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

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2019
OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

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)

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

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

Common Stock, $0.01 par value	Trading Symbol	NASDAQ
(Title of each class)	CASI	(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 ☒

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 ☒

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 ☒ 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 such files). Yes ☒ No ☐

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 ☒

As of June 30, 2019, the aggregate market value of the shares of common stock held by non-affiliates was approximately $194,144,774.

As of March 11, 2020, 99,023,760 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, 2019. 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.

CASI PHARMACEUTICALS, INC.
FORM 10-K - FISCAL YEAR ENDED DECEMBER 31, 2019

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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: the difficulty of executing our business strategy in China; our ability to design and implement a development plan for our ANDAs; the development of major public health concerns, including the coronavirus or other pandemics arising in China or elsewhere; 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 U.S. Food and Drug Administration (FDA), National Medical Products Administration (NMPA), or other regulatory 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 CID-103, CNCT19, and our other early-stage products under development; risks that result 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; our ability to protect our intellectual property rights; 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, 2019 (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 relate to events or information 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.

CASI Pharmaceuticals, Inc. ("CASI" or the "Company") (Nasdaq: CASI) is a U.S. biopharmaceutical company focused on developing and commercializing innovative therapeutics and pharmaceutical products with a product portfolio that includes approved and investigational assets. In August 2019, the Company launched its first commercial product, EVOMELA® (Melphalan for Injection), in China that is approved for use as a conditioning treatment prior to stem cell transplantation in the multiple myeloma setting. The Company's other core hematology/oncology assets in its pipeline include (i) an autologous CD19 CAR-T investigative product (CNCT19) being developed as a treatment for patients with B-ALL and B-NHL; (ii) CID-103, an anti-CD38 monoclonal antibody being developed for the treatment of patients with multiple myeloma; and (iii) greater China rights to ZEVALIN® (Ibritumomab Tiuxetan), a CD20-directed radiotherapeutic antibody, that is approved in the U.S. to treat patients with NHL. The Company's oncology assets also include China rights to (i) octreotide long acting injectable (LAI) microsphere formulation indicated for the treatment of certain symptoms associated with particular neuroendocrine cancers and acromegaly, and (ii) a novel formulation of thiotepa, which has multiple indications and a long history of established use in the hematology/oncology setting, both of which are being developed for import registration and market approval in China. The Company has established and continues to expand its operational expertise and execution capability as it further enhances its product and pipeline portfolio.

We believe our product mix reflects a risk-balanced approach between products in various stages of development, between products that are innovative, proprietary and generic, with a greater emphasis on innovative therapeutics. We intend to continue to pursue building a robust pipeline of drug candidates for development and commercialization in China as our primary market, and if rights are available for the rest of the world.

We believe the China operations offer a significant market and growth potential due to the extraordinary increase in demand for high quality medicine coupled with regulatory reforms in China that facilitate the entry of new pharmaceutical products into the country. We will continue to in-license clinical-stage and late-stage drug candidates, and leverage our cross-border operations 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 regulatory, development and clinical strategies in both countries.

The Company's EVOMELA, ZEVALIN and MARQIBO® assets were originally licensed from Spectrum Pharmaceuticals, Inc. ("Spectrum") and the Company had supply agreements with Spectrum to support the Company's application for import drug registration and for commercialization purposes. On March 1, 2019, Spectrum completed the sale of its portfolio of FDA-approved hematology/oncology products including EVOMELA, ZEVALIN and MARQIBO to Acrotech Biopharma L.L.C. ("Acrotech"). The original supply agreements with Spectrum were assumed by Acrotech; Spectrum agreed to continue with a short-term supply agreement for EVOMELA for the initial commercial product supply in connection with the Company's launch, with the long-term supply assumed by Acrotech.

As part of the long-term strategy to support our future clinical and commercial manufacturing needs and to manage our supply chain for certain products, on December 26, 2018, we established CASI Pharmaceuticals (Wuxi) Co., Ltd. ("CASI Wuxi") to develop a future manufacturing facility in China to be located in the Wuxi Huishan Economic Development Zone in Jiangsu Province, China. The site is currently in the design and engineering phase.

Since its inception in 1991, the Company has incurred significant losses from operations and, as of December 31, 2019, has incurred an accumulated deficit of $523.9 million. In 2012, the Company shifted its business strategy to China and has since built an infrastructure in China that includes sales and marketing, medical affairs, and regulatory and clinical development. In 2014, the Company changed its name to "CASI Pharmaceuticals, Inc." The majority of the Company's operations are now located in China. The Company expects to continue to incur operating losses for the foreseeable future due to, among other factors, its continuing clinical and development activities. Our operations in China are conducted through our wholly-owned subsidiary, CASI Pharmaceuticals (China) Co., Ltd. ("CASI China"), which is located in Beijing, China. Through CASI China, we will focus on the China market devoting more resources and investment going forward.

Taking into consideration the cash balance as of December 31, 2019, the Company believes that it has sufficient resources to fund its operations at least through March 16, 2021. As of December 31, 2019, the Company had a cash balance of $53.6 million of which approximately $2.6 million was held by CASI China, and approximately $22.1 million was held by CASI Wuxi. 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.

CORE PRODUCT AND CANDIDATES IN HEMATOLOGY/ONCOLOGY

EVOMELA® (Melphalan for Injection) - Launched In China

EVOMELA (Melphalan for Injection) is an intravenous formulation of melphalan commercialized by Acrotech (formally by Spectrum) in the multiple myeloma treatment setting in the United States. The EVOMELA formulation avoids the use of propylene glycol, which is used as a co-solvent in other formulations of melphalan. The use of the Captisol technology to reformulate melphalan in EVOMELA allows for greater stability when reconstituted, allowing for longer preparation and infusion times. In August 2019, CASI launched EVOMELA in China as its first commercial product. The Company is also preparing for a post-marketing study required as part of the National Medical Products Administration (NMPA) marketing approval.

CNCT19 (CD19 CAR-T). CNCT19 targets CD19, a B-cell surface protein widely expressed during all phases of B-cell development and a validated target for B-cell driven hematological malignancies. CD19-targeted CAR constructs from several different institutions have demonstrated consistently high antitumor efficacy in children and adults with relapsed B-cell acute lymphoblastic leukemia (B-ALL), chronic lymphocytic leukemia (CLL), and B-cell non-Hodgkin lymphoma (B-NHL). In June 2019, the Company acquired exclusive worldwide license and commercialization rights to CNCT19 from Juventas Cell Therapy Ltd. ("Juventas), a China-based domestic company engaged in cell therapy. Juventas will continue to be responsible for the clinical development and regulatory submission and maintenance of CNCT19 regulatory applications, with CASI's participation on the joint steering committee. CASI will be responsible for the launch and commercialization of CNCT19 and for the payment of certain future development milestones and sales royalties. The China NMPA has approved the clinical trial applications for CNCT19 in Phase 1 studies in B-NHL and B-ALL. Juventas is making preparations for the trials and the Company expects that the dosing of the first patient will occur during 2020.

CID-103 (anti-CD38 monoclonal antibody). CID-103 is a novel investigational anti-CD38 monoclonal antibody being developed for the treatment of patients with multiple myeloma. Preclinical data demonstrate CID-103 to have enhanced activity against a broad array of malignancies which express CD38 and potentially better safety and best in class when compared to other CD38 monoclonal antibodies. In April 2019, the Company acquired exclusive worldwide rights to CID-103 from Black Belt Therapeutics Limited, which had previously obtained the program from Tusk Therapeutics Ltd. CID-103 is at the IND/IMPD submission stage of development, with a Phase 1 study targeted to start in the United Kingdom during 2020. CASI is responsible for all development and commercialization activities of the CID-103 program.

ZEVALIN® (Ibritumomab Tiuxetan). As part of our license transaction with Spectrum pursuant to which we acquired greater China rights to core product EVOMELA, we also acquired the greater China rights to FDA-approved ZEVALIN. ZEVALIN is a CD20-directed radiotherapeutic antibody indicated for the treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL). The ZEVALIN therapeutic regimen consists of two components: rituximab, and Yttrium-90 (Y-90) a beta-emitting radioisotope. 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 the development, import drug registration, and market approval of ZEVALIN in China and currently is in the planning/execution stage for the registration study.

Thiotepa. The Company has exclusive China license and distribution rights to a novel formulation of thiotepa, a chemotherapeutic agent, which has multiple indications including use as a conditioning treatment for use prior to hematopoietic stem cell transplantation. Thiotepa has a long history of established use in the hematology/oncology setting. CASI intends to advance the development, import drug registration, and market approval of this product in China. The Company expects the clinical development program to begin during 2020.

OTHER ONCOLOGY ASSETS

Octreotide LAI. Octreotide LAI formulations are considered a standard of care for the treatment of acromegaly and for the control of symptoms associated with certain neuroendocrine tumors. In October 2019, the Company acquired exclusive China development and distribution rights for Octreotide LAI from Pharmathen Global BV. Octreotide LAI has been approved in various European countries. CASI intends to advance the development, import drug registration, and market approval of this product in China. The Company expects the clinical development program to begin during 2020.

ANDAs. In January 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. In October 2018, the Company acquired an additional ANDA for tenofovir disoproxil fumarate. In late 2018, the Chinese government announced and rolled out new drug pricing reforms, the so-called "4+7" volume-based drug procurement and tenders' scheme. The drug pricing reform is more conducive to the international pharmaceutical companies. It primarily impacts the volume-based drug procurement in the Chinese local market and did not affect the ANDA's global pricing. In 2019, the Company delisted 7 ANDAs to match the Company's strategic development. For the rest of the held ANDAs, the Company's primary focus is the global market. As a result, the Company assessed that the "4+7" pilot program will have a limited impact on the potential pricing of the ANDA drugs in the China local market.

MARQIBO (Vincristine Sulfate Liposome Injection). As part of our license transaction with Spectrum pursuant to which we acquired greater China rights to our core product EVOMELA, we also acquired the greater China rights to MARQIBO. MARQIBO is a novel, sphingomyelin/cholesterol liposome-encapsulated, formulation of vincristine sulfate, a microtubule inhibitor, 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 March 2019, the Company received NMPA's approval of the Company's Clinical Trial Application (CTA) to allow for a trial to evaluate its efficacy and safety. However, due to the evolving standard of care environment, the rare and niche indication for this product, and our commitment to prioritize resources for our other programs, the Company considers this product to be non-core and is currently evaluating its options for this product.

CASI WUXI

On December 26, 2018, the Company, together with Wuxi Jintou Huicun Investment Enterprise, a limited partnership organized under Chinese law ("Wuxi LP") established CASI Wuxi to build and operate a manufacturing facility in the Wuxi Huishan Economic Development Zone in Jiangsu Province, China. The Company holds 80% of the equity interests in CASI Wuxi and Wuxi LP holds 20%.

In November 2019, CASI Wuxi entered into a lease agreement for the right to use state-owned land in China for the construction of a manufacturing facility. Pursuant to the agreement, CASI Wuxi has committed to invest land use right and property, plant and equipment of RMB1 billion (equivalent to US$ 143 million) within three years from the date of establishment of CASI Wuxi. The timing of the development and investment plans are subject to further discussion with the government. The Company is currently in the design and engineering phase for the facility and assessing the construction plan and timeline.

BUSINESS DEVELOPMENT

CASI has built a fully integrated, world class biopharmaceutical company dedicated to the successful development and commercialization of innovative and other therapeutic products.

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, (2) proprietary or licensed innovative drug candidates, and (3) select high quality pharmaceuticals that fit our therapeutic focus. 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 with a focus on hematological malignancies is our principal clinical and commercial target, we are opportunistic about other therapeutic areas that can address unmet medical needs.

RELATIONSHIPS RELATING TO PROGRAMS

Contract Manufacturing for EVOMELA. 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 EVOMELA. As an import product into China, we expect that future supply of EVOMELA will be continue to be met by our partner Acrotech and its contract manufacturers.

China Distributor for EVOMELA. 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 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 Key Opinion Leaders (KOL), physicians, hospital centers and the generating of sales.

Contract Manufacturing for ZEVALIN and MARQIBO. As import products into China, we expect that any clinical trial materials or commercial supply needed will similarly be supplied by our partner Acrotech and its contract manufacturers. With regard to Marqibo, the Company is currently evaluating its development strategy and options in light of an evolving standard of care for the niche indication and our commitment to prioritize resources for our other programs.

For CNCT19, under our license agreement with Juventas, Juventas continues to be responsible for the clinical development and regulatory submission of CNCT19, including the phase 1 trials, as well as responsible for manufacturing and supplying CASI with the future commercial supply of CNCT19. The Company will be responsible for the launch and commercialization of CNCT19. As CASI has an established sales and marketing team in the hematology oncology therapeutic area, we expect that the Company's internal marketing and sales team will directly be responsible for CNCT19 commercial activities, including, for example, direct interaction with physicians, hospital centers and the generation of sales.

For CID-103, the Company is responsible for all development and commercialization activities of the CID-103 program. We expect that our clinical materials and commercial inventory will be supplied by one or more contract manufacturers with whom we are in current discussions.

For Octreotide LAI, under our agreement with Pharmathen Global BV ("Pharmathen"), Pharmathen will be responsible for manufacturing and supplying CASI with clinical materials and commercial inventory.

For Thiotepa, under our agreement with Riemser Pharma GmbH ("Riemser"), Riemser will be responsible for manufacturing and supplying CASI with clinical materials and commercial inventory.

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 regards to our in-licensed drug EVOMELA, and drug candidates ZEVALIN and MARQIBO, we have acquired exclusive licenses to intellectual property to enable us to develop and commercialize the drug candidates in our greater China commercial markets.

With regards to our in-licensed anti-CD38 antibody candidate CID-103, we have acquired an exclusive license to patents around CID-103 and other anti-CD38 antibodies. This license covers 50 pending applications worldwide, directed to the antibodies themselves and treatment methods using the antibodies. The pending applications includes 5 pending USA patent applications, and 5 corresponding pending applications in each of Australia, Canada, China, Europe, India, Japan, Korea, New Zealand, and Singapore. We intend to further expand our patent portfolio and in the submission stage of additional applications.

The patent term for any patents granted from the earliest of these pending applications will expire in June 2038, assuming all annuities are paid and not considering any term extensions for regulatory approval that might be available.

With regards to our drug candidates Octreotide LAI and Thiotepa, we have acquired exclusive licenses to intellectual property and the know-how to enable us to develop and commercialize the drug candidates in the China market.

With regards to our proprietary ENMD-2076, for which we have discontinued development, we maintain a patent portfolio that includes 22 granted patents or allowed patent applications with patent term for U.S. Patent No. 7,563,787 expiring on March 5, 2027, and the patent terms of our granted patents in other countries expiring on September 29, 2026, assuming all maintenance fees and annuities are paid. Although we have discontinued development of ENMD-2076 in order to prioritized other aspects of our pipeline, such as our hematology oncology assets, our intellectual property for ENMD-2076 remains available for business development partnering.

