headquarters are located at 1701-1702, China Central Office Tower 1, No.81 Jianguo Road, Chaoyang District, Beijing, 100025 China. CASI China also leases laboratory space in Beijing, China which serves as our R&D Center. Management decisions are primarily being made out of CASI China where our executive team spends a substantial amount of time.

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. We also established a wholly-owned domestic China based subsidiary under which our preclinical activities are operated. In addition, CASI Wuxi was established on December 26, 2018, to own and operate the Wuxi manufacturing facility. Our staff in China currently consists of 112 full-time employees. Among its activities, our China operations help to oversee the Company's anticipated commercial launch, sales and marketing of Melphalan Hydrochloride for Injection (EVOMELA), technology transfer and local manufacturing for our ANDA products, local preclinical and clinical operation activities, as well as its NMPA regulatory activities. In addition, the Beijing operations include business development activities and executive management activities. We expect our operations in China to continue to grow.

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*. 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 incurred significant operating losses since inception and anticipate that we will continue to incur operating losses for the foreseeable future and may never achieve or maintain profitability.

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, 2018 we had an accumulated deficit of approximately $478.9 million. We expect that 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, our capital-raising efforts may not produce 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. 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. To become and remain profitable, we must successfully commercialize one or more product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, developing commercial scale manufacturing processes, obtaining marketing approval, manufacturing, marketing and selling any current and future product candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate sufficient revenue to achieve profitability.

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 existing shareholders. 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 our access to capital, cost of capital, and ability to execute our business plan as scheduled.

Access to capital markets is critical to our ability to operate. Traditionally, biopharmaceutical companies 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 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 the 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, 2018, we had cash and cash equivalents of approximately $84.2 million. We may continue to seek additional capital through public or private financing or collaborative agreements in 2019 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. 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 106.1 million China Renminbi ("RMB"), valued at approximately $15.4 million in U.S. dollars. On a consolidated basis this balance accounts for approximately 18% 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

The regulatory approval process of the regulatory authorities in the United States and China are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain approval by FDA and NMPA is unpredictable and typically takes many years following the commencement of preclinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities.

Our drug candidates could be delayed or fail to receive regulatory approval for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a drug candidate is safe and effective or that a biologic candidate is safe, pure, and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- reporting or data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval or require us to amend our clinical trial protocols;
- regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;
- failure to satisfy regulatory conditions regarding endpoints, patient population, available therapies and other requirements for our clinical trials in order to support marketing approval on an accelerated basis or at all;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

The FDA, NMPA or a comparable regulatory authority may require more information, including additional preclinical, chemistry, manufacturing and controls, and/or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to

resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates, the commercial prospects of that drug candidate may be harmed, and our ability to generate product sales revenues from any of those drug candidates may be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that candidate. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

The recent restructure of the Chinese drug regulatory authorities may delay approval of our products or drug candidates in China.

On March 17, 2018, China's highest legislative body, the National People's Congress, approved a sweeping government restructuring plan. This is generally considered to be the most comprehensive government restructuring that China has undertaken since its "Open Door" policy in the late 1970s. As part of the new plan, China has established a SAMR, which merges and undertakes the responsibilities previously held by the China Food and Drug Administration, the State Administration for Industry and Commerce (SAIC), General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), the Certification and Accreditation Administration (CAC), and the Standardization Administration of China (SAC). The central government expects to complete the restructuring at the state level by the end of 2018. Municipal and county level authorities must complete the restructure by the first quarter of 2019.

The new NMPA reports to the SAMR, is responsible for the review and approval of drugs, medical devices and cosmetics, and maintains its own branches at the provincial level and leave the post-approval enforcement authorities at the local level to the consolidated SAMR branches.

Although the NMPA is fully functional as of 2018, the reorganization will continue at the provincial and local levels through the first quarter of 2019. This massive restructuring exercise could result in the delay of key decision-making in various sectors, including the pharmaceutical and medical device industry. In addition, there could be delays in the NMPA's implementation of the new reform initiatives and disruption in the NMPA's routine operations due to personnel reshuffle.

We may not be able to commercialize our drugs or drug candidates in China without obtaining regulatory approval from NMPA.

We have exclusive licenses to develop and commercialize Melphalan Hydrochloride For Injection (EVOMELA), ibritumomab tiuxetan (ZEVALIN) and vinCRIStine sulfate LIPOSOME injection (MARQIBO) in Greater China. On December 3, 2018, we received NMPA's approval for importation, marketing and sales in China for Melphalan Hydrochloride for Injection (EVOMELA). In addition, we acquired a portfolio of 25 U.S. FDA-approved ANDAs, four ANDAs that are pending FDA approval, and one ANDA for tenofovir disoproxil fumarate (TDF) indicated for hepatitis B virus. 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 pursue commercialization of certain products from our ANDA portfolio that offer unique market and cost-effective manufacturing opportunities in China and/or in the U.S. However, the majority of our drug candidates are still in clinical or pre-clinical development in China.

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

- our inability to obtain/maintain 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;
- our or our partners' inability to secure widespread acceptance of our products from physicians, healthcare payors, patients and the medical community;
- our ability to win tenders through the collective tender processes in which we decide to participate;
- 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.

The commercial success of Melphalan Hydrochloride for Injection (EVOMELA) in China may be slow or limited for a variety of reasons.

On December 3, 2018, we received NMPA's approval for importation, marketing and sales in China for Melphalan Hydrochloride For Injection (EVOMELA). We will spend our time, resources and effort on the commercialization of our approved drug in China in the near future. However, there are no guarantees that we will be successfully commercialize the medicine in China.

Reimbursement and hospital listing may be the most critical market access factors for our commercialization success in China. There is no regular update schedule for the NRDL. The government has committed to updating the NRDL in 2019. Given that Melphalan Hydrochloride For Injection (EVOMELA) was approved in 2018, we may or may not qualify for the next NDRL update should it be implemented in 2019. Provincial governments have some discretion to add Melphalan Hydrochloride For Injection (EVOMELA) to provincial reimbursement drug lists. With or without being listed on the NRDL, we can apply for inclusion in the provincial reimbursement drug lists of selected provinces. Until Melphalan Hydrochloride For Injection (EVOMELA) is listed in the NRDL or the majority of provincial reimbursement drug lists, our market will be extremely limited given only a small portion of the Chinese population would be able to afford our drug through self-pay.

Even when Melphalan Hydrochloride For Injection (EVOMELA) has been included in a government hospital formulary, the NDRL or the provincial reimbursement drug list, we need to win tenders during the collective tender process in order to supply the drug to state-owned or state-controlled hospitals. If we are unable to win purchase contracts through the collective tender processes in which we decide to participate, there will be limited demand for Melphalan Hydrochloride For Injection (EVOMELA), and sales revenues from the drug will be materially and adversely affected. Last but not least, we need to ensure that Melphalan Hydrochloride For Injection (EVOMELA) has been quickly added to hospitals' formulary. If we were unable to quickly add Melphalan Hydrochloride For Injection (EVOMELA) to hospitals' formulary, doctors and patients will not have access to our drug through hospital pharmacies.

We conduct development and operations in China, which exposes us to risks associated with operating outside of the United States. Changes in international trade and economic policy by the U.S. and Chinese governments could have a material adverse effect on our business and operations.

We have operations and conduct business in China and we plan to continue to expand these operations. Therefore, we are subject to risks related to operating in foreign countries, which include unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements; other laws and regulatory requirements to which our business activities abroad are subject, such as the Foreign Corrupt Practices Act; changes in the political or economic condition of a specific country or region; fluctuations in the value of foreign currency versus the U.S. dollar; our ability to deploy overseas funds in an efficient manner; tariffs, trade protection measures, import or export

licensing requirements, trade embargoes, and sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), and other trade barriers; difficulties in attracting and retaining qualified personnel; and cultural differences in the conduct of business. There is currently significant uncertainty about the future relationship between the U.S. and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. The Trump Administration has called for substantial changes to U.S. foreign trade policy, including the possibility of imposing greater restrictions on international trade and significant increases in tariffs. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current political climate could adversely impact our business.

We are establishing a joint venture to build and operate a manufacturing facility in the Wuxi Huishan Economic Development Zone. The success of this joint venture is subject to uncertainty and may reduce our earnings, be difficult to accomplish, take longer than expected or require us to obtain additional financing.

We have invested approximately $21 million and intend to invest a total of approximately $80 million, of which $30 million is intended to be an investment in the value of certain ANDA products to be determined and transferred to the joint venture, proceeds to be used in the building and operating a manufacturing facility in the Wuxi Huishan Economic Development Zone in Jiangsu Province, China. The Company's total investment is intended to account for 80% of the equity of the joint venture. This joint venture may not achieve the expected goal as the planned manufacturing facility will not be entirely within our control. It can take years to build and establish a new manufacturing facility. Once built, the new facility might fail validation or not meet regulatory standards for a commercial manufacturing facility. In addition, we may not obtain or retain the requisite legal permits to manufacture in China, and costs or operational limitations may be imposed in connection with obtaining and complying with such permits. Our ability to establish and operate a manufacturing facility 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. The success of this joint venture also relies on our ability to make additional payments in the future, which is uncertain. Our plan may require us to obtain additional debt or equity financing, resulting in additional debt obligations, increased interest expense or dilution of equity ownership. If we are unable to establish a new manufacturing facility, purchase equipment, hire adequate personnel to support our manufacturing efforts or implement necessary process improvements, we may be unable to produce commercial materials or meet demand, if any should develop, for our product candidates. 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.

The retail prices of any product candidates that we develop may be subject to control, including periodic downward adjustment, by Chinese government authorities.

The price for pharmaceutical products is highly regulated in China, both at the national and provincial level. Price controls may reduce prices to levels significantly below those that would prevail in less regulated markets, or limit the volume of products that may be sold, either of which may have a material and adverse effect on potential revenues from sales of our drug products in China. Moreover, the process and timing for the implementation of price restrictions is unpredictable, which may cause potential revenues from the sales of our drug product to fluctuate from period to period.

The existence of counterfeit pharmaceutical products in pharmaceutical markets may compromise our brand and reputation and have a material adverse effect on our business, operations and prospects.

Counterfeit products, including counterfeit pharmaceutical products, are a significant problem, particularly in China. Counterfeit pharmaceuticals are products sold or used for research under the same or similar names, or similar mechanism of action or product class, but which are sold without proper licenses or approvals. Such products may be used for indications or purposes that are not recommended or approved or for which there is no data or inadequate data with regard to safety or efficacy. Such products divert sales from genuine products, often are of lower cost, often are of lower quality (having different ingredients or formulations, for example), and have the potential to damage the reputation for quality and effectiveness of the genuine product. If counterfeit pharmaceuticals illegally sold or used for research result in adverse events or side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Consumers may buy counterfeit pharmaceuticals that are in direct competition with our pharmaceuticals, which could have an adverse impact on our revenues, business and results of operations. In

addition, the use of counterfeit products could be used in non-clinical or clinical studies, or could otherwise produce undesirable side effects or adverse events that may be attributed to our products as well, which could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. With respect to China, although the government has recently been increasingly active in policing counterfeit pharmaceuticals, there is not yet an effective counterfeit pharmaceutical regulation control and enforcement system in China. As a result, we may not be able to prevent third parties from selling or purporting to sell our products in China. The proliferation of counterfeit pharmaceuticals has grown in recent years and may continue to grow in the future. The existence of and any increase in the sales and production of counterfeit pharmaceuticals, or the technological capabilities of counterfeiters, could negatively impact our revenues, brand reputation, business and results of operations.