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 research, development, testing, manufacture, labeling, sale, marketing, advertising, and distribution 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 the development and commercialization of drugs and biologics. 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 drugs or biologics. 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 and drugs, as the case may be.

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 and biologic candidates for regulatory approval is a costly and time-consuming process. Generally, a developer first must conduct preclinical studies in the laboratory and in animal model systems in accordance with applicable FDA requirements, including Good Laboratory Practice regulations, to gain preliminary information on an agent's effectiveness and to identify any safety problems. The results of these studies, together with manufacturing information and analytical data as well as protocols and detailed descriptions for proposed clinical investigations, are submitted to FDA as a part of an Investigational New Drug Application (IND) for a drug or biologic, which must become effective before human clinical trials of an investigational drug can begin. An IND application will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues, such as the conduct of the trials as outlined in the IND application, and places the clinical trial(s) on a clinical hold. In such a case, the IND application sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be certain that submission of an IND application will result in the FDA allowing clinical trials to begin.

We or our collaborators must then conduct adequate and well-controlled clinical trials, in accordance with applicable IND regulations, Good Clinical Practices ("GCPs"), and other clinical-trial related regulations, to establish the safety and efficacy of the candidate for each proposed indication 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. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an institutional review board ("IRB") for each institution where the trials will be conducted before the trial can begin, and each IRB must monitor the study until completion. Study subjects must provide informed consent and sign an informed consent form before participating in a clinical trial.

Clinical trials of drugs or biologics are normally done in three phases, although the phases may overlap or be combined. Phase 1 trials usually involve the initial introduction of the investigational candidate into humans to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase 2 trials normally involve trials in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks, and evaluate preliminarily the efficacy of the candidate for specific target indications. 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 may take several years to complete. Annual progress reports detailing the results of the clinical studies must be submitted to the FDA and IND safety reports must be submitted to the FDA and investigators within 15 calendar days for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. We or our collaborators, the FDA, or an IRB (with respect to a particular study site) may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after receiving initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of the product or, in certain circumstances, post-approval.

The FDA has various programs, including fast track designation, breakthrough therapy designation, priority review, accelerated approval, and, for regenerative medicine therapies, regenerative medicine advanced therapy designation, which are intended to expedite or simplify the process for the development, and FDA's review, of drugs and biologics (*e.g.*, granting approval on the basis of surrogate endpoints subject to post-approval trials). Generally, drugs or biologics that may be eligible for one or more of these programs are those intended to treat serious or life-threatening diseases or conditions, those with the potential to address unmet medical needs for those disease or conditions, and/or those that provide a meaningful benefit over existing treatments. Moreover, if a sponsor submits a marketing application for a product intended to treat certain rare pediatric or tropical diseases or for use as a medical countermeasure for a material threat, and that meets other eligibility criteria, upon approval such sponsor may be granted a priority review voucher that can be used for a subsequent application. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, these programs do not change the standards for approval and may not ultimately expedite the development or approval process.

If clinical trials of a product 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). For biological products, an applicant must file a Biologics License Application (BLA). In each case, FDA must approve the application before the product can be marketed commercially. NDAs and BLAs must include, among other things, detailed information about the product's chemistry, manufacture, controls, and proposed labeling and the results of preclinical studies and clinical trials. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of a drug, and safety, purity, and potency of a biologic, to the satisfaction of the FDA. A user fee must be paid with the submission of an NDA or BLA (unless a fee waiver applies) in order to support the cost of agency review, which is currently almost $3 million. FDA usually will inspect the facility or the facilities at which the drug is manufactured and will not approve the product unless the manufacturing and production and testing facilities are in compliance with current Good Manufacturing Practice (cGMP) regulations. In addition, FDA may also inspect clinical trial sites that generated data for the NDA or BLA as well as us or our collaborators as a clinical trial sponsor.

The testing and approval processes require substantial time and effort, and there can be no assurance that FDA will accept the application for filing or that any approval will be obtained on a timely basis, if at all. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, the FDA has ten months from the 60-day filing date in which to complete its initial review of a standard application and respond to the applicant. However, the time required by the FDA to review and approve NDAs and BLAs is variable and, to a large extent, beyond our control. Notwithstanding the submission of relevant data, the FDA may ultimately decide that an NDA or BLA does not satisfy its regulatory criteria and deny the approval. In such instance, FDA will issue a Complete Response Letter, describing all the deficiencies that the FDA has identified in an application that must be satisfactorily addressed before it can be approved. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Further, even if such additional information is submitted, the FDA may ultimately decide that the application does not satisfy the criteria for approval. The FDA may also refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee, but the Agency historically has tended to follow such recommendations. In addition, the FDA may condition marketing approval on the conduct of specific post-marketing studies to further evaluate safety and effectiveness or a Risk Evaluation and Mitigation Strategy (REMS) that may include both special labeling and controls, known as Elements to Assure Safe Use, on the distribution, prescribing, dispensing and use of a drug product. After approval is obtained, a marketed product is subject to continuing regulatory requirements and review relating to 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 consistent 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, mandated labeling changes, or withdrawal of the product from the market, as well as possible civil or criminal sanctions.

Drugs and biological products may be eligible to receive certain regulatory exclusivities upon approval. For example, a drug that constitutes a new chemical entity (*i.e.*, an active moiety that has not been previously approved in another NDA) is entitled to five years of exclusivity during which FDA may not accept an ANDA or 505(b)(2) NDA for filing referencing such chemical entity, unless a "Paragraph IV certification" is made in which case FDA may accept such applications four years after initial approval of the new chemical entity. In addition, three years of exclusivity can be awarded for applications (including supplements) containing the results of new clinical investigations (other than bioavailability studies) conducted by the applicant and essential to the FDA's approval of new versions or conditions of use of previously approved drug products, such as new indications, delivery mechanisms, dosage forms, strengths, or other conditions of use. A reference biological product is granted twelve years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. Moreover, a drug or biologic may receive orphan drug designation if intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product in the United States. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which restricts FDA from approving any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, by providing a major contribution to patient care, or in instances of an inability to assure drug supply.

FDA may approve generic drugs and biological products through abbreviated pathways. Generic drugs may be marketed upon approval of an ANDA, which contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved drug. Approval is generally supported by data from bioequivalence studies, rather than complete preclinical and clinical studies. Biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product are eligible for an abbreviated approval pathway. Although licensure of biosimilar or interchangeable products is generally expected to require less than the full complement of product-specific preclinical and clinical data required for reference products, the FDA has considerable discretion over the kind and amount of scientific evidence required to demonstrate biosimilarity and interchangeability. Under section 610 of the Further Consolidated Appropriations Act, 2020, entitled "Actions for Delays of Generic Drugs and Biological Products", generic drug and biosimilar developers may sue brand manufacturers, or generic or biosimilar manufacturers, to obtain sufficient quantities of reference product necessary for approval of the developers' generic or biosimilar product. If a generic drug or biosimilar developer is successful in its suit, the defendant manufacturer would be required to provide sufficient quantities of product on commercially-reasonable, market-based terms and may be required to pay the developer's reasonable attorney's fees and costs as well as financial compensation under certain circumstances. While intended to facilitate the timely entry of lower-cost generic and biosimilar products, we cannot determine what effect this new private right of action may have on the development and approval of generic drug and biosimilar products at this time.

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 or permanently bar companies and 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. FDA's debarment authority has also been expanded to apply to certain import-related offenses. In addition to debarment, the FDA has numerous enforcement and disciplinary powers, including the authority to withdraw approval of an application or to approve an application under certain circumstances, to suspend the distribution of all drugs approved or developed in connection with certain wrongful conduct, and various civil and criminal penalties. The FDA may also withdraw product approval or take other corrective measures if, among other things, 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 (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 (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 certain government healthcare programs (e.g., Medicare and Medicaid), 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 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 EVOMELA, which has been launched, ZEVALIN and 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 last amended on August 26, 2019, 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. The newly amended Law of the PRC on the Administration of Pharmaceuticals became effective on December 1, 2019.

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

The Marketing Authorization Holder System. Pursuant to the newly amended Law of the PRC on the Administration of Pharmaceuticals, the Marketing Authorization Holder System, previously implemented in a few pilot regions in China, is now implemented nationwide. Companies and research and development institutions can be drug marketing authorization holders after they receive drug approvals. The drug marketing authorization holder are responsible for their products throughout the life cycle, including nonclinical studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the newly amended law.

The marketing authorization holders may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed pharmaceutical manufacturers, and may engage pharmaceutical distribution enterprises with a valid drug distribution license to sell their products. Upon receiving the marketing authorizations from the NMPA, a drug marketing authorization holder may transfer its drug marketing authorization and the transferee should have the capability of quality management, risk prevention and control, and liability compensation to ensure the safety, effectiveness and quality controllability of drugs, and fulfill the obligations of the drug marketing authorization holder.

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 and the drug/API registration approval to produce pharmaceutical products and API for marketing in China. Pursuant to the newly amended Law of the PRC on the Administration of Pharmaceuticals, the GMP certification has been cancelled, but with its cancellation, drug manufacturing enterprises are still required to strictly comply with GMP requirements. GMP requirements 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. The drug manufacturing license is valid for five years, and must be renewed at least six months before its expiration date.

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, and Phase 4 clinical trials may be conducted at the post-marketing surveillance stage, 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.

Phase 4 –assess therapeutic efficacy and adverse reactions post-approval. The purpose is, by conducting a new drug's post-marketing study, to assess therapeutic efficacy and adverse reactions when the drug is widely used, to evaluate overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose, among others.

Collecting and Using Patients' Biospecimens and Derived Data. Foreign-invested sponsors that collect and use patients' biospecimens in clinical trials are required to file with the China Human Genetic Resources Administrative Office, or the HGRAO, under the Ministry of Science and Technology, or the MOST. In 2017, the MOST issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval for collecting and using human genetic resources for the purpose of commercializing a drug in the PRC. In June 2019, the State Council of PRC issued the Regulation on the Administration of PRC Human Genetic Resources, which formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities.

Pursuant to this new HGR Regulation, a new notification system (as opposed to the advance approval approach originally in place) was put in place for clinical trials using PRC patients' biospecimens at clinical study sites without involving the export of such specimens outside of China. Under the new rule, a notification filing specifying the type, quantity and usage of the biospecimens, among others, with the HGRAO is required before conducting such clinical trials. The collection and use of PRC patients' biospecimens in international collaboration in basic scientific research are still subject to the approval of the HGRAO.

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 first 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 and therapeutic efficacy of originator products. In 2016, the Chinese regulatory authorities announced that imported generic drugs must also pass the GQCE in China. 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 elevate 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.

Pricing. 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 to prevailing market price). 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 updated the NRDL in November 2019 to include 70 new drugs. Previous updates to the NRDL occurred in 2017 and 2009. In addition, there were also NRDL price negotiations in 2018 and 2019. 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 entering 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.

"4+7" Volume-based Drug Procurement and Tenders. In June 2018, the State Council decided to launch a new round of drug pricing and procurement reform. The reform policy aims to lower drug costs for patients, reduce transaction costs for enterprises, regulate drug use of hospitals, and improve the centralized drug procurement and pricing system. This reform is implemented mainly by the National Healthcare Security Administration, or the NHSA, a new agency established in 2018 as part of the institutional restructuring with a mandate for pricing and procurement of drugs and medical disposables. The NHC supports the reform by introducing policy that encourages purchasing and prescribing of the selected drug. The NMPA is responsible for the quality assurance of the drugs submitted for tenders.

The national pilot scheme for centralized volume-based drug procurement and tenders under the reform was launched in November 2018. The selected drugs must pass the GQCE on quality and effectiveness.

The centralized volume-based procurement is open to all approved enterprises that manufacture drugs on the government-set procurement list in China. Based on published results in 2019, the procurement list rise to 33 generic drugs and was expanded to 25 provinces.

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 approximately 125 full-time employees, 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 commercial, regulatory and related 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. We also lease office and laboratory space from a related party at 425 Eccles Ave South San Francisco, CA 94080. 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 approximately 110 full-time employees. Among its activities, our China operations help to oversee the Company's sales and marketing of EVOMELA and the anticipated commercial activities of our pipeline products, technology transfer, 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.

Investing in our securities involves a high degree of risk and uncertainty. Before making an investment decision, you should carefully consider the risks described below, and all other information contained or incorporated by reference in our filings with the SEC. We expect to update these Risk Factors from time to time in the periodic and current reports that we file with the SEC. Please refer to these subsequent reports for additional information relating to the risks associated with investing in our common stock. If any of such risks and uncertainties actually occurs, our business, financial condition, and results of operations could be severely harmed. This could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

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, 2019, we had an accumulated deficit of approximately $523.9 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 preclinical, clinical, marketing 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, commercial and other corporate transactions that could negatively affect our financial condition and prospects.

We may consider strategic, commercial, 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, we have funded our operations by 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 additional development efforts. We require significant capital for research and development for our product candidates, clinical trials, and marketing activities. 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 have limited 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 and commercialization of our products and product candidates.

We will require substantial funds in addition to our existing working capital to develop and commercialize our products and product candidates and to otherwise 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 and expansion of marketing and sales capabilities;
- manufacturing;
- the regulatory approval process; or
- product launch and distribution.

At December 31, 2019, we had cash and cash equivalents of approximately $53.6 million. We may continue to seek additional capital through public or private financing or collaborative agreements in 2020 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.

Risks Related to Doing Business in China

Our business and operations may be adversely affected by the recent coronavirus outbreak or other similar outbreaks.

For the fiscal year ended December 31, 2019, we generated $4.1 million in commercial revenues through sales of EVOMELA (Melphalan For Injection) in China. We have established and continue to expand our operational expertise and execution capability to further enhance our product and pipeline portfolio. In addition, as part of the strategy to support our future clinical and commercial manufacturing needs and to manage our supply chain for certain products, we plan to construct a cGMP manufacturing facility in Wuxi, China.

We are currently encountering operational limitations due to the outbreak of the coronavirus, or COVID-19, first reported in Wuhan, Hubei Province, China in December 2019. In response to COVID-19, the Chinese government has implanted quarantines in Wuhan and surrounding areas and implemented significant restrictions on travel. In addition, international carriers have suspended flights to parts of mainland China and Hong Kong. The Chinese government also has imposed work restrictions that prohibit many employees from going to work. These quarantines, travel bans, and other restrictions, including reprioritization by hospitals to attend to COVID-19 patients, have adversely affected our sales and marketing teams' ability to expand our commercial sales of EVOMELA. Numerous variables and uncertainties related to the COVID-19 outbreak limit our ability to assess the overall impact on our current business and future strategy.

In addition to affecting our current operations, a prolonged outbreak of COVID-19 or other significant contagious diseases in the human population in China or elsewhere could result in a widespread health crisis. Such a crisis could adversely affect the economies and financial markets of other countries, resulting in an economic downturn or limiting access to the capital markets to fund our short-term and long-term plans.

We conduct a majority of our operations in China, which exposes us to risks associated with operating outside of the U.S. 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.

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 cash and cash equivalents of approximately 171.9 million China Renminbi ("RMB"), valued at approximately $24.7 million in U.S. dollars as of December 31, 2019. On a consolidated basis this balance accounts for approximately 46% 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 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 the support of our in-licensing efforts. Furthermore, because repatriation of funds requires the prior approval of SAFE and the PBOC, such repatriation could be delayed, restricted or limited.

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.

The China government exerts substantial influence over the manner in which we must conduct our business activities.

The China government has exercised and continues to exercise substantial control over virtually every sector of the Chinese economy through regulation and state ownership. Our ability to operate in China may be harmed by changes in its laws and regulations, including those relating to taxation, import and export tariffs, environmental regulations, land use rights, property, healthcare regulations, and other matters. We believe that our operations in China are in material compliance with all applicable legal and regulatory requirements. However, the central or local governments of the jurisdictions in which we operate may impose new, stricter regulations or interpretations of existing regulations that would require additional expenditures and efforts on our part to ensure our compliance with such regulations or interpretations.

Accordingly, government actions in the future, including any decision not to continue to support recent economic reforms and to return to a more centrally planned economy or regional or local variations in the implementation of economic policies, could have a significant effect on economic conditions in China or particular regions thereof and could require us to divest ourselves of any interest we then hold in Chinese properties, subsidiaries, or joint ventures.

Uncertainties with respect to the China legal system may limit legal protections available to us and 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 the evolution of 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.

We are subject to the Foreign Corrupt Practice Act and China laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties for the purpose of obtaining or retaining business.

We are subject to the Foreign Corrupt Practice Act, or FCPA, and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by U.S. persons and issuers as defined by the statute, for the purpose of obtaining or retaining business. We have agreements with third parties and most of our operations are in China. China also strictly prohibits bribery of government officials. Our activities in China create the risk of unauthorized payments or offers of payments by our employees, consultants, sales agents, manufacturers and distributors, even though they may not always be subject to our control. Although it is our policy to implement safeguards to discourage these practices by our employees, our existing safeguards and any future improvements may prove to be less than effective, and our employees, consultants, sales agents, or distributors may engage in conduct for which we might be held responsible. Violations of the FCPA or Chinese anti-corruption laws may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition. In addition, the U.S. government may seek to hold us liable for successor liability of FCPA violations committed by companies in which we may invest or acquire in the future.

China regulations relating to investments in offshore companies by China residents may subject our China-resident stockholders, beneficial owners or our China subsidiary to liability or penalties, limit our ability to inject capital into our China subsidiary or limit our China subsidiary's ability to increase their registered capital or distribute profits to us.

The State Administration of Foreign Exchange , or SAFE, promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37, on July 4, 2014, which replaced the former circular commonly known as "SAFE Circular 75" promulgated by SAFE on October 21, 2005. SAFE Circular 37 requires China residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such China residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as increase or decrease of capital contributed by China individuals, share transfer or exchange, merger, division or other material event. In the event that a China shareholder holding interests in a special purpose vehicle fails to fulfill the required SAFE registration, the China subsidiaries of that special purpose vehicle may be prohibited from making profit distributions to the offshore parent and from carrying out subsequent cross-border foreign exchange activities, and the special purpose vehicle may be restricted in its ability to contribute additional capital into its China subsidiary. Moreover, failure to comply with the various SAFE registration requirements described above could result in liability under China law for evasion of foreign exchange controls. According to the Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment released on February 13, 2015 by SAFE, local banks will examine and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration, under SAFE Circular 37 from June 1, 2015.

According to SAFE Circular 37, our stockholders or beneficial owners, who are China residents, are subject to SAFE Circular 37 or other foreign exchange administrative regulations in respect of their investment in our company. We may not be aware of the identities of all of our stockholders or beneficial owners who are China residents, and we do not

know whether they are aware of SAFE Circular 37. We do not have control over our stockholders or beneficial owners and there can be no assurance that all of our China-resident stockholders or beneficial owners will comply with SAFE Circular 37 and subsequent implementation rules, and there is no assurance that the registration under SAFE Circular 37 and any amendment will be completed in a timely manner, or will be completed at all. The failure of our stockholders or beneficial owners who are China residents to register or amend their foreign exchange registrations in a timely manner pursuant to SAFE Circular 37 and subsequent implementation rules, or the failure of future stockholders or beneficial owners who are China residents to comply with the registration procedures set forth in SAFE Circular 37 and subsequent implementation rules, may subject such stockholders or beneficial owners or our China subsidiary to fines and legal sanctions. Failure to register or comply with relevant requirements may also limit our ability to contribute additional capital to our China subsidiaries and limit our China subsidiaries' ability to distribute dividends to us. Because a majority of our operating activities take place in and our strategic focus is on China, any such limitations would have a material adverse effect on our business, financial condition and results of operations.

We may be subject to fines and legal sanctions by SAFE or other China government authorities if we or our employees who are China citizens fail to comply with regulations relating to employee stock options granted by companies listed on exchanges outside of China to China citizens.

On February 15, 2012, SAFE promulgated the Circular on Relevant Issues Concerning the Foreign Exchange Administration for Domestic Individuals' Participating in the Share Incentive Plans of Overseas-Listed Companies, or SAFE Circular 7, replacing earlier rules promulgated in 2007. Under SAFE Circular 7, China resident individuals who participate in a share incentive plan of a company that is listed on an overseas exchange are required to register with SAFE and complete certain other procedures. All participants to a plan need to retain a China agent through Chinese subsidiaries of the overseas listed company to handle foreign exchange registration, account opening, funds transfer and remittance and other related matters. An overseas agent should also be designated to handle matters in connection with the exercise or sale of share awards and proceeds transferring for the share incentive plan participants. We believe that our share incentive plans for our China resident employees are in compliance with SAFE Circular 7; however, any failure to comply with these or similar regulations in the future may subject us or our Chinese employees to fines and legal sanctions imposed by SAFE or other government authorities and may prevent us from further granting options under our share incentive plans to our employees. Such events could adversely affect our business operations.

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 EVOMELA in greater China, which was launched in China in August 2019, and a pipeline that includes (i) global rights to an autologous CD19 CAR-T investigative product (CNCT19) being developed as a treatment for patients with B-ALL and B-NHL; (ii) global rights to CID-103, an anti-CD38 monoclonal antibody being developed for the treatment of patients with multiple myeloma; (iii) greater China rights to two U.S. Food and Drug Administration (FDA)-approved hematology oncology drugs, consisting of ZEVALIN and MARQIBO; (iv) China rights to an octreotide long acting injectable (LAI) microsphere formulation indicated for the treatment of certain symptoms associated with particular neuroendocrine cancers and acromegaly, and (v) to a novel formulation of thiotepa, which has multiple indications and a long history of established use in the hematology/oncology. Our commercial focus is primarily China; however, the majority of our drug candidates are still in clinical development in China.

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

On December 3, 2018, we received the NMPA approval for importation, marketing and sales in China for EVOMELA, and on August 12, 2019, we announced the commercial launch of EVOMELA in China. We will continue to spend our time, resources and efforts on the commercialization of EVOMELA in China; however, there are no guarantees that we will successfully commercialize EVOMELA 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 National Reimbursement Drug List ("NRDL"). The China government recently announced the latest NRDL on August 20, 2019. Provincial governments have some discretion to add 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 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 EVOMELA through self-pay.

Even when EVOMELA has been included in a government hospital formulary, the NDRL or the provincial reimbursement drug lists, 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 EVOMELA, and sales revenues from EVOMELA will be materially and adversely affected. In addition, we need to ensure that EVOMELA has been quickly added to hospitals' formulary. If we were unable to quickly add EVOMELA to hospitals' formulary, doctors and patients will not have access to EVOMELA through hospital pharmacies.

The restructuring 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 the State Administration for Market Regulation ("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 has completed the restructuring at the state level, but municipal and county-level restructuring are still ongoing.

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 into 2020. 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 reshuffling.

In addition, the recently 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 EVOMELA, our revenue from such sales is largely expected to be self-paid by patients, which may make our drug candidates less desirable. Even if the NHSA or any of its local counterparts include EVOMELA in the NRDL or provincial Reimbursement Drug List, 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 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.

The success of our 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 intend to invest approximately $80 million in CASI Pharmaceuticals (Wuxi) Co., Ltd, a joint venture that will build and operate a manufacturing facility in the Wuxi Huishan Economic Development Zone in Jiangsu Province, China. As of December 31, 2019, we have invested $21 million in cash, transferred selected ANDAs valued at $30 million and will invest an additional $29 million in cash in the future. 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.

Risks Relating to Our Auditors

The audit reports included in this Annual Report on Form 10-K are prepared by auditors who are not currently inspected by the PCAOB and, as such, our stockholders are deprived of the benefits of such inspection.

As an auditor of companies that are publicly traded in the U.S. 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 U.S. 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 its audit reports 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. Such 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 U.S. 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 Capital Market. 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 U.S. 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 Business

The regulatory approval process of the regulatory authorities in the U.S. 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;
- delays in subject enrollment or interruptions in clinical trial supplies or investigational product;
- 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 or biologic 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 product candidates, the commercial prospects of that candidate may be harmed, and our ability to generate product sales revenues from any of those candidates may be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our 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 product candidates.

Our success in commercializing these drugs and biologics 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;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization;
- generic and biosimilar competition; and
- regulatory exclusivities or patents held by competitors that may inhibit our products' entry to the market.

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.

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 EVOMELA or any other product candidates.

We are in the process of building our sales and marketing team with technical expertise and supporting distribution capabilities to successfully commercialize EVOMELA and our other product candidates. We may not be able to hire a sales force in 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 capabilities, distribution capabilities or external infrastructure would adversely impact the commercialization of 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 EVOMELA and future products.

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 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; and
- 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 sale and marketing infrastructure and a distribution network, we will have difficulty commercializing EVOMELA and our future product revenue will suffer, which would adversely affect our business and financial condition. If we decide to enter into arrangements with third parties to perform sales, marketing and other 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 may 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 may 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 candidates 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 products 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 or biologic for marketing, the product's sponsor must comply with several post-marketing obligations that continue until the product is discontinued. These post-marking obligations include the reporting of adverse events to the agency within specified timeframes, 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. FDA may also require or request the withdrawal of the product from the market. Any of these post-marketing regulatory actions could materially affect our sales and, therefore, have the potential to adversely affect our business, financial condition, results of operations and cash flows.

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 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 FFDCA, and its regulations which prohibit, among other things, the introduction or delivery for introduction into interstate commerce of any food, drug, device, biologic, or cosmetic that is adulterated or misbranded;
- the PHSA, which prohibits, among other things, the introduction into interstate commerce of biological product unless a biologics license is in effect for that product;
- 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;
- HIPAA and its 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;
- 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 U.S. 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 rules 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 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 U.S. 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 U.S. 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 U.S., 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.

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 for our business success. The loss of any of these people could impede the achievement of our development and business objectives. We do not carry key man life insurance on the lives of any of our key personnel. There is intense competition for human resources, including management, in the scientific fields in which we operate and there can be no assurance that we will be able to attract and retain qualified personnel necessary for the successful development and commercialization 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 specialized consultants to assist us in formulating certain areas of our clinical and development 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 Intellectual Property

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 U.S., 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.

If we are unable to protect our intellectual property rights our business and competitive position would be harmed.

We have in-licensed worldwide rights to an investigational anti-CD38 monoclonal antibody and an anti-CD19 T-cell therapy product candidate, and we may in-license other product candidates in the future. Our success, competitive position and future revenues with respect to these product candidates will depend, in part, on our ability to protect our intellectual property. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We attempt to protect our proprietary position by maintaining trade secrets and by filing U.S. and foreign patent applications related to our in-licensed technology, inventions and improvements that are important to the development of our business. Our failure to do so may adversely affect our business and competitive position.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. We may not be able to protect our intellectual property rights throughout the world. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the U.S. or in many jurisdictions outside of the U.S. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property and therefore we cannot predict with certainty whether any patent applications that we have filed or that we may file in the future will be approved, will cover our products or product candidates or that any resulting patents will be enforced. In addition, third parties may challenge, seek to invalidate, limit the scope of or circumvent any of our patents, once they are issued. Thus, any patents that we own or license from third parties or joint venture or development partners may not provide any protection against competitors. Any patent applications that we have filed or that we may file in the future, or those we may license from third parties or joint venture or development partners, may not result in patents being issued. Moreover, disputes between our licensing or joint development partners and us may arise over license scope, or ownership, assignment, inventorship and/or rights to use or commercialize patent or other proprietary rights, which may adversely impact our ability to obtain and protect our proprietary technology and products. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies or products.

Patent protection for our anti-CD19 T-cell therapy product candidate may not be available and may be subject to infringement claims in China and other countries.

Although we have entered into an exclusive worldwide licensing and commercialization rights agreement with Juventas Cell Therapy Ltd., a China-based domestic company, for an autologous anti-CD19 T-cell therapy product candidate, Juventas retains ownership of, and all other rights to, the intellectual property rights associated with this product candidate. As a result, we are dependent on Juventas to ensure that its proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. Juventas has not filed patent applications covering this product candidate in China or in other countries. Accordingly, even if we are successful in commercializing an anti-CD19 T-cell therapy in China, Juventas may be unable to obtain intellectual property rights in China or in other countries, including the U.S. As a result, we may be unable to prevent other companies from competing with us or alleging

infringement by competitors. The lack of patent protection may limit our ability to sell our product and may severely and adversely affect our financial results, business and business prospects.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business

Third parties may assert patent or other intellectual property infringement claims against us, or Juventas, or our other licensors arising from the manufacture, use and sale of our current or future product candidates in China or in any other jurisdictions we ultimately commercialize in. The validity of our current or future patents or patent applications or those of our licensors may be challenged in litigation, interference or derivation proceedings, opposition, post grant review, inter parts review, or other similar enforcement and revocation proceedings, provoked by third parties or brought by us, may be necessary to determine the validity of our patents or patent applications or those of our licensors. Our patents could be found invalid, unenforceable, or their scope significantly reduced.

An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We have agreed not to develop or seek to commercialize any T-cell therapy product specifically binding to CD19.

Under the terms of our license agreement with Juventas Cell Therapy Ltd., unless otherwise agreed to by Juventas or specifically permitted under the license, we have agreed not to develop or seek to commercialize any other T-cell therapy product specifically binding to CD19 during the term of the license agreement and for three years thereafter. We also have agreed not to market or sell any such products during this period of time. As a result, we may not be able to develop or collaborate on other similar CD19 T-cell therapy products that could lead to a viable commercial product and could cause us to miss valuable future opportunities thus potentially severely and adversely affect our financial results, business and business prospects.