Uncertainties with respect to the China legal system could have a material adverse effect on us.

The legal system of China is a civil law system primarily based on written statutes. Unlike in a common law system, prior court decisions may be cited for reference but are not binding. Because the China legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules are not always uniform and enforcement of these laws, regulations and rules involve uncertainties, which may limit legal protections available to us. Moreover, decision makers in the China judicial system have significant discretion in interpreting and implementing statutory and contractual terms, which may render it difficult for us to enforce the contracts entered into with our business partners, customers and suppliers. Different government departments may have different interpretations of certain laws and regulations, and licenses and permits issued or granted by one government authority may be revoked by a higher government authority at a later time. Navigating the uncertainty and change in the China legal system will require the devotion of significant resources and time, and there can be no assurance that our contractual and other rights will ultimately be enforced.

Changes in China's economic, political or social conditions or government policies could have a material adverse effect on our business and operations.

Chinese society and the Chinese economy continue to undergo significant change. Adverse changes in the political and economic policies of the Chinese government could have a material adverse effect on the overall economic growth of China, which could adversely affect our ability to conduct business in China. The Chinese government continues to adjust economic policies to promote economic growth. Some of these measures benefit the overall Chinese economy, but may also have a negative effect on us. For example, our financial condition and results of operations in China may be adversely affected by government control over capital investments or changes in tax regulations. As the Chinese pharmaceutical industry grows and evolves, the Chinese government may also implement measures to change the structure of foreign investment in this industry. We are unable to predict the frequency and scope of such policy changes, any of which could materially and adversely affect our liquidity, access to capital and its ability to conduct business in China. Any failure on our part to comply with changing government regulations and policies could result in the loss of our ability to develop and commercialize our product candidates in China.

We are currently building our sales and distribution infrastructure. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing Melphalan Hydrochloride For Injection (EVOMELA) or any other product candidates.

In December of 2018, we received NMPA's approval for importation, marketing and sales in China for Melphalan Hydrochloride For Injection (EVOMELA). We are in the process of establishing a sales and marketing team with technical expertise and supporting distribution capabilities to successfully commercialize EVOMELA, or to outsource this function to a third party. Both of these options can be expensive and time consuming. In addition, we may not be able to hire a sales force in the China that is large enough or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our sales, marketing and distribution capabilities would adversely impact the commercialization of Melphalan Hydrochloride For Injection (EVOMELA) and other product candidates.

We have limited experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We will need to commit significant time and financial and managerial resources to

maintain and further develop our marketing and sales force to ensure they have the technical expertise required to address any challenges we may face with the commercialization of Melphalan Hydrochloride For Injection (EVOMELA).

Factors that may inhibit our efforts to maintain and develop our commercialization capabilities include:

- our ability to retain an adequate number of effective commercial personnel in the medical markets we intend to target;
- our ability to train sales personnel, who may have limited experience with our company or Melphalan Hydrochloride For Injection (EVOMELA), to deliver a consistent message regarding the medicine and be effective in convincing physicians to prescribe it;
- a 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;
- unforeseen costs and expenses associated with maintaining and further developing an independent sales and marketing organization.

If we are not successful in establishing and maintaining an effective sales and marketing infrastructure, we will have difficulty commercializing Melphalan Hydrochloride For Injection (EVOMELA) and our future product revenue will suffer, which would adversely affect our business and financial condition. If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, 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 are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

We may need new collaborative partners to further develop and commercialize products, and if we enter into such arrangements, we may lose control over the development and approval process.

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 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**.**

We face significant competition from other biotechnology and pharmaceutical companies and our business will suffer if we fail to compete effectively.

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.

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.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for product candidate we develop. We will not achieve our business plan if the acceptance of our products is inhibited by price competition or reimbursement issues or if physicians switch to other new drug products or choose to reserve our product candidates for use in limited circumstances. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

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 or 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.

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.

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.

Successful commercialization of 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 the Patient Protection and Affordable Care Act (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 or replaced, it is unclear how the replacement statute may impact our business. If PPACA is not repealed or replaced, 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.

In China, the newly created National Healthcare Security Administration (NHSA), an agency responsible for administering China's social security system, organized a price negotiation with drug companies for 18 oncology drugs in October 2018, which resulted in a price reduction by over 50%. The NHSA included 17 of the 18 oncology drugs on the NRDL after the price negotiation. We may also be invited to attend the price negotiation with NHSA upon receiving regulatory approval in China, but we will likely need to significantly reduce our prices, and to negotiate with each of the provincial healthcare security administrations on reimbursement ratios. If we were to successfully launch commercial sales of Melphalan Hydrochloride For Injection (EVOMELA), our revenue from such sales is

largely expected to be self-paid by patients, which may make our drug candidates less desirable. On the other hand, if the NHSA or any of its local counterpart includes our Melphalan Hydrochloride For Injection (EVOMELA) in the NRDL or provincial RDL, which may increase the demand for our drug candidates, our potential revenue from the sales of our drug candidates may still decrease as a result of lower prices.

The success of our business depends upon the members of our senior management team 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 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. We also 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.

Risks Relating to Our Reliance on Third Parties

Independent clinical investigators and contract research organizations that we engage to conduct our clinical trials may not devote sufficient time or attention to our clinical trials or be able to repeat their past success.

We depend on independent clinical investigators and contract research organizations ("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 plan to build and operate a manufacturing facility in the Wuxi Huishan Economic Development Zone in Jiangsu Province, China. 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. Our manufacturing processes are, and we expect future manufacturing processes 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 NMPA 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 Auditors

The Audit Report Included in this Annual Report on Form 10-K is Prepared by Auditors Who Are Not Currently Inspected by the Public Company Accounting Oversight Board and, as such, Our Stockholders are Deprived of the Benefits of Such Inspection.

As an auditor of companies that are publicly traded in the United States and a firm registered with the Public Company Accounting Oversight Board ("PCAOB"), our independent registered public accounting firm is required under the laws of the United States to undergo regular inspections by the PCAOB. However, because we have substantial operations within China, our independent registered public accounting firm's audit documentation related to their audit report included in this Annual Report on Form 10-K is located in China. The PCAOB is currently unable to conduct full inspections in China or review audit documentation located within China without the approval of Chinese authorities.

Inspections of other auditors conducted by the PCAOB outside of China have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in China prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, stockholders may be deprived of the benefits of PCAOB inspections, and may lose confidence in our reported financial information and procedures and the quality of our financial statements.

Proceedings Instituted by the SEC Against Certain China-Based Accounting Firms, Including Our Independent Registered Public Accounting Firm, Could Result in our Financial Statements being Determined to Not be in Compliance with the Requirements of the Exchange Act.

In late 2012, the SEC commenced administrative proceedings under Rule 102(e) of its Rules of Practice and also under the Sarbanes-Oxley Act of 2002 against the Chinese member firms of the "big four" accounting firms, including our independent registered public accounting firm. The Rule 102(e) proceedings initiated by the SEC relate to the failure of these firms to produce certain documents, including audit work papers, in response to a request from the SEC pursuant to Section 106 of the Sarbanes-Oxley Act of 2002. The auditors located in China claim they are not in a position lawfully to produce such documents directly to the SEC because of restrictions under Chinese law and specific directives issued by the China Securities Regulatory Commission ("CSRC"). The issues raised by the proceedings are not specific to our auditor or to us, but potentially affect equally all PCAOB-registered audit firms based in China and all businesses based in China (or with substantial operations in China) with securities listed in the United States. In addition, auditors based outside of China are subject to similar restrictions under Chinese law and CSRC directives in respect of audit work that is carried out in China which supports the audit opinions issued on financial statements of entities with substantial China operations.

If our independent registered public accounting firm were denied, even temporarily, the ability to practice before the SEC, and we are unable to timely find another independent registered public accounting firm to audit and issue an opinion on our financial statements, our financial statements could be determined not to be in compliance with the requirements of the Exchange Act. Such a determination could ultimately lead to delisting of our common stock from Nasdaq. Moreover, any negative news about the proceedings against these audit firms may adversely affect investor confidence in companies with substantial China-based operations listed on securities exchanges in the United States. All of these factors could materially and adversely affect the market price of our common stock and our ability to access the capital markets.

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.

The volatile price of our stock makes it difficult for investors to predict the value of their investments, to sell shares at a profit at any given time, or to plan purchases and sales in advance. Our common stock price has fluctuated from year-to-year and quarter-to-quarter and will likely continue to be volatile. During 2018, our stock price has ranged from $2.77 to $8.23. We expect that the trading price of our common stock is likely to be highly volatile in response to a variety of factors that are beyond our control, such as:

- our ability to maintain regulatory approval for Melphalan Hydrochloride For Injection (EVOMELA) and obtain regulatory approval for our other product candidates;
- issues in importation, marketing and sales of Melphalan Hydrochloride For Injection (EVOMELA);
- the results of our current and any future clinical trials of Ibritumomab Tiuxetan (ZEVALIN) or our other product candidates;
- the success of our joint venture to build and operate a manufacturing facility in China;
- the commercialization of our portfolio of ANDAs;
- publicity regarding actual or potential clinical test results relating to products under development by our competitors or us;
- initiating, completing or analyzing, or a delay or failure in initiating, completing or analyzing, pre-clinical or clinical trials or animal trials or the design or results of these trials for products in development;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- achievement or rejection of regulatory approvals for products in development by our competitors or us;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning our collaborations and supply chain;
- regulatory developments in the United States and foreign countries;

- economic or other crises and other external factors;
- the loss of key employees;
- period-to-period fluctuations in our revenues and other results of operations;
- changes in financial estimates by securities analysts; or
- publicity or activity involving possible future acquisitions, strategic investments, partnerships or alliances.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. 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.

If securities or industry analysts publish inaccurate or unfavorable research about our business, our stock price could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who may cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline.

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.

The headquarters of CASI China are currently located in Beijing, China with approximately 12,100 square feet of office space and with approximately 11,000 square feet of laboratory space. In addition, as of December 31, 2018, we leased approximately 6,068 square feet of office space in Rockville, Maryland. Our lease on behalf of CASI Wuxi for buildings to be developed and constructed for the Wuxi manufacturing facility covers approximately 214,500 square feet. 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

Our common stock trades on The Nasdaq Capital Market under the symbol “CASI.” As of March 25, 2019, there were approximately 302 holders of record of our common stock.

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. pharmaceutical company with a platform to develop and accelerate the launch of pharmaceutical products and innovative therapeutics in China, U.S., and throughout the world. We are focused on acquiring, licensing, developing and commercializing products that address areas of unmet medical need. We intend to execute our plan to become a leading platform to launch medicines in the greater China market leveraging our China-based regulatory and commercial competencies and our global drug development expertise. We conduct substantially all of our operations through our wholly-owned subsidiary, CASI China, which is headquartered in Beijing, China. CASI China has established China operations that are growing as we continue to further in-license or acquire products for our pipeline.

Our product pipeline features the following: (1) U.S. FDA-approved hematology oncology drugs in-licensed from Spectrum for the greater China market, consisting of Melphalan Hydrochloride For Injection (EVOMELA), Ibritumomab Tiuxetan (ZEVALIN) and Vincristine Sulfate Liposome Injection (MARQIBO), (2) a portfolio of 26 FDA-approved abbreviated new drug applications ("ANDAs"), including entecavir and TDF indicated for hepatitis B virus; and (3) four pipeline ANDAs that are pending FDA approval. We intend to prioritize a select subset of the ANDAs for product registration and commercialization in China. In addition to these advanced products, our pipeline includes a proprietary Phase 2 drug candidate, ENMD-2076, that we have previously determined not to pursue as a single agent, and instead we are exploring the feasibility of combination as a clinical strategy. We also have proprietary early-stage immune-oncological potential candidates in preclinical development.

We believe our product mix reflects a risk-balanced approach between products in various stages of development, between products that are branded and non-branded, and between products that are proprietary and generic. We intend to continue building a significant product pipeline of high quality pharmaceuticals, as well as innovative drug candidates for commercialization in China and for the rest of the world. For in-licensed products, 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 our drug development strategy. For our FDA-approved ANDAs, we intend to select and commercialize certain niche products from the portfolio that complement our therapeutic focus areas and which offer unique market and cost-effective manufacturing opportunities in China and/or in the U.S.

We believe the China operations offer a significant market and growth potential due to extraordinary increase in demand for high quality medicine coupled with regulatory reforms in China that make it easier for global pharmaceutical companies to introduce new pharmaceutical products into the country. We will continue to in-license clinical-stage and late-stage drug candidates, and leverage our platform and expertise, and hope to be the partner of choice to provide access to the China market. We expect the implementation of our plans will include leveraging our resources and expertise in both the U.S. and China so that we can maximize development and clinical strategies concurrently under U.S. FDA and China NMPA regulatory regimes.

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 commercial launches. In December 2018, we received NMPA approval of Melphalan Hydrochloride For Injection (EVOMELA), for:

- use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma, and
- the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.

We intend to begin commercializing this drug through CASI China beginning in 2019 using EVOMELA supplied through Spectrum and its suppliers. All future needs will be sourced from Acrotech and its suppliers.

The Company is building an internal commercial team to prepare for the launch of our first commercial product, Melphalan Hydrochloride for Injection (EVOMELA) in 2019. As part of the strategy to support our future clinical and commercial manufacturing needs and to manage our supply chain for certain products, the Company has established CASI Wuxi to construct a cGMP manufacturing facility in Wuxi, China. The site is currently in the design and engineering phase with construction expected to begin in 2019. Through CASI China, we will focus on China market devoting more resources and investment going forward.

Since inception, the Company has incurred significant losses from operations and has incurred an accumulated deficit of $478.9 million. The Company expects to continue to incur operating losses for the foreseeable future due to, among other factors, its continuing clinical and development activities. In September 2018, the Company entered into securities purchase agreements with certain institutional investors, accredited investors and current stockholders, pursuant to which the Company agreed to sell up to 9,048,504 shares of its common stock with accompanying warrants to purchase 2,714,548 shares of its common stock in a $48.5 million private placement (the "September 2018 Financing"). The Company held its initial closing on September 24, 2018 and second closing on

October 10, 2018 (the "September and October 2018 Closings"). The Company has received gross proceeds of $37.5 million. The Company does not expect to receive any further proceeds from the September 2018 Financing.

Additionally, in March 2018, the Company entered into securities purchase agreements pursuant to which the Company issued 15,432,091 shares of its common stock with accompanying warrants to purchase 6,172,832 shares of its common stock and received $50 million in gross proceeds in a private placement (the "March 2018 Financing"). The March 2018 Financing closing included an investment from ETP Global Fund, L.P., a healthcare investment fund. The managing member of Emerging Technology Partners, LLC ("ETP"), which is the general partner of ETP Global Fund, L.P., is also the Executive Chairman of the Company. The March 2018 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 member of the Company's Board of Directors. Net proceeds from the September and October 2018 Closings, and the March 2018 Financing are being used to prepare for the launch of the Company's first commercial product in China, Melphalan Hydrochloride For Injection (EVOMELA), to support the Company's business development activities, to advance the development of the Company's pipeline, to support its marketing and commercial planning activities, and for other general corporate purposes.

Taking into consideration the cash balance as of December 31, 2018 and its commitments to fund CASI Wuxi, the Company believes that it has sufficient resources to fund its operations at least through March 29, 2020. As of December 31, 2018, approximately $15.4 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.

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:

- *Impairment of Long-lived Assets* - the Company evaluates the value reflected in its consolidated balance sheets of long-lived assets, such as property and equipment and definitive-lived intangible assets, 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 2018 and 2017.

- *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 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* - The Company records compensation expense associated with service and performance-based stock options in accordance with provisions of authoritative guidance. The estimated fair value of service-based awards is determined using option pricing models that use unobservable inputs and is generally amortized on a straight-line basis over the requisite service period and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period. The estimated fair value of performance-based awards is measured on the grant date and is recognized when it is determined that it is probable that the performance condition will be achieved.

RESULTS OF OPERATIONS

Years Ended December 31, 2018 and 2017.

Revenues and Cost of Product Sales. There were no revenues recorded for the years ended December 31, 2018 and 2017.

Research and Development Expenses. Our 2018 research and development expenses totaling $8,507,000 as compared to $7,595,000 in 2017, a 12% increase. Research and development expenses totaling $8,507,000 for the year ended December 31, 2018 included direct project costs of $2,405,000 related to our ANDAs acquired in 2018, $244,000 related to ENMD-2076, $1,247,000 for drugs in-licensed from Spectrum, and $1,670,000 for preclinical development activities primarily in China. 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 increase in research and development costs in 2018, as compared to 2017, primarily reflects expenses associated with regulatory costs for the ANDAs in 2018, offset by higher costs related to the quality testing phase of the NMPA regulatory review of ZEVALIN and EVOMELA in 2017.

At December 31, 2018, and, since acquired, accumulated direct project expenses for our ANDAs acquired in 2018 totaled $2,405,000; $28,755,000 for ENMD-2076; $5,783,000 for drugs in-licensed from Spectrum; and for preclinical development activities primarily in China, accumulated project expenses totaled $5,035,000. Our research and development expenses also include non-cash stock-based compensation totaling $740,000 and $272,000, respectively, for 2018 and 2017. The balance of our research and development expenditures includes facility costs and other departmental overhead, expenditures related to the non-clinical support of our programs, and non-cash amortization expense of $1,305,000 related to our acquired ANDAs.

We expect the majority of our research and development expenses for 2019 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 for 2019 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 NMPA 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 $8,507,000 in 2018 from $7,595,000 in 2017.

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 $1,455,000 in 2018 and $333,000 in 2017. The increase in 2018 as compared to 2017 primarily reflects regulatory costs associated with our ANDAs acquired in January 2018.

- *Clinical Trial Costs* – Clinical trial costs, which include clinical site fees, monitoring costs and data management costs, decreased to ($18,000) in 2018 from $417,000 in 2017. This decrease primarily relates to higher patient costs and clinical trial management costs associated with our Phase 2 clinical trial in advanced fibrolamellar carcinoma (FLC) during the 2017 period compared to the 2018 period as the trial has completed.

- *Lab Supplies* – Laboratory supplies associated with our pre-clinical activities increased to $308,000 in 2018 from $294,000 in 2017 due to the continued activities in our China research and development lab.

- *Contract Manufacturing Costs* – The costs of manufacturing or acquiring the material used in development activities associated with our ANDAs as well as clinical trials for our product candidates is reflected in contract manufacturing. These costs include bulk manufacturing, encapsulation and fill and finish services, and product release costs. Contract manufacturing costs decreased in 2018 to $418,000 from $2,987,000 in 2017. The higher cost in 2017 primarily reflects costs associated with the purchase of ZEVALIN and EVOMELA in 2017 from our partner Spectrum for NMPA quality testing purposes to support CASI's application for import drug registration.

- *Personnel Costs* – Personnel costs increased to $3,666,000 in 2018 from $2,644,000 in 2017. This variance is primarily attributed to increased salary and benefit costs associated with new employees in China, as well as an increase in non-cash stock compensation expense of $468,000 in 2018 as compared to 2017.

- Also reflected in our 2018 research and development expenses are outsourced consultant costs of $242,000, facility and related expenses of $793,000, and amortization of acquired ANDAs of $1,305,000. In the corresponding 2017 period, these expenses totaled $213,000, $485,000, and $0, respectively. The variance in outsourced consultant costs reflect the timing of services related to regulatory activities. The increase in facilities and related expenses is primarily due to a full year of leased lab space in China in 2018 compared to a partial year in 2017, as well as new leased office space in China in April 2018 and October 2018. The increase in amortization of acquired ANDAs is due to the January 2018 and October acquisition of ANDAs.

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

General and administrative expenses increased to $17,997,000 in 2018 from $3,156,000 in 2017. The increase in expenses in 2018, compared to 2017 reflects an increase in non-cash stock-based compensation expense totaling $4,997,000, primarily associated with stock option awards issued to the Company's Executive Chairman; an increase in salary, benefits and recruitment expense totaling $2,553,000, primarily related to sales and marketing efforts to prepare for the anticipated launch of the Company's first commercial product in China, as well as other general and administrative functions; approximately $1,747,000 associated with additional professional services fees and investor and public relations activities; and increased facility cost of $435,000 due to new leased office space in China. The increase in general and administrative expenses for the 2018 also includes $1,380,000 associated with our Executive Chairman's services in connection with the September and October 2018 Closings, and increased costs of approximately $2,636,000 associated with business development and exploratory acquisition activities, including $1.5 million related to due diligence and related services for certain business development activities incurred by ETP on our behalf.

Interest income, net. Interest income, net for the years ended December 31, 2018 and 2017 was $39,988 and $1,009, respectively. This includes interest income of $48,196 and $15,985, respectively, offset by interest expense on our note payable of $7,500 for both years and non-cash interest expense of $708 and $7,476, respectively,

representing the amortization of the debt discount.

Change in fair value of contingent rights. As consideration for the licensing arrangements with Spectrum, the Company issued Spectrum certain contingent rights ("Contingent Rights") to purchase additional shares of its common stock. The Contingent Rights were considered derivative liabilities and were recorded initially at their estimated fair value and were marked to market each reporting period until settlement. The Contingent Rights were fully settled during 2017, so there was no change in the fair value of the Contingent Right for the year ended December 30, 2018. The change in fair value of the Contingent Rights for the years ended December 31, 2017 was $19,891.