Risks Relating to Our Reliance on Third Parties or Natural Disasters

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 or deviates from regulatory requirements, GCPs, or the protocol, it could delay the approval of our FDA applications and our introduction of new products. 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, as well as any failure of us or our collaborators to effectively monitor and audit our CROs and clinical trials, could adversely affect clinical development of our products.

We have no current manufacturing capacity and rely on limited suppliers 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 products and we have limited experience in these activities. The manufacturing processes for the pipeline 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 of our products. If we engage directly in manufacturing, 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, including deviations from cGMP, could result in product defects, which could require us to delay shipment of products or recall products previously shipped, as well as regulatory action. 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. We expect our 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 cGMP 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 cGMP and who are able to produce our products in accordance with applicable regulatory standards. Failure by a manufacturer of our products to comply with cGMP 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 U.S., failure to comply with cGMP or other applicable legal requirements can lead to federal seizure of violated products, injunctive actions brought by the federal government, inability to export product, and potential criminal and civil liability on the part of a company and its officers and employees.

We or the third parties upon whom we rely on may be adversely affected by epidemic outbreaks, earthquakes, tornadoes, hurricanes or other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

We have offices in Rockville, Maryland, and a wholly owned subsidiary in Beijing, China through which substantially all of our operations are conducted. We also rely and intend to rely on third parties, including our clinical research organizations, third party manufacturers, and certain other important vendors and consultants in China and in United States. The occurrence of one or more epidemic outbreaks such as Ebola, Zika, SARS-CoV, COVID-19 or measles, natural disasters, such as tornadoes, hurricanes, fires, floods, hail storms and earthquakes, unusual weather conditions, terrorist attacks or disruptive political events in regions where we operate our business could adversely affect the operations of the third parties we rely on and our business, results of operations, financial condition and our prospects.

If an epidemic outbreak, natural disaster, power outage or other event occurred that prevented us or the third parties we rely on from using all or a significant portion of our or their offices, damaged critical infrastructure or disrupted operations, it may be difficult, or in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

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 2019, our stock price has ranged from $2.85 to $4.15. 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 EVOMELA and obtain regulatory approval for our other product candidates;
- issues in importation, marketing and sales of EVOMELA;
- the results of any future clinical trials of ZEVALIN or our other product candidates;
- the success of our joint venture to build and operate a manufacturing facility in China;
- the clinical development of CID-103 and CNCT19;
- 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, preclinical 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 s 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 15,034 square feet of office space. In addition, as of December 31, 2019, we leased approximately 6,068 square feet of office space in Rockville, Maryland. CASI Wuxi entered into a land lease in November 2019 to construct the Wuxi manufacturing facility. We also lease office and laboratory space from a related party at 425 Eccles Ave South San Francisco, CA 94080. 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 11, 2020, there were approximately 290 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

CASI Pharmaceuticals, Inc. ("CASI" or the "Company") (Nasdaq: CASI) is a U.S. biopharmaceutical company focused on developing and commercializing innovative therapeutics and pharmaceutical products, with a product portfolio that includes approved and investigational assets. In August 2019, the Company launched its first commercial product, EVOMELA® (Melphalan for Injection), in China that is approved for use as a conditioning treatment prior to stem cell transplantation in the multiple myeloma setting. The Company's other core hematology/oncology assets in its pipeline include (i) an autologous CD19 CAR-T investigative product (CNCT19) being developed as a treatment for patients with B-ALL and B-NHL; (ii) CID-103, an anti-CD38 monoclonal antibody being developed for the treatment of patients with multiple myeloma; and (iii) greater China rights to ZEVALIN® (Ibritumomab Tiuxetan), a CD20-directed radiotherapeutic antibody, that is approved in the U.S. to treat patients with NHL. The Company's oncology assets also include China rights to (i) octreotide long acting injectable (LAI) microsphere formulation indicated for the treatment of certain symptoms associated with particular neuroendocrine cancers and acromegaly, and (ii) a novel formulation of thiotepa, which has multiple indications and a long history of established use in the hematology/oncology setting, both of which are being developed for import registration and market approval in China. The Company has established and continues to expand its operational expertise and execution capability as it further enhances its product and pipeline portfolio.

We believe our product mix reflects a risk-balanced approach between products in various stages of development, between products that are innovative, proprietary and generic, with a greater emphasis on innovative therapeutics. We intend to continue to pursue building a robust pipeline of drug candidates for development and commercialization in China as our primary market, and if rights are available for the rest of the world.

We believe the China operations offer a significant market and growth potential due to the extraordinary increase in demand for high quality medicine coupled with regulatory reforms in China that facilitate the entry of new pharmaceutical products into the country. We will continue to in-license clinical-stage and late-stage drug candidates, and leverage our cross-border operations 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 regulatory, development and clinical strategies in both countries.

The Company's EVOMELA, ZEVALIN and MARQIBO® assets were originally licensed from Spectrum Pharmaceuticals, Inc. ("Spectrum") and the Company had supply agreements with Spectrum to support the Company's application for import drug registration and for commercialization purposes. On March 1, 2019, Spectrum completed the sale of its portfolio of FDA-approved hematology/oncology products including EVOMELA, ZEVALIN and MARQIBO to Acrotech Biopharma L.L.C. ("Acrotech"). The original supply agreements with Spectrum were assumed by Acrotech; Spectrum agreed to continue with a short-term supply agreement for EVOMELA for the initial commercial product supply in connection with the Company's launch, with the long-term supply assumed by Acrotech.

As part of the long-term strategy to support our future clinical and commercial manufacturing needs and to manage our supply chain for certain products, on December 26, 2018, we established CASI Pharmaceuticals (Wuxi) Co., Ltd. ("CASI Wuxi") to develop a future manufacturing facility in China to be located in the Wuxi Huishan Economic Development Zone in Jiangsu Province, China. The site is currently in the design and engineering phase.

Since its inception in 1991, the Company has incurred significant losses from operations and, as of December 31, 2019, has incurred an accumulated deficit of $523.9 million. In 2012, the Company shifted its business strategy to China and has since built an infrastructure in China that includes sales and marketing, medical affairs, and regulatory and clinical development. In 2014, the Company changed its name to "CASI Pharmaceuticals, Inc." The majority of the Company's operations are now located in China. The Company expects to continue to incur operating losses for the foreseeable future due to, among other factors, its continuing clinical and development activities. Our operations in China are conducted through our wholly-owned subsidiary, CASI Pharmaceuticals (China) Co., Ltd. ("CASI China"), which is located in Beijing, China. Through CASI China, we will focus on the China market devoting more resources and investment going forward.

Taking into consideration the cash balance as of December 31, 2019, the Company believes that it has sufficient resources to fund its operations at least through March 16, 2021. As of December 31, 2019, the Company had a cash balance of $53.6 million of which approximately $2.6 million was held by CASI China, and approximately $22.1 million was held by CASI Wuxi. 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.

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. On July 19, 2019, the Company entered into an amendment to the Sales Agreement reducing the maximum amount that may be sold under the Sales Agreement to $20 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 (the "Registration Statement") 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, 2019, approximately $19.5 million remained available under the Sales Agreement.

On July 19, 2019, the Company entered into an Open Market Sale Agreement℠ with Jefferies LLC (the "Open Market Agreement"). Pursuant to the terms of the Open Market Agreement, the Company may elect to sell from time to time, at its option, up to $30 million in shares of the Company's common stock, through Jefferies LLC, as sales agent. Any sales of shares pursuant to the Open Market Agreement will be made under the Company's Registration Statement and the related prospectus supplement and the accompanying prospectus, as filed with the SEC on July 19, 2019. As of March 16, 2020, the Company has issued approximately 493,000 shares with net proceeds of approximately $1,539,000.

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

Long-lived assets, including property and equipment, operating lease right-of-use ("ROU") assets and intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Such events and circumstances include the use of the asset or asset group in current research and development projects and any potential alternative uses of the asset or asset group. If circumstances require a long-lived asset or asset group be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary. Impairment charges recorded in 2019 were $386,000 related to fixed asset impairments, compared to $0 in 2018.

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, 2019 and 2018.

Operating Items

Revenues

Product Sales

Revenues consist of product sales of EVOMELA that launched during August 2019. Revenue was $4.1million for the year ended 2019 compared to $0 million for the year ended December 31, 2018.

Lease Income

Lease income consists primarily of an equipment lease with a Juventas (a related party). Lease income was $68,000 for the year ended December 31, 2019 compared to $0 for the year ended December 31, 2018.

Operating Expenses

Costs of Revenues

Costs of revenues consists primary of the cost of inventories of EVOMELA and sales-based royalties related to the sale of EVOMELA.

Costs of revenues were $3.9 million for the year ended December 31, 2019 compared to $0 million for the year ended December 31, 2018. The increase is due to the launch of EVOMELA that occurred during August 2019. Cost of revenues have been impacted by a transitional supply agreement that is in the process of being modified with an alternate manufacturer. We expect the unit cost of inventories of EVOMELA to be considerably reduced in the future.

Research and Development Expenses

Research and development (R&D) 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, facilities expenses, and amortization expense of acquired ANDAs.

Research and development expenses for the year ended December 31, 2019 were $9.7 million, compared with $8.5 million for the year ended December 31, 2018. The increase in R&D expenses primarily reflects higher regulatory costs associated with our ANDAs in 2019, costs incurred with the development of CID-103 and higher consulting and manufacturing related services.

Included in our research and development expenses for the year ended December 31, 2019 are direct project costs of $5.1 million related to our ANDAs acquired in 2018, $1.0 million for drugs in-licensed from Acrotech (previously Spectrum), $1.1 million for preclinical development activities primarily related to the CID-103 program, and $550,000 for preclinical development activities related to a terminated immune-oncology program. Research and development expenses for the year ended December 31, 2018 included direct project costs of $2.4 million related to our ANDAs acquired in January 2018, $1.2 million for drugs in-licensed from Spectrum, and $1.7 million for preclinical development activities primarily related to a terminated immune-oncology program.

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 for the year ended December 31, 2019 were $27.3 million, compared with $18 million for the year ended December 31, 2018. The increase was related to a combination of factors primarily related to the Company's growth in China. These factors include an increase in salary, benefits and recruitment expense and facilities costs due to increases in head count to prepare for the anticipated launch of the Company's first commercial

product (EVOMELA), professional services fees (including audit and legal services), and an increase in non-cash stock compensation expense largely attributed to stock options issued to CASI's CEO, President of CASI, and other employees.

Selling and Marketing Expenses

Selling and marketing expenses are the direct costs related to the sales of EVOMELA that was launched in China in August 2019 such as sales force salaries, advertising, and other marketing efforts.

Selling and marketing expenses for the year ended December 31, 2019 were $3.1 million, compared with $0 for the year ended December 31, 2018.

Acquired in-process Research and Development

Acquired in-process R&D expenses for year ended December 31, 2019 were $7.0 million, primarily relating to the acquired Black Belt and Octreotide licenses, compared with $0.7 million for the year ended December 31, 2018, primarily relating to acquired ANDAs in January 2018.

Non-Operating Items

Interest income, net

Interest income, net for the year ended December 31, 2019 was $1.1 million compared with $40,000 for the year ended December 31, 2018. The increase in interest income is mainly due to higher cash balances and cash management strategies implemented by the Company during 2019.

Foreign exchange gains

Foreign exchange gains for the year ended December 31, 2019 was $800,000 compared with $0 for the year ended December 31, 2018. The foreign exchange transactions recorded in the consolidated financial statements are primarily due to USD denominated cash accounts that are held by held by our Chinese subsidiaries.

Change in fair value of investment in equity securities

The change in fair value of investment in equity securities for the year ended December 31, 2019 and 2018 was $288,000 and $320,00 respectively. The changes represent unrealized losses on the Company's equity investment securities.

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. Based on our current plans, we expect our current available cash and cash equivalents to meet our cash requirements for at least through March 16, 2021.

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, expansion of our operations, research and development, and for the acquisition of 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 stockholders may result, or the equity securities may have rights, preferences, or privileges senior to those of the holders of our common stock. If we fail to obtain additional capital when needed, we may be required to delay or scale back our commercialization efforts, our advancement of the Spectrum products, and the ANDA products, or plans for other product candidates, if any.

At December 31, 2019, we had cash and cash equivalents of approximately $53.6 million, with working capital of approximately $53 million. As of December 31, 2019, approximately $2.6 million of the Company's cash balance was held by the Company's wholly-owned subsidiary in China and approximately $22.1 million of the Company's cash balance was held by CASI Wuxi.

FINANCING ACTIVITIES

"Shelf" Registration Statement

We have an effective shelf registration statement, which allows us to 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.

Sales Agreements

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. On July 19, 2019, the Company entered into an amendment to the Sales Agreement reducing the maximum amount that may be sold under the Sales Agreement to $20 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 (the "Registration Statement") 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, 2019, approximately $19.5 million remained available under the Sales Agreement.

On July 19, 2019, the Company entered into an Open Market Sale Agreement℠ with Jefferies LLC (the "Open Market Agreement"). Pursuant to the terms of the Open Market Agreement, the Company may elect to sell from time to time, at its option, up to $30 million in shares of the Company's common stock, through Jefferies LLC, as sales agent.

Any sales of shares pursuant to the Open Market Agreement will be made under the Company's Registration Statement and the related prospectus supplement and the accompanying prospectus, as filed with the SEC on July 19, 2019. As of March 16, 2020, the Company has issued approximately 493,000 shares with net proceeds of approximately $1,539,000. As of December 31, 2019, there were approximately 59,000 shares issued with net proceeds of approximately $182,000.

INFLATION AND INTEREST RATE CHANGES

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

TABLE OF CONTRACTUAL OBLIGATIONS

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

OFF-BALANCE-SHEET ARRANGEMENTS

We had no off-balance sheet arrangements during fiscal year 2019.

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, 2019, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and President/Principal Financial Officer 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, and President/Principal Financial Officer 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, and President/Principal Financial Officer) to allow timely decisions regarding required disclosures. Based on such evaluation, our Chief Executive Officer, and President/Principal Financial Officer have concluded these disclosure controls and procedures are effective as of December 31, 2019.

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, 2019 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, and President/Principal Financial Officer, we conducted an assessment of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework 2013*. Based on our assessment, we concluded that our internal control over financial reporting was effective as of December 31, 2019. The effectiveness of our internal control over financial reporting as of December 31, 2019 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, 2019, 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, 2019, 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 sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the "consolidated financial statements"), and our report dated March 16, 2020 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 16, 2020

ITEM 9B. OTHER INFORMATION.

Our 2020 Annual Meeting of Stockholders will be held on June 16, 2020. 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, 2019.

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, 2019.