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 2019 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, 2020.

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, potential acquisition activities, research and development, and the China clinical development of Ibritumomab Tiuxetan (ZEVALIN) and Vincristine Sulfate Liposome Injection (MARQIBO) 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 Acrotech products or plans for other product candidates, if any, and potential acquisition activities.

At December 31, 2018, we had cash and cash equivalents of approximately $84.2 million, with working capital of approximately $88.7 million. As of December 31, 2018, approximately $15.4 million of the Company's cash balance was held by the Company's wholly-owned subsidiary in China. In February 2019, the Company funded its $21 million investment in CASI Wuxi.

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. Upon the change in functional currency, there was no 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, in September 2018, the Company entered into securities purchase agreements (the "September SPAs") with certain institutional investors, accredited investors and current stockholders, pursuant to which the Company agreed to sell up to 9,048,504 shares of its common stock with accompanying warrants to purchase 2,714,548 shares of its common stock in a $48.5 million private placement. The purchase price for each share of common stock and warrant was $5.36. The warrants are exercisable on March 23, 2019 at a $7.19 per share exercise price and expire on September 24, 2021. In September and October 2018, the Company completed two closings and issued a total of 6,996,266 shares of its common stock with accompanying warrants to purchase 2,098,877 shares of its common stock and received $37.5 million in gross proceeds. The fair value of the warrants issued is $6,254,653 or $2.98 per warrant, calculated using the Black-Scholes-Merton valuation model with a contractual life of 3 years, an assumed volatility of 88.39%, and a risk-free interest rate of 2.89%. The Company does not expect to receive any further proceeds from the September 2018 Financing. The September SPAs and warrants each include additional customary representations, warranties and covenants. The Company has filed a resale registration covering the shares of common stock issued and the shares of common stock underlying the warrants issued on Form S-3 (File No. 333-228383) which became effective on November 29, 2018.

Additionally, in March 2018, the Company entered into securities purchase agreements (the "March SPAs") with certain institutional investors, accredited investors and current stockholders, pursuant to which the Company issued 15,432,091 shares of its common stock with accompanying warrants to purchase 6,172,832 shares of its common stock and received $50 million in gross proceeds in a private placement. The purchase price for each share of common stock and warrant was $3.24. The warrants became exercisable on September 17, 2018 at a $3.69 per share exercise price, and will expire on March 21, 2023. The fair value of the warrants issued is $15,062,000, or $2.44 per warrant, calculated using the Black-Scholes-Merton valuation model with a contractual life of 5 years, an assumed volatility of 75.4%, and a risk-free interest rate of 2.69%. The March SPAs and warrants each include additional customary representations, warranties and covenants. The Company has filed a resale registration covering the shares of common stock issued and the shares of common stock underlying the warrants on Form S-3 (File No. 333-226206) which became effective on August 8, 2018.

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.

Any sales of shares pursuant to the Sales Agreement will be made under the Company's effective "shelf" 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 SEC on February 23, 2018.

In 2018, the Company issued 143,248 shares under the Sales Agreement resulting in net proceeds to the Company of approximately $475,000. As of December 31, 2018, approximately $24.5 million remained available under the Sales Agreement.

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 2018.

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, 2018, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial 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, Chief Financial 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, Chief Financial Officer, and Chief Operating Officer & General Counsel) to allow timely decisions regarding required disclosures. Based on such evaluation, our Chief Executive Officer, Chief Financial Officer, and Chief Operating Officer & General Counsel have concluded these disclosure controls and procedures are effective as of December 31, 2018.

Changes in Internal Control Over Financial Reporting

There have not been any changes in our internal control over financial reporting during the fourth quarter ended December 31, 2018 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 Financial Officer, and Chief Operating Officer & General Counsel, 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, 2018. The effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by KPMG Huazhen LLP, our independent registered public accounting firm, as stated in their report, which appears herein.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
CASI Pharmaceuticals, Inc.:

Opinion on Internal Control Over Financial Reporting

We have audited CASI Pharmaceuticals, Inc. and subsidiaries' ("the Company") internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheet of the Company as of December 31, 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively, the "consolidated financial statements"), and our report dated March 29, 2019 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those

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

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

/s/ KPMG Huazhen LLP

Beijing, China
March 29, 2019

ITEM 9B. OTHER INFORMATION.

Our 2019 Annual Meeting of Stockholders will be held on June 20, 2019. 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, 2018.

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 financial 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, 2018.

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, 2018.

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, 2018.

	(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	18,429,308	$2.44	6,834,234
Equity compensation plans not approved by security holders	0	$0.00	0
Total	18,429,308	$2.44	6,834,234

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, 2018.

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, 2018.

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 Common Stock Sales Agreement, dated February 23, 2018, 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 February 23, 2018)

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)

4.14	Form of Warrant (incorporated by reference to Exhibit 4.1 of our Form 8-K filed with the Securities and Exchange Commission on September 14, 2018)
10.1	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)
10.2	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)
10.3	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)
10.4	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)
10.5	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)
10.6	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)
10.7	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)
10.8	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)
10.9	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)
10.10	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)
10.11	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)
10.12	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 17, 2018)
10.13	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)
10.14	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)

10.15	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)
10.16	Asset Purchase Agreement, dated as of January 26, 2018, by and between CASI Pharmaceuticals, Inc. and Sandoz Inc. + (incorporated by reference to Exhibit 10.26 of our Form 10-K filed with the Securities and Exchange Commission on March 29, 2018)
10.17	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)
10.18	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 September 14, 2018)
10.19	Employment Agreement, effective as of September 28, 2018, between CASI Pharmaceuticals, Inc. and George Chi* (incorporated by reference to Exhibit 10.1 of our Form 8-K/A filed with the Securities and Exchange Commission on October 24, 2018)
10.20	Memorandum of Understanding, dated November 16, 2018, by and between Management Committee of Wuxi Hui-shan Economic Development Zone and CASI Pharmaceuticals, Inc.**
10.21	Investment Agreement, dated November 16, 2018, by and between Administrative Committee of Wuxi Huishan Economic Development Zone, Jiangsu Province and CASI Pharmaceuticals, Inc.**
10.22	Supplementary Agreement, dated November 16, 2018, by and between Administrative Committee of Wuxi Huishan Economic Development Zone, Jiangsu Province and CASI Pharmaceuticals, Inc.**
10.23	Shareholders' Agreement, dated November 16, 2018, between CASI Pharmaceuticals, Inc. and Wuxi Jintou Huicun Investment Enterprise (Limited Partnership) **
10.24	Lease Contract, by and between Wuxi Huishan New City Life Science & Technology Industry Development Co., Ltd. and CASI Pharmaceuticals, Inc. **
10.25	Joint Venture Contract on Establishment of CASI (Wuxi) Pharmaceuticals Co. Ltd. by and between CASI Pharmaceuticals, Inc. and Wuxi Jintou Huicun Investment Enterprise Limited Partnership, dated as of November 16, 2018 **
10.26	Labor Contract, effective as of September 1, 2018, between CASI (Beijing) Pharmaceuticals, Inc. and Wei (Larry) Zhang* **
16.1	Letter from CohnReznick dated September 27, 2018 (incorporated by reference to Exhibit 16.1 of our Form 8-K filed with the Securities and Exchange Commission on September 28, 2018)
21	Subsidiaries of the Registrant **
23.1	Consent of Independent Registered Public Accounting Firm **
23.2	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 Chief Financial Officer **
32.1	Rule 13a-14(b) Certification by Chief Executive Officer **
32.2	Rule 13a-14(b) Certification by Chief Financial 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, 2018, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2018 and 2017, (ii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2018 and 2017, (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018 and 2017 (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017 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, 2019

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, 2019
/s/George Chi George Chi	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 29, 2019
/s/Wei-Wu He Wei-Wu He	Executive Chairman	March 29, 2019
/s/James Z. Huang James Z. Huang	Director	March 29, 2019
/s/Franklin C. Salisbury Franklin C. Salisbury	Director	March 29, 2019
/s/Rajesh C. Shrotriya Rajesh C. Shrotriya	Director	March 29, 2019
/s/Y. Alexander Wu Y. Alexander Wu	Director	March 29, 2019
/s/ Quan Zhou Quan Zhou	Director	March 29, 2019

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

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
CASI Pharmaceuticals, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of CASI Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively, 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, 2018, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 29, 2019 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 the amounts and disclosures in the consolidated financial statements. Our audit 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 audit provides a reasonable basis for our opinion.

/s/ KPMG Huazhen LLP

We have served as the Company's auditor since 2019.

Beijing, China
March 29, 2019

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 sheet of CASI Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2017, and the related consolidated statement of operations and comprehensive loss, stockholders' equity and cash flows for the year 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 the results of its operations and its cash flows for the year 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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, 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 audit, 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 audit 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 audit 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 audit provides 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, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 84,204,809	$ 43,489,935
Investment in equity securities, at fair value	912,200	-
Prepaid expenses and other	7,447,611	322,493
Total current assets	92,564,620	43,812,428
Property and equipment, net	1,750,630	1,046,514
Intangible assets, net	18,784,727	-
Other assets	310,024	242,023
Total assets	$ 113,410,001	$ 45,100,965
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 968,048	$ 2,087,770
Payable to related party	-	2,228,366
Accrued liabilities	1,406,434	745,961
Note payable, net of discount	1,499,462	-
Total current liabilities	3,873,944	5,062,097
Note payable, net of discount	-	1,498,754
Other liabilities	73,591	-
Total liabilities	3,947,535	6,560,851
Commitments and contingencies (Note 17)		
Stockholders' equity:		
Preferred stock, $1.00 par value; 5,000,000 shares authorized and 0 shares issued and outstanding at December 31, 2018 and 2017	-	-
Common stock, $.01 par value: 170,000,000 shares authorized at December 31, 2018 and 2017; 95,366,813 shares and 69,901,625 shares issued at December 31, 2018 and 2017; 95,287,268 shares and 69,822,080 shares outstanding at December 31, 2018 and 2017, respectively	953,667	699,015
Additional paid-in capital	596,710,648	498,577,372
Treasury stock, at cost: 79,545 shares held at December 31, 2018 and 2017	(8,034,244)	(8,034,244)
Accumulated other comprehensive loss	(1,226,320)	-
Accumulated deficit	(478,941,285)	(452,702,029)
Total stockholders' equity	109,462,466	38,540,114
Total liabilities and stockholders' equity	$ 113,410,001	$ 45,100,965

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2018	**2017**
Revenues:		
Product sales	$ -	$ -
	-	-
Costs and expenses:		
Research and development	8,507,377	7,595,182
General and administrative	17,997,069	3,156,138
Acquired in-process research and development	686,998	-
	27,191,444	10,751,320
Interest income, net	(39,988)	(1,009)
Change in fair value of investment in equity securities	320,112	-
Change in fair value of contingent rights	-	19,891
Net loss	$ (27,471,568)	$ (10,770,202)
Net loss per share (basic and diluted)	$ (0.32)	$ (0.18)
Weighted average number of shares outstanding (basic and diluted)	84,752,152	61,513,988
Comprehensive loss:		
Net loss	$ (27,471,568)	$ (10,770,202)
Foreign currency translation adjustment	(1,226,320)	-
Total comprehensive loss	$ (28,697,888)	$ (10,770,202)