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, 2019.

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, 2019.

	(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	18,268,372	$ 2.58	11,389,078
Equity compensation plans not approved by security holders	0	$ 0.00	0
Total	18,268,372	$ 2.58	11,389,078

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, 2019.

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, 2019.

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)

1.2 Open Market Sale Agreement SM by and between CASI Pharmaceuticals, Inc. and Jefferies LLC dated July 19, 2019 (incorporated by reference from Exhibit 1.1 to our Current Report on Form 8-K filed on (July 19, 2019)

1.3 Amendment No. 1 to Common Stock Sales Agreement by and between CASI Pharmaceuticals, Inc. and H.C. Wainwright & Co., LLC dated July 19, 2019 (incorporated by reference from Exhibit 1.3 to our Current Report on Form 8-K filed on July 19, 2019)

3.1 Restated Certificate of Incorporation of CASI Pharmaceuticals, Inc. (incorporated by reference to exhibit 3.1 on our Form 10-Q for the quarter ended June 30, 2019 filed with the Securities and Exchange Commission on August 9, 2019)

3.2 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)

4.1 Description of Common Stock **

4.2 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)

4.3 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)

4.4 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 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)

10.5 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)

10.6 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)

10.7 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)

10.8 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)

10.9 Memorandum of Understanding, dated November 16, 2018, by and between Management Committee of Wuxi Huishan Economic Development Zone and CASI Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.20 of our Form 10-K filed with the Securities and Exchange Commission on March 29, 2019)

10.10 Investment Agreement, dated November 16, 2018, by and between Administrative Committee of Wuxi Huishan Economic Development Zone, Jiangsu Province and CASI Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.21 on our Form 10-K filed with the Securities and Exchange Commission on March 29, 2019)

10.11 Supplementary Agreement, dated November 16, 2018, by and between Administrative Committee of Wuxi Huishan Economic Development Zone, Jiangsu Province and CASI Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.22 on our Form 10-K filed with the Securities and Exchange Commission on March 29, 2019)

10.12 Shareholders' Agreement, dated November 16, 2018, between CASI Pharmaceuticals, Inc. and Wuxi Jintou Huicun Investment Enterprise (Limited Partnership) (incorporated by reference to Exhibit 10.23 on our Form 10-K filed with the Securities and Exchange Commission on March 29, 2019)

10.13 Lease Contract, by and between Wuxi Huishan New City Life Science & Technology Industry Development Co., Ltd. and CASI Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.24 on our Form 10-K filed with the Securities and Exchange Commission on March 29, 2019)

10.14 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 (incorporated by reference to Exhibit 10.25 on our Form 10-K filed with the SEC on March 29, 2019)

10.15 Labor Contract, effective as of September 1, 2018, between CASI (Beijing) Pharmaceuticals, Inc. and Wei (Larry) Zhang* (incorporated by reference to Exhibit 10.26 to the Company's Form 10-K filed with the SEC on March 29, 2019)

10.16 CASI Pharmaceuticals, Inc. 2011 Long Term Incentive Plan, as amended* (previously filed with, and incorporated herein by reference to the Company's Definitive Proxy Statement filed on April 30, 2019)

10.17 Exclusive Distribution Agreement, effective as of March 5, 2019, by and among CASI Pharmaceuticals, Inc, China Resources Guokang Pharmaceuticals Co., Ltd. and CASI (Beijing) Biopharmaceuticals Technology Co., Ltd. (incorporated by reference to Exhibit 10.1 to the Quarterly Report filed May 15, 2019)

10.18 Offer Letter from CASI Pharmaceuticals, Inc. to Dr. He dated March 22, 2019, effective April 2, 2019* (incorporated by reference to Exhibit 10.2 to the Quarterly Report filed May 15, 2019)

10.19 License Agreement by and between CASI Pharmaceuticals, Inc. and Black Belt Therapeutics Limited entered into as of April 16, 2019 (incorporated by reference to Exhibit 10.3 to the Quarterly Report filed May 15, 2019)+

10.20 Exclusive License Agreement by and between CASI Pharmaceuticals, Inc. and Juventas Cell Therapy Ltd. effective June 15, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q filed on August 9, 2019)+

10.21 Investment Agreement in respect of Juventas Cell Therapy Ltd effective June 15, 2019 (incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q filed on August 9, 2019)+

10.22 Contract for Assignment of the Right to the Use of the State-owned Construction Land (no. 3202842019CR0019) dated November 15, 2019 **

10.23 Form of CASI Pharmaceuticals, Inc. Performance-Contingent 2011 Long-Term Incentive Plan Non-Qualified Stock Option Grant Agreement (for Optionees in China)* (incorporated by reference to Exhibit 4.1 on our Quarterly Report on Form 10-Q filed May 15, 2019)

10.24 Form of CASI Pharmaceuticals, Inc. 2011 Long-Term Incentive Plan Non-Qualified Stock Option Grant Agreement (for Optionees in China)* (incorporated by reference to Exhibit 4.2 on our Quarterly Report on Form 10-Q filed May 15, 2019)

10.25 Form of CASI Pharmaceuticals, Inc. Performance-Contingent 2011 Long-Term Incentive Plan Non-Qualified Stock Option Grant Agreement (for Optionees in the US)* (incorporated by reference to Exhibit 4.3 on our Quarterly Report on Form 10-Q filed May 15, 2019)

10.26 Form of CASI Pharmaceuticals, Inc. 2011 Long-Term Incentive Plan Non-Qualified Stock Option Grant Agreement (for Optionees in the US)* (incorporated by reference to Exhibit 4.4 on our Quarterly Report on Form 10-Q filed May 15, 2019)

21 Subsidiaries of the Registrant **

23.1 Consent of Independent Registered Public Accounting Firm **

31.1 Rule 13a-14(a) Certification of Chief Executive Officer **

31.2 Rule 13a-14(a) Certification of Principal Financial Officer **

32.1 Rule 13a-14(b) Certification by Chief Executive Officer **

32.2 Rule 13a-14(b) Certification by Principal 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, 2019, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2019 and 2018, (ii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2019 and 2018, (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019 and 2018 (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018 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 240.24b-2. 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 16, 2020

CASI Pharmaceuticals, Inc.

By:/s/Wei-Wu He
Wei-Wu He
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/Wei-Wu He Wei-Wu He	Chief Executive Officer and Executive Chairman (Principal Executive Officer)	March 16, 2020
/s/Larry (Wei) Zhang Larry (Wei) Zhang	Principal Financial Officer	March 16, 2020
/s/James Z. Huang James Z. Huang	Director	March 16, 2020
/s/Franklin C. Salisbury Franklin C. Salisbury	Director	March 16, 2020
/s/Rajesh C. Shrotriya Rajesh C. Shrotriya	Director	March 16, 2020
/s/Y. Alexander Wu Y. Alexander Wu	Director	March 16, 2020
/s/ Quan Zhou Quan Zhou	Director	March 16, 2020

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 sheets of CASI Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years 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, 2019 and 2018, and the results of its operations and its cash flows for the years 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, 2019, 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 16, 2020 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 audits. 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 audits 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 audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG Huazhen LLP

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

Beijing, China
March 16, 2020

CASI Pharmaceuticals, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,621	$ 84,205
Investment in equity securities, at fair value	625	912
Accounts receivable, net of $0 allowance for doubtful accounts	1,293	-
Inventories	4,542	283
Prepaid expenses and other	1,420	7,165
Total current assets	61,501	92,565
Property and equipment, net	985	1,751
Intangible assets, net	16,895	18,785
Long-term investments	14,038	-
Right of use assets	8,708	-
Other assets	504	310
Total assets	$ 102,631	$ 113,411
LIABILITIES, REDEEMABLE NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,113	$ 968
Accrued liabilities	2,834	1,406
Note payable, net of discount	-	1,499
Total current liabilities	7,947	3,873
Other liabilities	1,019	74
Total liabilities	8,966	3,947
Commitments and contingencies (Note 20)		
Redeemable noncontrolling interest, at redemption value (Note 11)	20,670	-
Stockholders' equity:		
Preferred stock, $1.00 par value: 5,000,000 shares authorized and 0 shares issued and outstanding	-	-
Common stock, $.01 par value: 250,000,000 shares and 170,000,000 shares authorized at December 31, 2019 and 2018, respectively; 97,851,243 shares and 95,366,813 shares issued at December 31, 2019 and 2018, respectively; 97,771,698 shares and 95,287,268 shares outstanding at December 31, 2019 and 2018, respectively	979	954
Additional paid-in capital	606,686	596,712
Treasury stock, at cost: 79,545 shares held at December 31, 2019 and 2018	(8,034)	(8,034)
Accumulated other comprehensive loss	(2,728)	(1,227)
Accumulated deficit	(523,908)	(478,941)
Total stockholders' equity	72,995	109,464
Total liabilities, redeemable noncontrolling interest and stockholders' equity	$ 102,631	$ 113,411

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data)

	Year Ended December 31,	
	2019	2018
Revenues:		
Product sales	$ 4,063	$ -
Lease income	68	-
Total revenues	4,131	-
Costs and expenses:		
Costs of revenues	3,935	-
Research and development	9,748	8,507
General and administrative	27,336	17,997
Selling and marketing	3,103	-
Acquired in-process research and development	6,967	687
Total costs and expenses	51,089	27,191
Loss from operations	(46,958)	(27,191)
Non-operating income/(expense):		
Interest income, net	1,062	40
Foreign exchange gains	817	-
Change in fair value of investment in equity securities	(288)	(320)
Other income	5	-
Net loss	(45,362)	(27,471)
Less: loss attributable to redeemable noncontrolling interest	(395)	-
Accretion to redeemable noncontrolling interest redemption value	1,065	-
Net loss attributable to CASI Pharmaceuticals, Inc.	$ (46,032)	$ (27,471)
Net loss per share (basic and diluted)	$ (0.48)	$ (0.32)
Weighted average number of common shares outstanding (basic and diluted)	95,948	84,752
Comprehensive loss:		
Net loss	$ (45,362)	$ (27,471)
Foreign currency translation adjustment	(1,501)	(1,227)
Total comprehensive loss	$ (46,863)	$ (28,698)
Less: Comprehensive loss attributable to redeemable noncontrolling interest	(395)	-
Comprehensive loss attributable to common stockholders	$ (46,468)	$ (28,698)

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity
Years Ended December 31, 2019 and 2018
(In thousands, except share data)

	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, 2017	-	$ -	69,822,080	$ 699	$ (8,034)	$ 498,578	$ -	$ (452,702)	$ 38,541
Correction of immaterial error in prior year and cumulative effect adjustment due to the adoption of ASU 2016-01	-	-	-	-	-	-	-	1,232	1,232
Issuance of common stock and warrants pursuant to financing agreements	-	-	22,571,605	226	-	87,764	-	-	87,990
Issuance of common stock for options exercised	-	-	139,683	1	-	257	-	-	258
Repurchase of stock options to satisfy tax withholding obligations	-	-	-	-	-	(117)	-	-	(117)
Issuance of common stock from exercise of warrants	-	-	2,753,900	28	-	4,933	-	-	4,961
Stock issuance costs	-	-	-	-	-	(822)	-	-	(822)
Stock-based compensation expense, net of forfeitures	-	-	-	-	-	6,119	-	-	6,119
Foreign currency translation adjustment	-	-	-	-	-	-	(1,227)	-	(1,227)
Net loss attributable to CASI Pharmaceuticals, Inc.	-	-	-	-	-	-	-	(27,471)	(27,471)
Balance at December 31, 2018	-	$ -	95,287,268	$ 954	$ (8,034)	$ 596,712	$ (1,227)	$ (478,941)	$109,464
Issuance of common stock for options exercised	-	-	487,421	5	-	849	-	-	854
Repurchase of stock options to satisfy tax withholding obligations	-	-	-	-	-	(367)	-	-	(367)
Issuance of common stock pursuant to financing agreements	-	-	58,904	1	-	181	-	-	182
Issuance of common stock from exercise of warrants	-	-	1,938,105	19	-	3,256	-	-	3,275
Stock issuance costs	-	-	-	-	-	(190)	-	-	(190)
Stock-based compensation expense, net of forfeitures	-	-	-	-	-	7,310	-	-	7,310
Foreign currency translation adjustment	-	-	-	-	-	-	(1,501)	-	(1,501)
Net loss attributable to CASI Pharmaceuticals, Inc.	-	-	-	-	-	(1,065)	-	(44,967)	(46,032)
Balance at December 31, 2019	-	$ -	97,771,698	$ 979	$ (8,034)	$ 606,686	$ (2,728)	$ (523,908)	$ 72,995

See accompanying notes.

CASI Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31, 2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (45,362)	$ (27,471)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization for property and equipment	603	366
Net loss on disposal of property and equipment	2	5
Amortization of intangible assets	1,550	1,305
Write down of obsolete inventories	152	-
Loss on disposal of intangible assets	408	-
Impairment of equipment	386	-
Stock-based compensation expense	7,310	6,119
Acquired in-process research and development	6,967	553
Change in fair value of investment in equity securities	288	320
Non-cash interest	1	1
Changes in operating assets and liabilities:		
Accounts receivable	(1,293)	-
Inventories	(4,411)	(283)
Prepaid expenses and other assets	5,751	(6,944)
Right of use assets	424	-
Accounts payable	4,001	(1,097)
Payable to related party	153	(2,228)
Accrued liabilities and other liabilities	(173)	770
Net cash used in operating activities	(23,243)	(28,584)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from disposal of property and equipment	-	1
Purchases of property and equipment and intangible assets	(427)	(1,131)
Purchase of land use rights	(6,626)	-
Cash paid to acquire in-process research and development	(6,967)	-
Cash paid to acquire equity securities in Black Belt Tx Limited	(2,250)	-
Cash paid to acquire equity securities in Juventas Cell Therapy Ltd	(11,788)	-
Acquisition of Abbreviated New Drug Applications and related items	-	(20,643)
Net cash used in investing activities	(28,058)	(21,773)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayment of notes payable	(1,500)	-
Stock issuance costs	(190)	(822)
Proceeds from sale of common stock and warrants	182	87,990
Cash contribution from redeemable noncontrolling interest	20,000	-
Proceeds from exercise of stock options	854	258
Repurchase of stock options to satisfy tax withholding obligations	(367)	(117)
Proceeds from exercise of warrants	3,275	4,961
Payment of deferred offering costs	(209)	-
Net cash provided by financing activities	22,045	92,270
Effect of exchange rate change on cash and cash equivalents	(1,328)	(1,198)
Net increase (decrease) in cash and cash equivalents	(30,584)	40,715
Cash and cash equivalents at beginning of year	84,205	43,490
Cash and cash equivalents at end of year	$ 53,621	$ 84,205
Supplemental disclosure of cash flow information:		
Interest paid	$ 30	$ -
Income taxes paid	$ -	$ -

See accompanying notes.