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity
Years Ended December 31, 2018 and 2017

	Preferred Stock		Common Stock		Treasury	Additional Paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Stock	Capital	Loss	Deficit	Total
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
Correction of immaterial error in prior year and cumulative effect adjustment due to the adoption of ASU 2016-01	-	-	-	-	-	-	-	1,232,312	1,232,312
Issuance of common stock and warrants pursuant to financing agreements	-	-	22,571,605	225,716	-	87,764,500	-	-	87,990,216
Issuance of common stock for options exercised	-	-	139,683	1,397	-	256,551	-	-	257,948
Repurchase of stock options to satisfy tax withholding obligations	-	-	-	-	-	(117,194)	-	-	(117,194)
Issuance of common stock from exercise of warrants	-	-	2,753,900	27,539	-	4,933,078	-	-	4,960,617
Stock issuance costs	-	-	-	-	-	(821,780)	-	-	(821,780)
Stock-based compensation expense, net of forfeitures	-	-	-	-	-	6,118,121	-	-	6,118,121
Foreign currency translation adjustment	-	-	-	-	-	-	(1,226,320)	-	(1,226,320)
Net loss	-	-	-	-	-	-	-	(27,471,568)	(27,471,568)
Balance at December 31, 2018	-	$ -	95,287,268	$ 953,667	$ (8,034,244)	$ 596,710,648	$ (1,226,320)	$ (478,941,285)	$ 109,462,466

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (27,471,568)	$ (10,770,202)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization for property and equipment	365,555	117,779
Net loss on disposal of furniture and equipment	5,346	-
Amortization of intangible assets	1,305,379	-
Stock-based compensation expense	6,118,121	650,440
Acquired in-process research and development	552,863	-
Change in fair value of investment in equity securities	320,112	-
Non-cash interest	708	7,476
Change in fair value of contingent rights	-	19,891
Changes in operating assets and liabilities:		
Prepaid expenses and other	(7,226,256)	(361)
Accounts payable	(1,097,170)	849,365
Payable to related party	(2,228,366)	2,228,366
Accrued liabilities	771,348	495,011
Net cash used in operating activities	(28,583,928)	(6,402,235)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from sale of furniture and equipment	590	-
Purchases of property and equipment	(1,131,113)	(934,702)
Acquisition of abbreviated new drug applications and related items	(20,642,969)	-
Net cash used in investing activities	(21,773,492)	(934,702)
CASH FLOWS FROM FINANCING ACTIVITIES		
Stock issuance costs	(821,780)	(462,841)
Proceeds from sale of common stock and warrants	87,990,216	23,870,786
Proceeds from exercise of stock options	257,948	325,999
Repurchase of stock options to satisfy tax withholding obligations	(117,194)	-
Proceeds from exercise of warrants	4,960,617	-
Net cash provided by financing activities	92,269,807	23,733,944
Effect of exchange rate change on cash and cash equivalents	(1,197,513)	-
Net increase in cash and cash equivalents	40,714,874	16,397,007
Cash and cash equivalents at beginning of year	43,489,935	27,092,928
Cash and cash equivalents at end of year	$ 84,204,809	$ 43,489,935
Supplemental disclosure of cash flow information:		
Interest paid	$ -	$ -
Income taxes paid	$ -	$ -
Non-cash financing activity:		
Warrant issued to placement agent	$ -	$ 28,880
Partial settlement of contingent rights derivative	$ -	$ 4,142,157
Non-cash investing activity:		
Disposal of fully depreciated property and equipment, at cost	$ 14,997	$ 7,523

See accompanying notes.

1. DESCRIPTION OF BUSINESS

CASI Pharmaceuticals, Inc. ("CASI" or the "Company") (Nasdaq: CASI) is a U.S. pharmaceutical company with a platform to develop and accelerate the launch of pharmaceutical products and innovative therapeutics in China, U.S., and throughout the world. The Company is focused on acquiring, licensing, developing and commercializing products that address areas of unmet medical needs. The Company intends to execute its plan to become a leading platform to launch medicines in the greater China market leveraging its China-based regulatory and commercial competencies and its global drug development expertise. The Company conducts substantially all of its operations through its wholly-owned subsidiary, CASI Pharmaceuticals (Beijing) Co., Ltd. ("CASI China"), which is headquartered in Beijing, China. CASI China has established China operations that are growing as the Company continues to further in-license or acquire products for its pipeline. On December 26, 2018, the Company established CASI Pharmaceuticals (Wuxi) Co., Ltd. ("CASI Wuxi") in China that will begin to develop a manufacturing capability in China in 2019. The Company currently operates in one operating segment, which is the development of innovative therapeutics addressing cancer and other unmet medical needs for the global market.

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 Melphalan Hydrochloride For Injection (EVOMELA®) 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, Ibritumomab Tiuxetan (ZEVALIN®) approved in the U.S. for advanced non-Hodgkin's lymphoma, and Vincristine Sulfate Liposome Injection (MARQIBO®) approved in the U.S. for advanced adult Ph- acute lymphoblastic leukemia (ALL). On March 1, 2019, Spectrum sold these products, along with the licenses and contracts relating thereto, to Acrotech Biopharma L.L.C. ("Acrotech"). The Company does not expect any material adverse effect on its operations to result from the sale.

In January 2018, the Company acquired a portfolio of 25 U.S. Food and Drug Administration ("FDA") approved abbreviated new drug applications (ANDAs), and four ANDAs that are pending FDA approval, from Sandoz, Inc. ("Sandoz"). 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.

In October 2018, the Company entered into an agreement with Laurus Labs Limited ("Laurus"), a company organized under the Laws of India, pursuant to which the Company acquired one U.S. FDA-approved ANDA for tenofovir disoproxil fumarate ("TDF"), which is indicated for the treatment of hepatitis B virus.

As a result, the Company's product pipeline features the following: (1) U.S. FDA approved hematology oncology drugs in-licensed for the greater China market, consisting of Melphalan Hydrochloride For Injection (EVOMELA), Ibritumomab Tiuxetan (ZEVALIN) and Vincristine Sulfate Liposome Injection (MARQIBO), (2) a portfolio of 26 FDA-approved abbreviated new drug applications ("ANDAs"), including entecavir and TDF indicated for hepatitis B virus; and (3) four pipeline ANDAs that are pending FDA approval. The Company intends to prioritize a select subset of the ANDAs for product registration and commercialization in China. In addition to these advanced products, the Company's pipeline includes a proprietary Phase 2 drug candidate, ENMD-2076, that the Company has previously determined not to pursue as a single agent, and instead is exploring the feasibility of combination as a clinical strategy. The Company also has proprietary early-stage immune-oncological potential candidates in preclinical development.

The Company's product mix reflects a risk-balanced approach between products in various stages of development, between products that are branded and non-branded, and between products that are proprietary and generic. The Company intends to continue building a significant product pipeline of high quality, as well as innovative drug candidates for commercialization in China and 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 the Company's FDA-approved ANDAs, the Company intends to select and commercialize certain niche products from the portfolio that complements its therapeutic focus areas and which offer unique market and cost-effective manufacturing opportunities in China and/or in the U.S.

The Company believes the China operations offer a significant market and growth potential due to extraordinary increase in demand for high quality medicine coupled with regulatory reforms in China that make it easier for global pharmaceutical companies to introduce new pharmaceutical products into the country. The Company will continue to in-license clinical-stage and late-stage drug candidates, and leverage its platform and expertise, and hope to be the partner of choice to provide access to the China market. The Company expects the implementation of its plans will include leveraging the Company's resources and expertise in both the U S and China so that the Company can maximize development and clinical strategies concurrently under U.S. FDA and China National Medical Products Administration (NMPA, formerly the China Food and Drug Administration) regulatory regimes. 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 commercial launches. In December 2018, the Company received NMPA approval of Melphalan Hydrochloride For Injection (EVOMELA), for:

- use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma, and
- the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.

The Company intends to begin commercializing this drug through CASI China beginning in 2019 using EVOMELA supplied through Spectrum and its suppliers. All future needs will be sourced from Acrotech and its suppliers.

The Company is building an internal commercial team to prepare for the launch of its first commercial product, Melphalan Hydrochloride for Injection (EVOMELA) in 2019. As part of the strategy to support the Company's future clinical and commercial manufacturing needs and to manage its supply chain for certain products, the Company has established CASI Wuxi to construct a cGMP manufacturing facility in Wuxi, China. The site is currently in the design and engineering phase with construction expected to begin in 2019. Through CASI China, the Company will focus on China market devoting more resources and investment going forward.

Liquidity Risks and Management's Plans

Since inception, the Company has incurred significant losses from operations and has incurred an accumulated deficit of $478.9 million as of December 31, 2018. The Company expects to continue to incur operating losses for the foreseeable future due to, among other factors, its continuing clinical and development activities.

In September 2018, the Company entered into securities purchase agreements with certain institutional investors, accredited investors and current stockholders, pursuant to which the Company agreed to sell up to 9,048,504 shares of its common stock with accompanying warrants to purchase 2,714,548 shares of its common stock in a $48.5 million private placement (the "September 2018 Offering"). The Company held its initial closing on September 24, 2018 and second closing on October 10, 2018, receiving total gross proceeds of $37.5 million. The Company does not expect to receive any further proceeds from the September 2018 Offering.

In March 2018, the Company entered into securities purchase agreements pursuant to which the Company issued 15,432,091 shares of its common stock with accompanying warrants to purchase 6,172,832 shares of its common stock and received $50 million in gross proceeds in a private placement. This financing included an investment from ETP Global Fund, L.P., a healthcare investment fund; the managing member of Emerging Technology Partners, LLC (the general partner of ETP Global Fund, L.P.) is the Company's Executive Chairman of the Board of Directors. The 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. (the ultimate general partner of IDG-Accel Growth and IDG-Accel Investors) is a member of the Company's Board of Directors.

Net proceeds from the 2018 financings are being used to prepare for the launch of the Company's first commercial product in China, Melphalan Hydrochloride For Injection (EVOMELA), to support the Company's business development activities, to advance the development of the Company's pipeline, to support its marketing and commercial planning activities, and for other general corporate purposes.

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. In November 2018, the Company committed to invest up to $80 million in cash and assets in CASI Wuxi in furtherance of its drug development strategy in China and made an initial cash investment of $21 million in February 2019 (see Note 8). The remaining investment will be made over the next three years.

Taking into consideration the cash balance as of December 31, 2018 and its commitments to fund CASI Wuxi, the Company believes that it has sufficient resources to fund its operations at least through March 29, 2020. 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. 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

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP 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 fair value determination and recoverability of intangible assets, clinical trial accruals, deferred tax assets and liabilities and valuation allowance, and stock-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.

Consolidation and Foreign Currency Matters

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.

The Company's reporting currency is the U.S. dollar. Prior to 2018, the functional currency of the Company's subsidiary based in China was the U.S dollar. However, as discussed in Note 3, 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, and that it may allow its subsidiary in China to generate operating revenues from the China marketplace in the future and potentially sustain its own operations without the necessity of parent support. Accordingly, effective January 1, 2018, the functional currency of the Company's subsidiary based in China was

changed to the local currency of the China Renminbi ("RMB"). Upon the change in functional currency, there was no material impact on the consolidated financial statements. Accordingly, beginning January 1, 2018 translation gains and losses relating to the financial statements of the Company's China subsidiaries are included as accumulated other comprehensive loss in the accompanying consolidated balance sheets. 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 estimated using an average periodic exchange rate. Net gains or losses resulting from foreign currency denominated transactions are included in the consolidated statements of operations. There were no material gains or losses from foreign currency exchange transactions for the years ended December 31, 2018 and 2017.

Concentrations of Risk

Credit Concentration Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains its U.S. and RMB cash in bank deposit accounts, which, at times, may exceed regulated insured limits. The Company believes it is not exposed to significant credit risk on cash and cash equivalents.

Vendor Concentration Risk

The Company has a sole supplier for its EVOMELA product. To date, it has been sourced solely from Spectrum and its suppliers, and all future needs will be sourced from Acrotech and its suppliers. The Company's ability to qualify other providers of EVOMELA is limited by FDA regulations.

Fair Value of Financial Instruments

The majority of the Company's financial instruments (consisting principally of cash and cash equivalents, prepaid expenses, accounts payable, and accrued liabilities) are carried at cost which approximates their fair values due to the short-term nature of the instruments. The Company's investment in equity securities is carried at fair value (see Note 5). The Company's Note Payable is carried at amortized cost which approximates fair value due to its classification as a short-term note payable.

See Note 14 for additional fair value disclosures.

Cash and Cash Equivalents

Cash and cash equivalents include cash and highly liquid investments with original maturities of less than 90 days.

Inventories

Inventories consist of raw materials and are stated at the lower of cost or net realizable value. Cost is determined using a first-in, first-out method. The carrying value of raw materials inventory was approximately $283,000 as of December 31, 2018 and is included in "prepaid expenses and other assets" in the accompanying consolidated balance sheets.

Impairment of Long-Lived Assets

In accordance with authoritative guidance issued by the Financial Accounting Standards Board ("FASB"), the Company evaluates the value reflected in its consolidated balance sheets of long-lived assets, such as property and equipment and definitive-lived intangible assets, 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. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be

generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. No impairment charges were recorded in 2018 and 2017.

Research and Development Expenses

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

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 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, the Company accrues an amount based on estimates of the remaining non-cancelable obligations associated with winding down the clinical trial. At December 31, 2018 and 2017, clinical trial accruals were $150,893 and $402,773, respectively, and are included in accounts payable in the accompanying consolidated balance sheets.

Stock-Based Compensation

The Company records compensation expense associated with service and performance-based stock options in accordance with provisions of authoritative guidance. The estimated fair value of service-based awards is generally amortized on a straight-line basis over the requisite service period and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period. The estimated fair value of performance-based awards is measured on the grant date and is recognized when it is determined that it is probable that the performance condition will be achieved.

Income Taxes

Income tax expense is recognized 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 and operating loss and tax credit carryforwards 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 uses a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The Company recognizes interest and penalties related to uncertain tax positions, if any, in income tax expense. As of December 31, 2018 and 2017, 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.

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 30,211,133 and 17,849,331 as of December 31, 2018 and 2017, respectively, were anti-dilutive and, therefore, were not included in the computation of weighted average shares used in computing diluted loss per share.

New Accounting Pronouncements

Recently Adopted Pronouncements

In January 2016, the FASB issued ASU 2016-01, "Financial Instruments–Overall: Recognition and Measurement of Financial Assets and Financial Liabilities." In February 2018, the FASB issued ASU 2018-03, "Technical Corrections and Improvements to Financial Instruments–Overall: Recognition and Measurement of Financial Assets and Financial Liabilities." The accounting standards primarily affect 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 adopted ASU 2016-01 and ASU 2018-03 on January 1, 2018 and recorded a cumulative effect adjustment that decreased accumulated deficit by approximately $1.2 million. Effective January 1, 2018, the adoption date, changes in the fair value of the Company's investments in equity securities are recognized in the consolidated statements of operations and comprehensive loss (see Note 5).

In January 2017, the FASB issued ASU No. 2017-01, *Clarifying the Definition of a Business* (Topic 805). The amendments in the update provide a screen to determine when a set is not a business. If the screen is not met, the amendments in the update (1) require that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments provide a framework to assist entities in evaluating whether both an input and a substantive process are present. Lastly, the amendments in the update narrow the definition of the term output so that the term is consistent with how outputs are described in Topic 606. The ASU is effective for annual periods and interim periods within those annual periods beginning after December 15, 2017; earlier adoption is permitted under certain criteria. The Company adopted this ASU on January 1, 2018. While this ASU did not have a material effect on the Company's financial statements on the date of adoption, the Company did follow the new guidance in determining that its acquisition of ANDAs from Sandoz in January 2018 and from Laurus Labs in October 2018 were asset acquisitions (see Notes 3 and 4).

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 adopted ASU 2017-09 in the first quarter of 2018 and the adoption of this ASU did not have a material effect on the consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting* which includes updated guidance for share-based payment awards issued to non-employees. The updated standard aligns the accounting for share-based payment awards for non-employees with employees, except for guidance related to the attribution of compensation costs for non-employees. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those annual periods for public business entities, with early adoption permitted. The Company early adopted this standard on October 1, 2018. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

Unadopted Pronouncements

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. The standard must be applied using a modified retrospective approach. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842) Targeted Improvements, which offers a transition option to entities adopting the new lease standard. Under the transition option, entities can recognize a cumulative effect

adjustment to the opening balance of retained earnings of the year in which the new lease standard is adopted, rather than in the earliest period presented in their financial statements.

The Company plans to elect the transition option provided, which will not require adjustments to comparative periods nor require modified disclosures in those comparative periods. Upon adoption, the Company expects to elect the transition package of practical expedients permitted within the new standard, which among other things, allows the carryforward of the historical lease classification. While the Company has not completed its analysis, based on its current lease portfolio the Company currently estimates that the adoption ASC 842 will result in approximately $2.5 million to $3.5 million of right of use assets and lease liabilities being reflected on its Consolidated Balance Sheet.

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.

3. ACQUISITION OF ABBREVIATED NEW DRUG APPLICATIONS FROM SANDOZ

On January 26, 2018, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Sandoz. Pursuant to the Asset Purchase Agreement, the Company acquired a portfolio of 29 ANDAs, including 25 ANDAs approved by the FDA and four pipeline ANDAs that are pending FDA approval, limited quantities of certain active pharmaceutical ingredient ("API"), and certain manufacturing and other information related to the products (collectively, the ANDAs, API and other information are referred to as the "Acquired Assets"). To facilitate the sale and transition, the parties also entered into several limited term ancillary arrangements.

The Acquired Assets enhance the Company's strategic focus to build a robust pipeline and commercialize quality drug candidates in China. The Company intends to select and commercialize certain products from the portfolio that have unique market and cost-effective manufacturing opportunities in China (and potentially in the U.S.).

The total purchase price for the Acquired Assets was $18.0 million in cash. The Company accounted for the purchase of the Acquired Assets as an asset acquisition (consisting of a concentrated group of similar identifiable assets, including ANDAs and API). The total purchase price, along with approximately $1.2 million of transaction expenses, was allocated to the Acquired Assets based on their relative estimated fair values, as follows:

ANDAs	$18,608,000
API	564,000
Total value	$19,172,000

Of the total value allocated to the ANDAs, approximately $553,000 was immediately expensed as acquired in-process research and development since the 4 underlying ANDAs have not been approved by the FDA upon acquisition. Of the total value allocated to the API, approximately $134,000 was immediately expensed as acquired in-process research and development since the Company does not intend to use all of the API. The allocated cost of the capitalized ANDAs will be amortized over their estimated useful lives of 13 years. The capitalized API will be expensed in the period it is used or if its value is otherwise impaired.

The fair values of certain acquired ANDAs were estimated using the discounted cash flow method (an income approach), which involves the use of unobservable Level 3 inputs (see Note 14). The ANDAs will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable; no such triggering events were identified during the period from the date of acquisition to December 31, 2018.

4. ACQUISITION OF ABBREVIATED NEW DRUG APPLICATION FROM LAURUS LABS

In October 2018, the Company entered into an agreement with Laurus, pursuant to which the Company acquired from Laurus one U.S. FDA-approved ANDAs for TDF, which is indicated for the treatment of hepatitis B virus. The total purchase consideration was $3.0 million.

In October 2018, the Company made an initial payment of $700,000, and in December 2018, CASI paid $1.3 million as the second milestone was achieved. The Company accounted for the purchase of the TDF ANDA as an

asset acquisition and recognized both payments to Laurus, along with $35,121 of transaction expenses, as the cost of the acquired intangible asset (see Note 14). The remaining $1.0 million of contingent consideration will be recorded as an increase to the intangible asset when the subsequent milestones are probable to be met. The Company is amortizing the acquired intangible asset over its estimated useful life of 13 years; any subsequent increase in asset cost as a result of recognizing the contingent consideration will be expensed on a straight-line basis over the asset's remaining life.

5. INVESTMENT IN EQUITY SECURITIES

The Company has an equity investment in the common stock of a publicly traded company. Before January 1, 2018, the Company recorded the investment at its cost basis of $0. Because the fair value of this equity investment was readily determinable as of December 31, 2017, the investment would have been accounted for as available-for-sale securities with any unrealized holding gains and losses reported through accumulated other comprehensive income ("AOCI") as of December 31, 2017. The fair value of the investment was approximately $1.2 million as of December 31, 2017. As a result of the error, the investment and AOCI were understated by $1.2 million as of December 31, 2017. The Company corrected the consolidated balance sheet as of January 1, 2018, by increasing investment in equity securities and AOCI by $1.2 million. The Company evaluated the error on both quantitative and qualitative basis and determined that the error was not material and did not affect the trend of net loss or cash flows in previously issued financial statements. Additionally, the Company determined that correcting the error in 2018 did not have a material impact to the consolidated financial statements for 2018. Beginning on January 1, 2018 with the adoption of ASU 2016-01, changes in the fair value of the Company's investments in equity securities are recognized in the consolidated statements of operations. Upon adoption on January 1, 2018, the Company recorded a cumulative effect adjustment that decreased AOCI and accumulated deficit by $1.2 million. The combined effect of correction of the immaterial error and the adoption of the ASU 2016-01 is to increase investment in equity securities and decrease accumulated deficit by $1.2 million as of January 1, 2018. The fair value of this security was measured using its quoted market price, a Level 1 input as of December 31, 2018 and 2017 (see Note 14). The following table summarizes the Company's investment as of December 31, 2018:

Description	Classification	Cost	Gross unrealized gains	Aggregate fair value
Common stock	Investment	$ -	$ 912,200	$ 912,200

Unrealized loss on the Company's equity investment for year ended December 31, 2018 was $320,112 and is recognized as change in fair value of investment in equity securities in the accompanying consolidated statements of operations and comprehensive loss.