1. DESCRIPTION OF BUSINESS

CASI Pharmaceuticals, Inc. ("CASI" or the "Company") (Nasdaq: CASI) is a U.S. biopharmaceutical company focused on developing and commercializing innovative therapeutics and pharmaceutical products, with a product portfolio that includes approved and investigational assets. In August 2019, the Company launched its first commercial product, EVOMELA® (Melphalan for Injection), in China that is approved for use as a conditioning treatment prior to stem cell transplantation in the multiple myeloma setting. The Company's other core hematology/oncology assets in its pipeline include (i) an autologous CD19 CAR-T investigative product (CNCT19) being developed as a treatment for patients with B-ALL and B-NHL; (ii) CID-103, an anti-CD38 monoclonal antibody being developed for the treatment of patients with multiple myeloma; and (iii) greater China rights to ZEVALIN® (Ibritumomab Tiuxetan), a CD20-directed radiotherapeutic antibody, that is approved in the U.S. to treat patients with NHL. The Company's oncology assets also include China rights to (i) octreotide long acting injectable (LAI) microsphere formulation indicated for the treatment of certain symptoms associated with particular neuroendocrine cancers and acromegaly, and (ii) a novel formulation of thiotepa, which has multiple indications and a long history of established use in the hematology/oncology setting, both of which are being developed for import registration and market approval in China. The Company has established and continues to expand its operational expertise and execution capability as it further enhances its product and pipeline portfolio.

The Company's EVOMELA, ZEVALIN and MARQIBO® assets were originally licensed from Spectrum Pharmaceuticals, Inc. ("Spectrum") and the Company had supply agreements with Spectrum to support the Company's application for import drug registration and for commercialization purposes. On March 1, 2019, Spectrum completed the sale of its portfolio of FDA-approved hematology/oncology products including EVOMELA, ZEVALIN and MARQIBO to Acrotech Biopharma L.L.C. ("Acrotech"). The original supply agreements with Spectrum were assumed by Acrotech; Spectrum agreed to continue with a short-term supply agreement for EVOMELA for the initial commercial product supply in connection with the Company's launch, with the long-term supply assumed by Acrotech.

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, we established CASI Pharmaceuticals (Wuxi) Co., Ltd. ("CASI Wuxi") to develop a future manufacturing facility in China to be located in the Wuxi Huishan Economic Development Zone in Jiangsu Province, China. The site is currently in the design and engineering phase.

Certain line items in the 2018 consolidated balance sheet and consolidated statement of cash flows relating to inventories have been reclassified to conform to the December 31, 2019 presentation. Inventories in the amount of $283,000 as of December 31, 2018, which was previously included in prepaid expenses and other, has been separately presented on the consolidated balance sheet as of December 31, 2018.

Liquidity Risks and Management's Plans

Since its inception in 1991, the Company has incurred significant losses from operations and, as of December 31, 2019, has incurred an accumulated deficit of $523.9 million. In 2012, the Company shifted its business strategy to China and has since built an infrastructure in China that includes sales and marketing, medical affairs, and regulatory and clinical development. In 2014, the Company changed its name to "CASI Pharmaceuticals, Inc." The majority of the Company's operations are now located in China. The Company expects to continue to incur operating losses for the foreseeable future due to, among other factors, its continuing clinical and development activities. The Company's operations in China are conducted through its wholly-owned subsidiary, CASI Pharmaceuticals (China) Co., Ltd. ("CASI China"), which is located in Beijing, China. Through CASI China, the Company will focus on the China market devoting more resources and investment going forward.

Taking into consideration the cash and cash equivalents balance as of December 31, 2019, the Company believes that it has sufficient resources to fund its operations at least through March 16, 2021. As of December 31, 2019, approximately $2.6 million of the Company's cash balance was held by CASI China, and approximately $22.1 million of the Company's cash balance was held by CASI Wuxi. 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.

New License and Investment Agreements

Black Belt Therapeutics Limited:

In April 2019, the Company entered into a license agreement with Black Belt Therapeutics Limited ("Black Belt") for exclusive worldwide rights to CID-103, an investigational anti-CD38 monoclonal antibody (Mab) (formerly known as TSK011010). CID-103 is at the IND/IMPD submission stage of development, with a Phase 1 study targeted to start in the United Kingdom during 2020. CASI is responsible for all development and commercialization activities of the CID-103 program. Under the terms of the agreement, CASI obtained global rights to CID-103 for an upfront payment of 5 million euros ($5,657,500) as well as certain milestone and royalty payments. Because CID-103 underlying the acquired rights has not reached technological feasibility and has no alternative uses, the Company expensed 5 million euros as acquired in-process research and development in the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2019.

The Company also invested 2 million euros ($2,249,600), representing 15% shareholding, as an equity investment in Black Belt TX Ltd, a newly established company of Black Belt focusing on novel immuno-oncology targets (see Note 5).

Juventas Cell Therapy:

In June 2019, the Company entered into a license agreement for exclusive worldwide license and commercialization rights to an autologous anti-CD19 T-cell therapy product (CNCT19) from Juventas Cell Therapy Ltd. ("Juventas"). Juventas is a China-based domestic company engaged in cell therapy. Juventas will continue to be responsible for the clinical development and regulatory submission and maintenance of CNCT19 regulatory applications, with CASI's participation on the joint steering committee. CASI will be responsible for the launch and commercialization of CNCT19 and for the payment of certain future development milestones and sales royalties. CNCT19 was engineered from the CD19 CAR-T, and is used to treat cancer patients with relapsed B-cell acute lymphoblastic leukemia (B-ALL), chronic lymphocytic leukemia (CLL), and B-cell non-Hodgkin lymphoma (B-NHL). The China National Medical Products Administration (NMPA) has approved the clinical trial applications for CNCT19 in Phase 1 studies in B-NHL and B-ALL. Juventas is making preparations for the trials and the Company expects that the dosing of the first patient will occur during 2020.

All contingent payments will be recognized when the subsequent milestones are probable to be met (see Note 20). CASI Biopharmaceuticals (WUXI) Co., Ltd. ("CASI Biopharmaceuticals") also invested RMB 80 million (approximately $11.8 million), representing 16.3% shareholding, as an equity investment in Juventas (see Note 5).

Pharmathen Global BV:

On October 29, 2019, the Company entered into an exclusive distribution agreement with Pharmathen Global BV ("Pharmathen") for the development and distribution of octreotide long acting injectable (Octreotide LAI) microsphere in China. Octreotide LAI formulations are considered a standard of care for the treatment of acromegaly and for the control of symptoms associated with certain neuroendocrine tumors. Octreotide LAI has been approved in various European countries. CASI intends to advance the development, import drug registration, and market approval of this product in China. The Company expects the clinical development program to begin during 2020.

The terms of the agreement include an upfront payment of 1 million euros, paid in 2019, and up to 2 million euros of additional milestone payments. CASI is responsible for the development, import drug registration, product approval and commercialization in China. CASI has a 10-year non-royalty exclusive distribution period after the product launch at agreed supply costs for the first three years.

Sales of EVOMELA

In December 2018, CASI received NMPA approval of EVOLEMA for the 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. In March 2019, CASI entered into an exclusive distribution agreement with China Resources Guokang Pharmaceuticals Co., Ltd. ("CRGK" or the "distributor"), pursuant to which it is the sole customer and distributor for the sale of EVOMELA in China. Commercial sales of EVOMELA were launched in August 2019. For the year ended December 31, 2019, the Company recognized $4.1 million of revenues from sales of EVOMELA under this arrangement.

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 significant accounting estimates relate to recoverability of intangible assets and long-term investments, net realizable value and obsolescence allowance for inventory, deferred tax assets and valuation allowance, allowance for doubtful accounts, 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

The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries, in which CASI, directly or indirectly, has a controlling financial interest. These subsidiaries include Miikana Therapeutics, Inc. ("Miikana"), CASI China, CASI Wuxi and CASI Biopharmaceuticals. 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.

Foreign Currency Translation and Transactions

The accompanying consolidated financial statements of the Company are reported in US dollars. The financial position and results of operations of the Company's subsidiaries in the PRC are measured using the Renminbi (RMB), which is the local and functional currency of these entities. Assets and liabilities of the Company's PRC subsidiaries are translated into US$ using the exchange rates in effect at the consolidated balance sheet date. The revenues and expenses of these entities are translated into US$ at the weighted average exchange rates for the period. The resulting translation gains (losses) are recorded in accumulated other comprehensive income (loss) as a component of shareholders' equity.

Transactions denominated in foreign currencies are remeasured into the functional currency at the exchange rates prevailing on the transaction dates. Foreign currency denominated financial assets and liabilities are remeasured at the exchange rates prevailing at the balance sheet date. Net gains or losses resulting from foreign currency denominated transactions are recorded in foreign exchange gain (losses) in the consolidated statements of operations.

Revenue Recognition

Product sales recognized in the consolidated statements of operations are considered revenue from contracts with customers and, accordingly, the Company recognizes revenue using the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price, including the identification and estimation of variable consideration;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when we satisfy a performance obligation.

The Company recognizes revenue on sales of EVOMELA when the control of the product is transferred to the distributor, which occurs upon delivery of the product to the carrier appointed by the distributor, in an amount that reflects the consideration to which the Company expects to be entitled to in exchange for the product, excluding amounts collected

on behalf of third parties (e.g. value-added taxes). Payment terms for these sales are due within 90 days. The arrangement does not include any variable consideration.

The costs of assurance type warranties that provide the customer the right to exchange purchased product that does meet appropriate quality standards are recognized when they are probable and are reasonably estimable. There was no product exchange during the year ended December 31, 2019. As of December 31, 2019, the Company did not incur, and therefore did not defer, any material costs to obtain or fulfill contracts. The Company did not have any contract assets or contract liabilities as of December 31, 2019.

Concentrations of Risk

Cash Concentration Risk

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 select other providers of EVOMELA is limited by FDA regulations.

Sales Concentration Risk

CRGK is the sole customer of the Company's EVOMELA product sales in China. All revenues for the year ended December 31, 2019 were generated from sales to CRGK in China, and all the Company's accounts receivable balance as of December 31, 2019 was due from CRGK.

The Company extends credit to CRGK on an unsecured basis and maintains an allowance for doubtful accounts for estimated losses inherent in its accounts receivable. In establishing the required allowance, management considers the historical losses, customer's financial condition, the amount of accounts receivables in dispute, the accounts receivables aging and the customer's payment pattern. The Company determined that no allowance for doubtful accounts was necessary as of December 31, 2019. The balance of accounts receivable as of December 31, 2019 has been subsequently collected.

Fair Value of Financial Instruments

The majority of the Company's financial instruments (consisting principally of cash and cash equivalents, accounts receivable, 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 also had a note payable which was paid off during the year ended December 31, 2019 (see Note 10). The Company's note payable was carried at amortized cost which approximates fair value due to its classification as a short-term note payable.

See Note 17 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 that are readily convertible to known amounts of cash.

Inventories

Inventories consist of EVOMELA finished goods and raw materials to be used in production of ANDAs and are stated at the lower of cost or net realizable value. Cost is determined using a first-in, first-out method. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Adjustments are recorded to write down the carrying amount of any obsolete and excess inventory to its estimated net realizable value based on historical and forecasted demand.

Costs of Revenues

Costs of revenues consist primarily of the cost of inventories of EVOMELA and sales-based royalties related to the sale of EVOMELA.

Investments

Investment in equity securities with readily determinable fair value are measured at fair values, and any changes in fair value are recognized in earnings. Where the fair value of an investment in equity securities is not readily determinable, the Company recognizes such investment in long-term investments, and uses the measurement alternative of cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

For equity investments measured at fair value with changes in fair value recorded in earnings, the Company does not assess whether those securities are impaired. For equity investments without readily determinable fair value, at each reporting period, the Company makes a qualitative assessment considering impairment indicators to evaluate whether the investment is impaired. Impairment indicators that the Company considers include, but are not limited to, (i) the deterioration of earnings performance, credit rating, asset quality, or business prospects of the investee, (ii) a significant adverse change in the regulatory, economic, or technological environment of the investee, (iii) a significant adverse change in the general market condition of either the geographic area or the industry in which the investee operates. If a qualitative assessment indicates that the investment is impaired, the Company has to estimate the investment's fair value and if the fair value is less than the investment's carrying value, the Company recognizes an impairment loss in non-operating expenses equal to the difference between the carrying value and fair value.

Dividend income is recognized in other income when earned.

Leases

The Company adopted Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* ("ASC 842") and subsequent amendments issued by FASB on January 1, 2019, using a modified retrospective method for leases that exist at, or are entered into after, January 1, 2019, and has not recast the comparative periods presented in the consolidated financial statements.

Prior to the adoption of ASC 842, operating leases were not recognized on the balance sheet of the Company, instead rent expenses with fixed escalating payments and/or rent holidays were recognized on a straight-line basis over the lease term.

Upon adoption of ASC 842, ROU assets and lease liabilities are recognized upon lease commencement for operating leases based on the present value of lease payments over the lease term. As the rate implicit in the lease cannot be readily determined, the Company uses incremental borrowing rate at the lease commencement date in determining the imputed interest and present value of lease payments. The incremental borrowing rate was determined based on the rate of interest that the Company would have to borrow an amount equal to the lease payments on a collateralized basis over a similar term. The incremental borrowing rate is primarily influenced by the risk-free interest rate of China and the US, the Company's credit rating and lease term, and is updated for measurement of new lease liabilities.

For operating leases, the Company recognizes a single lease cost on a straight-line basis over the remaining lease term.

The Company has elected not to recognize ROU assets or lease liabilities for leases with an initial term of 12 months or less; the Company recognizes lease expense for these leases on a straight-line basis over the lease term. In addition, the Company has elected not to separate non-lease components (e.g., common area maintenance fees) from the lease components.

Land use rights acquired are assessed in accordance with ASC 842 and recognized in right-of-use assets if they meet the definition of lease.

Impairment of Long-Lived Assets

Long-lived assets, including property and equipment, operating lease right-of-use ("ROU") assets and intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the

carrying amount of an asset may not be recoverable. Such events and circumstances include the use of the asset or asset group in current research and development projects and any potential alternative uses of the asset or asset group. If circumstances require a long-lived asset or asset group be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary. Impairment charges recorded in 2019 were $386,000 related to fixed asset impairments, compared to $0 in 2018.

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.

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 recognized on a straight-line basis over the requisite service period and 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. A valuation allowance is provided to reduce the amount of deferred income tax assets if it is considered more likely than not that some portion or all of the deferred income tax assets will not be realized.

The Company recognizes in its consolidated financial statements the impact of a tax position if a tax return position or future tax position is "more likely-than-not" to be sustained upon examination, based on the technical merits of the position. Tax positions that meet the "more-likely-than-not" recognition threshold are measured at the largest amount of tax benefit that has a greater than fifty percent likelihood of being realized upon settlement. The Company recognizes interest and penalties related to uncertain tax positions, if any, in income tax expense.

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 28,112,092 and 30,211,133 as of December 31, 2019 and 2018, 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).

Effective January 1, 2019, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2016-02, *Leases* ("Topic 842"). The guidance amends the accounting requirements for leases and requires lessees to recognize assets and liabilities related to long-term leases on the balance sheets and expands disclosure requirements regarding leasing arrangements. The Company adopted this guidance on a modified retrospective basis and used the following practical expedients:

- the Company did not reassess if any expired or existing contracts are or contain leases;
- the Company did not reassess the classification of any expired or existing leases.

Additionally, the Company made ongoing accounting policy elections whereby it (i) does not recognize Right-of-use ("ROU") assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combines lease and non-lease components for facilities leases, which primarily relate to ancillary expenses such as common area maintenance charges and management fees of operating leases.

Upon adoption of the new guidance on January 1, 2019, the Company recorded right of use assets of approximately $3.0 million and recognized lease liabilities of approximately $3.2 million. There was no cumulative effect impact to accumulated deficit as of January 1, 2019. No adjustments were made to prior comparative periods.

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 nonsubstantive. 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.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. The new guidance requires a customer in a cloud computing arrangement (i.e., hosting arrangement) that is a service contract to follow the internal-use software guidance in ASC 350-40 to determine which implementation costs to capitalize as assets or expense as incurred. Capitalized implementation costs related to a hosting arrangement that is a service contract will be amortized over the term of the hosting arrangement, beginning when the module or component

of the hosting arrangement is ready for its intended use. The update is effective for calendar-year public business entities in 2020. For all other calendar-year entities, it is effective for annual periods beginning in 2021 and interim periods in 2022. Early adoption is permitted. The Company early adopted this guidance effective January 1, 2019. The net impact to the financial statements was approximately $140,000 of capitalized cost.

Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 326)* ("ASU 2016-13") and subsequent amendments to the initial guidance including ASU No. 2018-19, ASU No. 2019-04, and ASU No. 2019-05 (collectively, "Topic 326"). Topic 326 requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost. This standard is effective for annual and interim periods beginning after December 15, 2019 and early adoption is permitted for annual and interim periods beginning after December 15, 2018. The adoption of the new standard is not expected to have a material impact on the consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting For Income Taxes*. The new guidance removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for goodwill and allocating taxes to members of a consolidated group. The new guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently accessing the impact that the new standards will have on its consolidated financial statements.

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

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.

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).

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 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, AT FAIR VALUE AND LONG-TERM INVESTMENTS

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 statement of operations each reporting period. The fair value of this security was measured using its quoted market price, a Level 1 input, and was approximately $0.6 million as of December 31, 2019 and $0.9 million on December 31, 2018 (see Note 17).

The following table summarizes the Company's investment as of December 31, 2019:

(In thousands) Description	Classification	Cost	Gross unrealized gains	Aggregate fair value
Common stock	Investment	$ -	$ 625	$ 625

Unrealized losses on the Company's equity investment for the year ended December 31, 2019 and 2018 were $288,000 and $320,000, respectively, and are recognized as change in fair value of investment in equity securities in the accompanying consolidated statements of operations and comprehensive loss.

In April 2019, in conjunction with its license agreement entered into with Black Belt, the Company made a 2 million euro ($2,249,600) equity investment in a newly established, privately held UK Company (see Note 1).

In June 2019, in conjunction with its license agreement entered into with Juventas, the Company, through its China subsidiary, made a RMB 80 million ($11,788,000) equity investment in Juventas, a privately held, China-based company (see Note 1).

As the Company does not have significant influence over operating and financial policies of Black Belt TX Ltd and Juventas, and the equity interests do not have readily determinable fair value, the investments in Black Belt TX Ltd and Juventas are stated at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment. The Company did not record any adjustments or impairments during the year ended December 31, 2019.

6. INVENTORIES

Inventories at December 31, 2019 and 2018 consisted of the following:

(In thousands)	December 31 2019	2018
Finished goods	$ 4,514	$ -
Raw materials	28	283
Total	$ 4,542	$ 283

Provisions to write-down the carrying amount of obsolete inventory related to ANDAs that were disposed to its estimated net realizable value amounted to $152,000 and $0 for the years ended December 31, 2019 and 2018, respectively, and were recorded as expenses in the consolidated statements of comprehensive loss.

7. LEASES

As discussed in Note 2, effective January 1, 2019, the Company adopted Topic 842. At the inception of a contract, the Company determines if the arrangement is, or contains, a lease. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Rent expense is recognized on a straight-line basis over the lease term.

The Company has made accounting policy elections whereby it (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combines lease and non-lease components for facilities leases, which primarily relate to ancillary expenses such as common area maintenance charges and management fees of its operating leases. Operating lease ROU assets are included in other assets (noncurrent) and operating lease liabilities (see below) are included in accrued liabilities and other liabilities (noncurrent) in the consolidated balance sheets as of December 31, 2019. As of December 31, 2019, the Company did not have any finance leases.

All of the Company's existing leases as of December 31, 2019 are classified as operating leases. As of December 31, 2019, the Company has five material operating leases for land, facilities and office equipment with remaining terms expiring from 2021 through 2069 and a weighted average remaining lease term of 49.16 years. The Company has fair value renewal options for three of the Company's existing leases, none of which are considered reasonably certain of being exercised or included in the minimum lease term. Weighted average discount rates used in the calculation of the lease liability is 5.16%. The discount rates reflect the estimated incremental borrowing rate, which includes an assessment of the credit rating to determine the rate that the Company would have to pay to borrow, on a collateralized basis for a similar term, an amount equal to the lease payments in a similar economic environment.

In November 2019, CASI Wuxi entered into a fifty-year lease agreement for the right to use state-owned land in China for the construction of a manufacturing facility. The land parcel is 74,028.40 square meters. The Company is currently in the design and engineering phase for the facility and assessing the construction plan and timeline. The Company classifies this lease as an operating lease. The Company prepaid all of the lease payments for the land use right in 2019 in the amount of RMB45 million (equivalent to US$6.6 million).

Rent expense for the year ended December 31, 2019 was approximately $1,315,000. There was no variable lease costs or sublease income for leased assets for the year ended December 31, 2019.

The impact of Topic 842 on the December 31, 2019 consolidated balance sheet was as follows:

(In thousands)	**December 31, 2019**
Right of use assets	$ 8,708
Accrued liabilities	1,182
Other liabilities	1,019
Total lease liabilities	$ 2,201

Supplemental cash flow information related to leases was as follows:

(In thousands)	**Year ended December 31, 2019**
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows	$ 1,315
Right of use assets obtained in exchange for lease obligations:	$ 2,157

A maturity analysis of our operating leases as of December 31, 2019 follows:

Future undiscounted cash flows:

(In thousands)	
2020	1,403
2021	892
2022	191
Thereafter	-
Total	2,486
Discount factor	(285)
Lease liability	2,201
Amounts due within 12 months	1,182
Non-current lease liability	$ 1,019

As previously disclosed in the consolidated financial statements for the year ended December 31, 2018 and under the previous lease standard (Topic 840), future minimum annual lease payments for the years subsequent to December 31, 2018 and in aggregate are as follows:

(In thousands)	
2019	$ 1,312
2020	1,297
2021	857
2022	130
Thereafter	-
Total minimum payments	$ 3,596

Rental expense for the year ended December 31, 2018 was approximately $916,000.

8. 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. Depreciation and amortization expense are determined on a straight-line basis. Depreciation and amortization expense were $603,000 and $366,000 in 2019 and 2018, respectively.

Property and equipment consist of the following:

	December 31,	
(In thousands)	2019	2018
Furniture and equipment	$ 1,305	$ 1,698
Leasehold improvements	792	739
Total property, plant and equipment, gross	2,097	2,437
Accumulated depreciation and amortization	(726)	(686)
Impairment of property, plant and equipment	(386)	-
	$ 985	$ 1,751

The Company recognized impairment of approximately $386,000 during the year ended December 31, 2019 related to equipment which was leased to a related party (see Note 18).

9. INTANGIBLE ASSETS

Intangible assets include ANDAs that were acquired as part of 2018 asset acquisitions and US marketed generic products and capitalized cost related to a cloud computing arrangement (CCA). 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 amortized over their estimated useful lives of 13 years, using the straight-line method. The cloud computing arrangement is amortized over its useful life of 5 years.

For the year ended December 31, 2019 and 2018 there were no intangible asset impairments.

Intangible assets at December 31, 2019 consists of the following:

(In thousands) Asset	Purchase Price	Accumulated Amortization	Estimated useful lives
ANDAs	$ 18,002	$ (3,122)	13 years
TDF ANDA	2,035	(185)	13 years
Others	210	(45)	5 years
Total	$ 20,247	$ (3,352)	

The changes in intangible assets for the year ended December 31, 2019 are as follows:

(In thousands)	
Balance as of December 31, 2018	$ 18,785
Additions	192
Disposal	(408)
Amortization expense	(1,550)
Foreign currency translation adjustment	(124)
Balance as of December 31, 2019	$ 16,895

Expected future amortization expense is as follows as of December 31, 2019:

(In thousands)	
2020	$ 1,540
2021	1,540
2022	1,540
2023	1,540
2024	1,499
2025 and thereafter	9,236

10. NOTE PAYABLE

As part of the license arrangements with Spectrum (see Note 18), 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 Sheet as of December 31, 2018. For the years ended December 31, 2019 and 2018, the Company recognized $5,600 and $7,500 of interest expense related to the promissory note, respectively. The note payable was paid off in September 2019 before the due date.

11. REDEEMABLE NONCONTROLLING INTEREST

On December 26, 2018, the Company, together with Wuxi Jintou Huicun Investment Enterprise, a limited partnership organized under Chinese law (“Wuxi LP”) established CASI Wuxi to build and operate a manufacturing facility in the Wuxi Huishan Economic Development Zone in Jiangsu Province, China. The Company holds 80% of the equity interests in CASI Wuxi and 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 (transferred in May 2019), and (iii) an additional $29 million cash payment within three years from the date of establishment of CASI Wuxi. Wuxi LP holds 20% of the equity interest in CASI Wuxi through its investment in RMB of $20 million in cash (paid in March 2019). As the transfer of ANDAs valued at $30 million was to the Company’s consolidated subsidiary (CASI Wuxi), the Company recognized the transfer of the ANDAs at their carrying value and did not recognize a gain on the transfer.

Pursuant to the investment contract between the Company and Wuxi LP and Articles of Association of CASI Wuxi, the Company has the call option to purchase the 20% equity interest in CASI Wuxi held by Wuxi LP at any time

within 5 years from the date of establishment of CASI Wuxi (i.e. up to December 26, 2023). Wuxi LP has the put option to require the Company to redeem the 20% equity interest in CASI Wuxi at any time after December 26, 2023. The redemption value under both the Company's embedded put option and Wuxi LP's embedded call option is equal to $20 million plus interest at the bank loan interest rate issued by the People's Bank of China for the period beginning with the initial capital contribution by Wuxi LP to the date of redemption. In addition, Wuxi LP has the put option to require the Company to redeem the 20% equity interest in CASI Wuxi at $20 million upon the occurrence of any of the following conditions: (i) the Company fails to fulfill its investment obligation to CASI Wuxi; (ii) CASI Wuxi suffers serious losses, discontinued operation, dissolution, goes into process of bankruptcy liquidation; or (iii) the Company substantially violates the investment contract and Articles of Association of CASI Wuxi.

The investment of Wuxi LP in CASI Wuxi is treated as redeemable noncontrolling interest and is classified outside of permanent equity on the consolidated balance sheets because (1) the noncontrolling interest is not mandatorily redeemable financial instruments, and (2) it is redeemable at the option of the holder, or upon the occurrence of an event that is not solely within the control of the Company. The Company initially recorded the redeemable noncontrolling interest at its fair value of $20 million. The carrying amount of the redeemable noncontrolling interest is subsequently recorded at the greater of the amount of (1) the initial carrying amount, increased or decreased for the redeemable noncontrolling interest's share of net income or loss in CASI Wuxi or (2) the redemption value, assuming the noncontrolling interest is redeemable at the balance sheet date. Accretion of the carrying amount of redeemable noncontrolling interest to the redemption value is recorded in additional paid-in capital.

Changes in redeemable noncontrolling interest during the year ended December 31, 2019 are as follows:

(In thousands)	
Balance as of December 31, 2018	$ -
Cash contribution by Wuxi LP	20,000
Share of CASI Wuxi net loss	(395)
Accretion of redeemable noncontrolling interest	1,065
Balance as of December 31, 2019	$ 20,670

12. STOCKHOLDERS' EQUITY

The Company had 250 million and 170 million of authorized common stock at December 31, 2019 and 2018, respectively. The Company had 5 million of authorized preferred stock as December 31, 2019 and 2018. The Company held 79,545 of shares of common stock in treasury at its acquisition cost at December 31, 2019 and 2018.

Common Stock Sales Agreements

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. On July 19, 2019, the Company entered into an amendment to the Sales Agreement reducing the maximum amount that may be sold under the Sales Agreement to $20 million.

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, 2019, approximately $19.5 million remained available under the Sales Agreement.

On July 19, 2019, the Company entered into an Open Market Sale Agreement℠ with Jefferies LLC (the "Open Market Agreement"). Pursuant to the terms of the Open Market Agreement, the Company may elect to sell from time to time, at its option, up to $30 million in shares of the Company's common stock, through Jefferies LLC, as sales agent.

Any sales of shares pursuant to the Open Market Agreement will be made under the Company's Registration Statement and the related prospectus supplement and the accompanying prospectus, as filed with the SEC on July 19, 2019. In 2019, the Company issued 58,904 shares under the Open Market Agreement resulting in net proceeds to the Company of approximately $182,000. At December 31, 2019, approximately $29.8 million remained available under the Open Market Agreement. Subsequent to December 31, 2019 and through March 16, 2020, the Company issued 434,336 shares under the Open Market Agreement, resulting in net proceeds to the Company of approximately $1,357,000.

Securities Purchase Agreements

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 ("September 2018 Offering"). 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 2018, the Company 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 Company does not expect to receive any further proceeds from the September 2018 Offering. 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%.

Stock purchase warrants activity for the year ended December 31, 2019 and 2018 is as follows:

	Number of Warrants	Weighted Average Exercise Price
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
Issued	-	$ -
Exercised	(1,938,105)	$ 1.69
Expired	-	$ -
Outstanding at December 31, 2019	9,843,720	$ 4.43
Exercisable at December 31, 2019	9,843,720	$ 4.43

All outstanding warrants are equity classified.