6. PROPERTY AND EQUIPMENT

Furniture and equipment are stated at cost and are depreciated over their estimated useful lives of 3 to 5 years. Leasehold improvements are stated at cost and are amortized over the shorter of their useful lives or the lease term (see Note 17). Depreciation and amortization expense is determined on a straight-line basis. Depreciation and amortization expense was $365,555 and $117,779 in 2018 and 2017, respectively.

Property and equipment consists of the following:

	December 31,	
	2018	2017
Furniture and equipment	$1,697,294	$ 1,150,052
Leasehold improvements	739,390	268,734
	2,436,684	1,418,786
Less: accumulated depreciation and amortization	(686,054)	(372,272)
	$1,750,630	$1,046,514

The Company did not identify and recognize any impairment of its property and equipment in 2018 and 2017.

7. INTANGIBLE ASSETS

Intangible assets were acquired as part of the 2018 asset acquisitions from Sandoz and Laurus and include ANDAs for a total of 26 previously marketed generic products (see Notes 3 and 4). These intangible assets were originally recorded at relative estimated fair values based on the purchase price for the asset acquisitions and are stated net of accumulated amortization.

The ANDAs are being amortized over their estimated useful lives of 13 years, using the straight-line method. Management reviews finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable, in a manner similar to that for property and equipment. No impairment losses related to intangible assets were recognized in the year ended December 31, 2018.

Net definite-lived intangible assets at December 31, 2018 consists of the following:

Asset	Gross Value	Accumulated Amortization	Estimated useful lives
ANDAs	$18,054,985	($1,291,775)	13 years
TDF ANDA	$ 2,035,121	($ 13,604)	13 years
Total	$20,090,106	($1,305,379)	

Expected future amortization expense is as follows for the years ending December 31:

2019	$1,546,691
2020	1,546,691
2021	1,546,691
2022	1,546,691
2023	1,546,691
2024 and thereafter	11,051,272

8. ESTABLISHMENT OF CASI WUXI

On December 26, 2018, the Company established CASI Wuxi to build and operate a manufacturing facility in the Wuxi Huishan Economic Development Zone in Jiangsu Province, China. The Company will invest, over time, $80 million in CASI Wuxi. The Company's investment will consist of (i) $21 million in cash (paid in February 2019), (ii) a transfer of selected ANDAs valued at $30 million, and (iii) an additional $29 million cash payment within three years from the date of establishment of CASI Wuxi. Additionally, Wuxi Jintou Huicun Investment Enterprise (Limited Partnership), a limited partnership organized under Chinese law, shall contribute the equivalent in RMB of USD $20 million in cash in CASI Wuxi. As of December 31, 2018, both parties have not made their first contribution.

9. NOTE PAYABLE

As part of the license arrangements with Spectrum (see Note 16), the Company issued to Spectrum a $1.5 million 0.5% secured promissory note originally due March 17, 2016, which was subsequently amended and extended to September 17, 2019. 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 each of the years ended December 31, 2018 and 2017, the Company recognized $7,500 of interest expense related to the promissory note.

10. STOCKHOLDERS' EQUITY

The Company had 170 million of authorized common stock and 5 million of authorized preferred stock at December 31, 2018 and 2017. The Company held 79,545 of shares of common stock in treasury at its acquisition cost at December 31, 2018 and 2017.

In September 2018, the Company entered into securities purchase agreements with certain institutional investors, accredited investors and current stockholders, pursuant to which the Company agreed to sell up to 9,048,504 shares of its common stock with accompanying warrants to purchase 2,714,548 shares of its common stock in a $48.5 million private placement. The purchase price for each share of common stock and warrant was $5.36. The warrants are exercisable on March 23, 2019 at a $7.19 per share exercise price and expire on September 24, 2021. In September and October 2018, the Company completed two closings and issued a total of 6,996,266 shares of its common stock with accompanying warrants to purchase 2,098,877 shares of its common stock and received $37.5 million in gross proceeds. The estimated fair value of the equity-classified warrants issued is $6,254,653 or $2.98 per warrant, calculated using the Black-Scholes-Merton valuation model with a contractual life of 3 years, an assumed volatility of 88.39%, and a risk-free interest rate of 2.89%.

In March 2018, the Company entered into securities purchase agreements with certain institutional investors, accredited investors and current stockholders, pursuant to which the Company issued 15,432,091 shares of its common stock with accompanying warrants to purchase 6,172,832 shares of its common stock and received $50 million in gross proceeds in a private placement. The purchase price for each share of common stock and warrant was $3.24. The warrants became exercisable on September 17, 2018 at a $3.69 per share exercise price and will expire on March 21, 2023. The estimated fair value of the equity-classified warrants issued is $15,062,000, or $2.44 per warrant, calculated using the Black-Scholes-Merton valuation model with a contractual life of 5 years, an assumed volatility of 75.4%, and a risk-free interest rate of 2.69%.

In February 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. 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. In 2018, the Company issued 143,248 Shares under the Sales Agreement resulting in net proceeds to the Company of approximately $475,000. As of December 31, 2018, approximately $24.5 million remained available under the Sales Agreement.

In October 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. 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 estimated fair value of the equity-classified 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 estimated fair value of the equity-classified 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%.

Stock purchase warrants activity for 2018 and 2017 is as follows:

	Number of Shares	Weighted Average Exercise Price
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
Issued	8,271,709	$4.58
Exercised	(2,753,900)	$1.80
Expired	-	-
Outstanding at December 31, 2018	11,781,825	$3.98
Exercisable at December 31, 2018	9,682,948	$3.28

All outstanding warrants are equity classified.

11. EMPLOYEE RETIREMENT PLAN

The Company sponsors the CASI Pharmaceuticals, Inc. 401(k) Plan and Trust. The plan covers substantially all U.S. 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 $151,148 and $70,167 in 2018 and 2017, respectively.

12. STOCK-BASED COMPENSATION

The Company has adopted various stock compensation plans for executive, scientific and administrative personnel of the Company, as well as outside directors and consultants. In June 2018, the Company's stockholders approved an amendment to the 2011 Long-Term Incentive Plan, increasing the number of shares of common stock reserved for issuance from 14,230,000 to 20,230,000 to be available for grants and awards. Stock options granted under the plans generally vest over periods varying from immediately to one to five years, are not transferable and generally expire ten years from the date of grant. As of December 31, 2018, a total of 6,834,234 shares remained available for grant under the Company's 2011 Long-Term Incentive Plan.

The Company's net loss for the twelve months ended December 31, 2018 and 2017 includes $6,118,121 and $650,440, 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:

	2018	2017
Research and development	$740,398	$271,733
General and administrative	5,377,723	378,707
Total share-based compensation expense	$6,118,121	$650,440

Compensation expense related to stock options is recognized over the requisite service period, which is generally the option vesting term of up to five years. Awards with performance conditions are expensed when it is probable that the performance condition will be achieved. For the years ended December 31, 2018 and 2017, $643,875 and $30,500, respectively was expensed for share awards with performance conditions that became probable during that period.

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 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.

Following are the weighted-average assumptions used in valuing the stock options granted to employees during the years ended December 31, 2018 and 2017:

	Year ended December 31,	
	2018	2017
Expected volatility	78.78%	78.88%
Risk free interest rate	2.80%	1.96%
Expected term of option	5.77 years	6.29 years
Expected dividend yield	0.00%	0.00%

The weighted average fair value of stock options granted was $4.49 and $0.73 in 2018 and 2017, respectively.

A summary of the Company's stock option plans and of changes in options outstanding under the plans during the years ended December 31, 2018 and 2017 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2016	9,535,306	$1.57		
Exercised	(154,545)	$2.11		$168,000
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		
Exercised	(156,283)	$1.65		$643,000
Granted	7,336,000	$4.01		
Expired	(285,594)	$1.55		
Forfeited	(50,130)	$3.28		
Outstanding at December 31, 2018	18,429,308	$2.44	7.61	$33,694,004
Exercisable at December 31, 2018	9,755,668	$1.57	6.21	$24,728,420

The aggregate intrinsic value is calculated as the difference between (i) the closing price of the common stock at December 31, 2018 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. Cash received from option exercises under all share-based payment arrangements for the year ended December 31, 2018 and 2017 was approximately $258,000 and $326,000, respectively.

In March 2018, the Compensation Committee of the Board of Directors (the "Board") approved a grant of stock options to the Company's Executive Chairman exercisable for 1.0 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 4.0 million shares of common stock that will vest if, within 18 months of the date of grant, specific operational and strategic milestones are achieved.

The following summarizes information about stock options that are outstanding at December 31, 2018:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31, 2018	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable at December 31, 2018	Weighted Average Exercise Price
$0.00 - $1.00	3,754,554	7.95	$ 0.93	2,458,613	$ 0.90
$1.01 - $2.00	6,859,938	5.98	$ 1.53	6,606,410	$ 1.54
$2.01 - $4.00	5,931,000	8.83	$ 3.18	425,788	$ 2.44
$4.01 - $7.00	1,642,000	9.10	$ 6.25	125,541	$ 6.25
$7.01 - $9.00	241,816	8.22	$ 8.01	139,316	$ 8.00
	18,429,308	7.61	$ 2.44	9,755,668	$ 1.57

As of December 31, 2018, there was approximately $8,844,000 of total unrecognized compensation cost related to non-vested stock options, excluding not-probable performance condition options. That cost is expected to be recognized over a weighted-average period of 3 years.

13. INCOME TAXES

As a result of net operating losses, the Company did not recognize a consolidated provision (benefit) for income taxes in either period. For financial reporting purposes, loss before taxes includes the following components:

	2018	2017
United States	$ (19,819,835)	$(8,658,120)
China	(7,651,733)	(2,112,082)
Total	$(27,471,568)	$(10,770,202)

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 and operating loss and tax credit carryforwards. Significant components of the Company's deferred income tax assets and liabilities as of December 31, 2018 and 2017 are as follows:

	December 31, 2018	2017
Deferred income tax assets:		
Net operating loss carryforwards	$ 97,701,000	$ 96,786,000
Research and development credit carryforward	8,957,000	9,592,000
Intangible assets	4,378,000	4,184,000
Equity-based compensation	4,075,000	3,812,000
Other	81,000	164,000
Valuation allowance for deferred income tax assets	(115,192,000)	(114,538,000)
Net deferred income tax assets	$ -	$ -

The Company has U.S. federal and state net operating loss (NOL) carryforwards of approximately $380,904,000 at December 31, 2018. The Company also has People's Republic of China ("PRC") NOL carryforwards of approximately $13,066,000 at December 31, 2018.

U.S. federal NOL carryforwards generated prior to 2018 begin to expire in 2019. The Company also has research and experimentation ("R&E") tax credit carryforwards of approximately $8,957,000 as of December 31, 2018 that begin to expire in 2019. 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.