13. NET LOSS PER SHARE

Net loss per share (basic and diluted) was computed by dividing net loss attributable to common stockholders, considering the accretions to redemption value of the redeemable noncontrolling interest, by the weighted average number of shares of common stock outstanding. Outstanding stock options and warrants totaling 28,112,092 and 30,211,133 as of December 31, 2019 and 2018, respectively, were anti-dilutive and, therefore, were not included in the computation of weighted average shares used in computing diluted loss per share.

The following table sets forth the basic and diluted net loss per share computation and provides a reconciliation of the numerator and denominator for the periods presented:

(In thousands, except per share data)	Year Ended December 31, 2019	2018
Numerator:		
Net loss attributable to CASI Pharmaceuticals, Inc.	$ (46,032)	$ (27,471)
Denominator:		
Weighted average number of common shares	95,948	84,752
Denominator for basic and diluted net loss per share calculation	95,948	84,752
Net loss per share		
—Basic and diluted	$ (0.48)	$ (0.32)

14. EMPLOYEE BENEFIT 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 $217,000 and $151,000 in 2019 and 2018, respectively.

Full time employees of the Company in the PRC participate in a government mandated defined contribution plan, pursuant to which certain pension benefits, medical care, employee housing fund and other welfare benefits are provided to employees. Chinese labor regulations require that the PRC subsidiaries of the Company make contributions to the government for these benefits based on certain percentages of the employees' salaries. The Company has no legal obligation for the benefits beyond the contributions made. The total amounts for such employee benefits, which were expensed as incurred, were approximately $1,780,000 and $724,000 for the years ended December 31, 2019 and 2018, respectively.

15. 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 2019, 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 20,230,000 to 25,230,000 to be available for grants and awards. As of December 31, 2019, a total of 11,389,078 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, 2019 and 2018 includes $7,310,000 and $6,119,000, 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:

(In thousands)	Year ended December, 2019	2018
Research and development	$ 466	$ 741
General and administrative	6,844	5,378
Share-based compensation expense	$ 7,310	$ 6,119

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, 2019 and 2018, approximately $73,000 and $644,000 was expensed for share awards with performance conditions that became probable during the year, respectively.

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.

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, 2019 and 2018:

	Year ended December 31,	
	2019	**2018**
Expected volatility	77.30%	78.78%
Risk free interest rate	1.87%	2.80%
Expected term of option	6.05 years	5.77 years
Expected dividend yield	0.00%	0.00%

The weighted average fair value of stock options granted during the years ended December 31, 2019 and 2018 were $2.20 and $4.49, respectively.

A summary of the Company's stock option plans and changes in options outstanding under the plans during the years ended December 31, 2019 and 2018 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term In Years	Aggregate Intrinsic Value
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		
Exercised	(599,002)	$ 1.43		$ 1,124,000
Granted	5,834,808	$ 3.01		
Expired	(7,090)	$ 3.69		
Forfeited	(1,389,652)	$ 1.17		
Cancelled	(4,000,000)	$ 3.22		
Outstanding at December 31, 2019	18,268,372	$ 2.58	6.30	$ 16,414,546
Vested and expected to vest at December 31, 2019	18,018,372	$ 2.57	6.38	$ 16,414,546
Exercisable at December 31, 2019	11,192,819	$ 1.99	4.52	$ 15,311,057

The aggregate intrinsic value is calculated as the difference between (i) the closing price of the common stock at December 31, 2019 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 twelve months ended December 31, 2019 and 2018 was $854,000 and $258,000, 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.

In April 2019, the 2018 performance-based option awarded to the Company's Chairman and CEO, covering 4 million shares of common stock was cancelled. At the date of cancellation, the performance condition of the option award was not expected to vest based on the original vesting conditions, and therefore no compensation cost was recognized on the cancellation date. On June 20, 2019, the Company's stockholders approved a grant of stock options to the Company's Chairman and CEO at the 2019 Annual Meeting. Under the terms of the grant, the Company's Chairman and CEO received a stock option covering 4 million shares of common stock, at an exercise price of $2.85, vesting upon the earlier of (i) the completion of a transformative event by the Company as determined at the discretion of the Company's compensation committee and (ii) April 2, 2021, the second anniversary of the date of his appointment as CEO.

The following summarizes information about stock options that are outstanding at December 31, 2019:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31, 2019	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable at December 31, 2019	Weighted Average Exercise Price
$0.00 - $1.00	2,193,853	3.70	$ 0.91	2,193,853	$ 0.91
$1.01 - $2.00	6,682,402	3.84	$ 1.52	6,605,614	$ 1.53
$2.01 - $4.00	7,511,301	8.81	$ 3.04	1,656,495	$ 3.11
$4.01 - $7.00	1,639,000	8.11	$ 6.25	495,041	$ 6.28
$7.01 - $9.00	241,816	7.22	$ 8.10	241,816	$ 8.10
	18,268,372	6.30	$ 2.58	11,192,819	$ 1.99

As of December 31, 2019, there was approximately $13,639,000 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 2.2 years.

16. INCOME TAXES

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

(In thousands)	**2019**	**2018**
United States	$ (28,957)	$ (19,820)
Foreign	(16,405)	(7,651)
Total	$ (45,362)	$ (27,471)

Significant components of the Company's deferred income tax assets and liabilities as of December 31, 2019 and 2018 are as follows:

	December 31,	
(In thousands)	**2019**	**2018**
Deferred income tax assets:		
Net operating loss carryforwards	$ 94,828	$ 97,701
Research and development credit carryforward	7,740	8,957
Intangible assets	5,733	4,378
Equity-based compensation	5,423	4,075
Other	396	81
Valuation allowance for deferred income tax assets	(114,120)	(115,192)
Net deferred income tax assets	$ -	$ -

The Company has U.S. federal and state net operating loss (NOL) carryforwards of approximately $356,300,000 at December 31, 2019. The Company also has People's Republic of China ("PRC") NOL carryforwards of approximately $25,000,000 at December 31, 2019.

The Company's U.S. federal NOL carryforwards generated prior to 2018 begin to expire in 2020. The Company also has research and experimentation ("R&E") tax credit carryforwards of approximately $7,740,000 as of December 31, 2019 that begin to expire in 2020. 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 100% valuation allowance has been recognized to reduce the net deferred tax assets to zero because it is more likely than not that the Company could not generate sufficient taxable income in the future to realize the benefit of deferred income tax assets.

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

(In thousands)	2019	2018
Tax benefit at statutory rate	($ 9,526)	($ 5,769)
State taxes	(1,701)	(1,098)
Attribute expiration	12,461	7,200
Nondeductible expenses	453	29
Other	(608)	(82)
Change in applicable tax rates	(7)	(934)
Change in valuation allowance	(1,072)	654
	$ -	$ -

The Company had $2,986,000 of unrecognized tax benefits as of December 31, 2018 related to net R&E tax credit carryforwards. For the year ended December 31, 2019, there was a net reduction of unrecognized tax benefits of $405,000 related to R&E tax credits. The Company has a full valuation allowance at December 31, 2019 and 2018 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 2020. As of December 31, 2019 and 2018, 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 related to income taxes.

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

(In thousands)	2019	2018
Unrecognized tax benefits balance at January 1	$ 2,986	$ 3,198
Reductions for tax positions of prior periods	(405)	(214)
Additions for tax positions of current period	-	2
Unrecognized tax benefits balance at December 31	$ 2,581	$ 2,986

The Company and each of its PRC subsidiaries file income tax returns in the United States and the PRC, respectively. 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 1999 are open to examination by the taxing authorities. According to the PRC Tax Administration and Collection Law, the statute of limitations is three years if the underpayment of taxes is due to computational errors made by the taxpayer or the withholding agent. The statute of limitations is extended to five years under special circumstances where the underpayment of taxes is more than RMB100,000 (approximately $14,334). In the case of transfer pricing issues, the statute of limitations is ten years. There is no statute of limitations in the case of tax evasion. The PRC tax returns for the Company's PRC subsidiaries are open to examination by the PRC tax authorities for the tax years beginning in 2014.

17. FAIR VALUE MEASUREMENTS

The majority of the Company's financial instruments (consisting of cash and cash equivalents, account receivable, 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 also had a note payable which was paid off during the year ended December 31, 2019 (see Note 10). The notes payable was carried at amortized cost which approximates fair value due to its classification as a short-term note payable.

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. The Company's investment in this equity security 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). The fair value of the common stock is based on quoted market price for the investee's common stock, a Level 1 input.

The following tables presents the Company's financial assets and liabilities accounted for at fair value on a recurring basis as of December 31, 2019 and December 31, 2018, by level within the fair value hierarchy:

(In thousands)

Description	Fair Value at December 31, 2019	Level 1	Level 2	Level 3
Investment in common stock	$ 625	$ 625	$ -	$ -

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

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

The Company has no financial assets and liabilities that are measured at fair value on a non- recurring basis.

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

Description	Fair Value at December 31, 2019	Level 1	Level 2	Level 3
Long-lived assets	$ 287	$ -	$ -	$ 287

The long-lived assets represent equipment leased to Juventas (Note 18).

As of December 31, 2019, equipment leased to Juventas with a total carrying amount of $673,000 were written down to their fair value of $287,000, resulting in an impairment charge of $386,000, representing the difference between total carrying amount and fair value of these long-lived assets, which was calculated based on Level 3 Inputs. No impairment was recorded for the year ended December 31, 2018.

18. RELATED PARTY TRANSACTIONS

In June 2019, CASI Pharmaceuticals, Inc. entered into a license agreement for exclusive worldwide license and commercialization rights to CNCT19 from Juventas (see Note 1). Transactions with Juventas are considered to be related party transactions as the Company's CEO and Chairman is the chairman and one of the founding shareholders of Juventas. A committee of independent directors of CASI negotiated the terms of the investment and license agreements and recommended that the board of directors approve the transaction. The Company's CEO did not participate in the committee's deliberations or the board of directors' approval of the transaction.

On July 1, 2019 the Company entered into a one-year equipment lease with Juventas in the amount of RMB80,000 (approximately $15,000) a month, which is classified as an operating lease. During the year ended December 31, 2019, the Company recognized lease income of $68,000 and expects to recognize approximately $69,000 of additional lease income in 2020 related to this lease. The lease can be extended after one year. There were no other material transactions with Juventas during the year ended December 31, 2019.

The Company had certain product rights and perpetual exclusive licenses from Spectrum Pharmaceuticals, Inc. ("Spectrum") to develop and commercialize EVOMELA (Melphalan Hydrochloride For Injection) ("EVOMELA"), ZEVALIN (Ibritumomab Tiuxetan) ("ZEVALIN") and MARQIBO (Vincristine Sulfate Liposome Injection) ("MARQIBO") in the greater China region. Spectrum is a greater than a 10% shareholder of the Company.

Based on the original licenses, the Company had supply agreements with Spectrum for the purchase of EVOMELA, ZEVALIN, and MARQIBO in China for quality testing purposes to support the Company's application for import drug registration and for commercialization purposes. On March 1, 2019, Spectrum completed the sale of its portfolio of seven FDA-approved hematology/oncology products including EVOMELA, MARQIBO, and ZEVALIN to Acrotech. The original supply agreements with Spectrum for EVOMELA, MARQIBO, and ZEVALIN were assumed by Acrotech; Spectrum agreed to continue with a short-term supply agreement for EVOMELA for the initial commercial product supply for the greater China region.

As part of the license arrangements with Spectrum, the Company issued to Spectrum a secured promissory note originally due March 17, 2016, which was subsequently amended and extended to September 17, 2019. The principal of the secured promissory note is $1.5 million and the coupon interest rate is 0.5%. The Company paid this note, including accrued interest in full during the year ended December 31, 2019.

In 2018, the Company entered into commercial purchase obligation commitments for EVOMELA from Spectrum totaling approximately $9.2 million under the short-term supply agreement for EVOMELA. As of December 31, 2019, the Company has paid $7.6 million relating to the manufacturing and purchase of the EVOMELA commercial product supply and the amount due to Spectrum of $0.2 million was reflected in accounts payable in the consolidated financial statements. As of December 31, 2019, $4.5 million was reflected in inventories as the goods have been received and $3.3 million has been included in costs of revenues and as of December 31, 2018, $4.9 million of the advance payments were reflected in prepaid expenses and other in the accompanying consolidated financial statements. The Company also accrued approximately $2.6 million for material costs related to EVOMELA during the year ended December 31, 2019 which are included in accrued expenses.

In 2018, 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 Chief Executive Officer and 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 Chief Executive Officer and Chairman, and the former Company's Chief Executive Officer who has resigned in April 2019 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 Chief Executive Officer and Chairman and the former 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.

19. ACROTECH 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);
- Ibritumomab Tiuxetan (ZEVALIN); and
- Vincristine Sulfate Liposome Injection (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, the former owner of EVOMELA, received notification from the U.S. Food and Drug Administration ("FDA") of the grant of approval of its New Drug Application (NDA) for EVOMELA primarily for use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma. In December 2016, the 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 has in place an experienced commercial team with a successful track record to execute the commercial sales of EVOMELA that launched in August 2019. The Company is also preparing for a post-marketing study required as part of the NMPA marketing approval.

The Company is in the process of advancing the development of ZEVALIN in China. 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 conduct a registration trial to evaluate the efficacy and safety of ZEVALIN. The Company intends to advance the development, import drug registration, and market approval of ZEVALIN in China and currently is in the planning/execution stage for the registration study.

In 2016, the NMPA accepted for review the Company's import drug registration application for MARQIBO. In March 2019 the Company received NMPA's approval of the Company's MARQIBO CTA to allow for a trial to evaluate its efficacy and safety. The Company is currently evaluating its options in an evolving standard of care environment for the approved rare and niche indication.

20. COMMITMENTS AND CONTINGENCIES

In 2018, the Company entered into purchase obligation commitments for EVOMELA from Spectrum for approximately $9.2 million (see Note 18). All of these EVOMELA purchase commitments have been delivered as of October 2019.

In conjunction with the Black Belt and Juventas agreements entered into during 2019 (see Note 1), the Company is responsible for certain milestone and royalty payments. As of December 31, 2019, no milestones have been achieved.

In conjunction with the Pharmathen agreement entered into during 2019 (see Note 1), the Company is responsible for certain milestone payments. As of December 31, 2019, no milestones have been achieved.

In conjunction with the Laurus Labs agreement entered into during 2018 (see Note 4), the Company is responsible for certain remaining milestone payments. As of December 31, 2019, the remaining milestones have not been achieved.

In November 2019, CASI Wuxi entered into a lease agreement for the right to use state-owned land in China for the construction of a manufacturing facility. Pursuant to the agreement, CASI Wuxi commits to invest land use right and property, plant and equipment of RMB1 billion (equivalent to US$143 million) within three years from the date of establishment of CASI Wuxi. The timing of the development and investment plans are subject to further discussion with the government. The Company is currently in the design and engineering phase for the facility and assessing the construction plan and timeline.

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.