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 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:

	2018	2017
Tax benefit at statutory rate	$ (5,769,000)	$ (3,662,000)
Effect of tax law change	-	52,258,000
State taxes	(1,098,000)	(290,000)
Net R&E credit adjustment	(7,000)	(185,000)
Net operating loss expiration	7,200,000	50,000
Nondeductible expenses	29,000	6,000
Change in valuation allowance	654,000	(48,117,000)
Other	(75,000)	125,000
Changes in applicable tax rates	(934,000)	(185,000)
	$ -	$ -

The Company had $3,198,000 of unrecognized tax benefits as of December 31, 2017 related to net R&E tax credit carryforwards. For the year ended December 31, 2018, there were net reduction of unrecognized tax benefits of $212,000 related to R&E tax credits. The Company has a full valuation allowance at December 31, 2018 and 2017 against the full amount of its net deferred tax assets and, therefore, there was no impact on the Company's financial position. The Company does not expect significant changes to the unrecognized benefit during 2019.

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

	2018	2017
Unrecognized tax benefits balance at January 1	$3,198,000	$3,133,000
Additions for Tax Positions of Prior Periods	-	3,000
Reductions for Tax Positions of Prior Periods	(214,000)	-
Additions for Tax Positions of Current Period	2,000	62,000
Unrecognized tax benefits balance at December 31	$2,986,000	$3,198,000

Due to the existence of tax attribute carryforwards (which are currently offset by a full valuation allowance), all of the Company's tax returns since 1998 are open to examination by the taxing authorities.

14. 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—Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

- Level 2—Observable market-based inputs other than quoted prices in active markets for identical assets or liabilities.

- Level 3—Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

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

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the hierarchy.

The Company has an equity investment in the common stock of publicly traded company. Beginning on January 1, 2018 with the adoption of ASU 2016-01, the Company's investment in this equity security is considered a trading security and is carried at its estimated fair value, with changes in fair value reported in the consolidated statement of operations and comprehensive loss each reporting period (see Note 5).

As part of the consideration for the licensing arrangements with Spectrum (see Note 16), the Company issued Spectrum certain contingent rights ("Contingent Rights") to purchase additional shares of its common stock, which Contingent Rights expire upon the occurrence of certain events. The Contingent Rights provided 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, and expired on the earlier of raising an aggregate of $50 million or September 17, 2019. Based on the terms and conditions of the Contingent Rights, the Company determined that the Contingent Rights were a derivative financial instrument that is not indexed to its common stock and therefore was 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 included estimates of the Company's future capital requirements, and the timing, probability, size and characteristics of those capital raises, among other inputs. Spectrum exercised its Contingent Rights and the Company issued Spectrum 1,519,096 shares of common stock during 2017. As a result of the exercise, the contingent right liability was fully settled as of December 31, 2018 and 2017.

The following tables presents the Company's financial assets and liabilities accounted for at fair value on a recurring basis as of December 31, 2018 and December 31, 2017, by level within the fair value hierarchy:

Description	Fair Value at December 31, 2018	Level 1	Level 2	Level 3
Investment in common stock	$ 912,200	$ 912,200	$ -	$ -
Contingent Rights	$ -	$ -	$ -	$ -

Description	Fair Value at December 31, 2017	Level 1	Level 2	Level 3
Investment in common stock	$ 1,232,312	$1,232,312	$ -	$ -
Contingent Rights	$ -	$ -	$ -	$ -

The following table sets forth a summary of changes in the fair value of Level 3 liabilities measured at fair value on a recurring basis for the year ended December 31, 2017:

Description	Balance at December 31, 2016	Change in Fair value	Settled in 2017	Balance at December 31, 2017
Contingent Rights	$ 4,122,266	$ 19,891	$(4,142,157)	$ -

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

In connection with entering into the various securities purchase agreements in 2018 and 2017, the Company issued shares of its common stock along with detachable stock purchase warrants. The Company allocates the proceeds received to the common stock and warrants on a relative fair value basis. The fair value of the common stock is based on quoted market price for the Company's common stock, a Level 1 input. The fair value of the stock purchase warrants is determined using the Black-Scholes-Merton option pricing model which uses Level 3 unobservable inputs. See Note 10 for discussion of the unobservable inputs used to estimate the fair value of the equity-classified stock purchase warrants.

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

The Company has no 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 and intangible assets, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the years ended December 31, 2018 and 2017.

In 2018 the Company acquired certain ANDAs pursuant to transactions accounted for as asset acquisitions. The intangible assets acquired from Sandoz (see Note 3) were estimated using the discounted cash flow method (an income approach), which involves the use of Level 3 inputs such as estimates for projected sales, expenses, and cash flows, expected income and value-added tax rates, and a required rate of return adjusted for both industry and Company-specific risks, among other inputs. The fair values of the remaining ANDAs were estimated using a multiple of values method (an income approach), which involved using Level 3 inputs such as estimated addressable markets and market penetration rates. The fair value of the API was estimated using Level 2 inputs, such as quoted market prices for similar API from various suppliers or other sources.

The intangible asset acquired from Laurus (see Note 4) was recognized at its estimate fair value which was determined based on the total purchase price paid (including transaction expenses) since only one asset was acquired.

15. RELATED PARTY TRANSACTIONS

The Company has supply agreements with Spectrum for the purchase of EVOMELA, ZEVALIN, and MARQIBO in China for quality testing purposes to support CASI's application for import drug registration and for commercialization purposes. The former CEO of Spectrum is also a member of CASI's Board and Spectrum is the Company's largest shareholder. In 2018, the Company entered into commercial purchase obligation commitments for EVOMELA from Spectrum for approximately $9.2 million. As of December 31, 2018, the Company paid $4,850,000 as a deposit for the purchase of EVOMELA expected to be delivered in 2019. The advance payments made to Spectrum are reflected as prepaid expense and other in the accompanying consolidated balance sheet as of December 31, 2018. Additionally, the Company incurred and paid $120,000 to Spectrum in 2018 for services to support the development of MARQIBO, which is included in research and development expense for the year ended December 31, 2018. In 2017, under supply agreements with Spectrum, the Company received shipments of EVOMELA, ZEVALIN, and MARQIBO, in China for quality testing purposes to support CASI's application for import drug registration. The total cost of the materials was approximately $2,705,000, which is included in research and development expense for the year ended December 31, 2017. 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. As of December 31, 2018, there were no material amounts payable to Spectrum.

Emerging Technology Partners, LLC ("ETP") incurred approximately $1.5 million of expenses on the Company's behalf for due diligence and related services (the "Services") for certain business development activities. The Company's Executive Chairman is the founder and managing member of ETP. The expenses incurred in connection with the Services is included as general and administrative expenses in the accompanying consolidated statement of operations for the year ended December 31, 2018; the amount was paid in October 2018.

The Company's Executive Chairman, and the Company's Chief Executive Officer played a key role in identifying and securing potential investors for the September 2018 Offering. As a result, the Company did not have to pay a commission to, or incur additional expenses for, a placement agent. In exchange for their services, which were deemed to be outside the scope of their responsibilities as officers and directors of the Company, the Company paid $1,380,000 and $120,000 to the Executive Chairman and the Chief Executive Officer, respectively. These payments are included as general and administrative expenses in the accompanying consolidated statement of operations for the year ended December 31, 2018; the amount was paid in October 2018.

16. LICENSE ARRANGEMENTS

The Company has certain product rights and perpetual exclusive licenses from Acrotech 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"):

Melphalan Hydrochloride For Injection (EVOMELA)("EVOMELA");
Ibritumomab Tiuxetan (ZEVALIN) ("ZEVALIN"); and
Vincristine Sulfate Liposome Injection (MARQIBO), ("MARQIBO").

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.

In March 2016, Spectrum received notification from the 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 NMPA accepted for review the Company's import drug registration application for EVOMELA and in 2017 granted priority review of the import drug registration clinical trial application (CTA). On December 3, 2018 the Company received NMPA's approval for importation, marketing and sales in China for EVOMELA. The Company is building an internal commercial team to prepare for the commercial launch EVOMELA in 2019. The Company is also preparing for a post-marketing study.

The Company is in various stages of the regulatory and development process to obtain marketing approval for ZEVALIN and MARQIBO in its territorial region, with ZEVALIN commercially available in Hong Kong. In 2017, the NMPA accepted for review the Company's import drug registration for ZEVALIN including both the antibody kit and the radioactive Yttrium-90 component. On February 12, 2019, the Company received NMPA's approval of the Company's CTA to allow for a confirmatory registration trial to evaluate the efficacy and safety of ZEVALIN. In 2016, the NMPA accepted for review the Company's import drug registration application for MARQIBO. On March 4, 2019 the Company received NMPA's approval of the Company's CTA to allow for a confirmatory registration trial to evaluate the efficacy and safety of MARQIBO. The Company intends to advance both of these products.

17. COMMITMENTS AND CONTINGENCIES

In 2018, the Company entered into purchase obligation commitments for EVOMELA from Spectrum for approximately $9.2 million. In March 2019, the Company entered into an additional purchase obligation commitment for EVOMELA from Spectrum for approximately $3.1 million. The Company expects all of the EVOMELA product to be delivered in 2019. As of December 31, 2018, the Company paid $4.8 million as a deposit for the purchase of EVOMELA. The deposits made to Spectrum are reflected as prepaid expense and other in the accompanying consolidated balance sheet.

In 2018, the Company committed to invest $80 million in CASI Wuxi, of which $21 million was invested in February 2019 (see Note 8).

In 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, 2018, 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 from Spectrum 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, if any, 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 2019. The Company does not anticipate any payment obligations for its MARQIBO program in 2019. The Company does anticipate sales of EVOMELA in 2019 which is expected to result in royalty payment obligations in 2019.

In April 2018, the Company entered into a lease agreement for office space in China that continues through April 2021. In October 2018, the Company entered into a lease agreement for additional office space in China that continues through November 2021. The Company also leases lab space in China that continues through May 2022. In October 2018, the Company amended the lease for its principal executive offices in Rockville, MD, effective November 1, 2018 to increase the total space covered under the lease to 6,068 square feet. The Company also extended the lease term from December 31, 2019 to July 31, 2022.

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

2019	$1,311,707
2020	1,297,102
2021	856,832
2022	129,918
Thereafter	-
Total minimum payments	$3,595,559

Rental expense for the years ended December 31, 2018 and 2017 was approximately $916,000 and $440,000, respectively. In 2018 the Company entered into a lease on behalf of CASI Wuxi; the minimum lease payments for this lease, totaling approximately $3,789,000 beginning in November 2019 and expiring in 2024 are not included in the above table.

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.

18. SUBSEQUENT EVENT

In March 2019, the Company entered into an exclusive distribution agreement with China Resources Guokang Pharmaceuticals Co., Ltd. ("CRGK"), pursuant to which CRGK will be the exclusive distributor of EVOMELA in the People's Republic of China (excluding Hong Kong, Macau and Taiwan).

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