

**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 June 30, 2017

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 000-50484

**MEI Pharma, Inc.**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

**51-0407811**  
(I.R.S. Employer  
Identification No.)

**3611 Valley Centre Drive, Suite 500, San Diego, CA 92130**  
(Address of principal executive offices) (Zip Code)

**(858) 369-7100**  
(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.00000002 par value	The NASDAQ Stock Market LLC

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

**None**  
(Title of Class)

Indicate by a check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by a check mark if the registrant is not required to file reports pursuant to Section 13 or Section 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by checkmark 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 Exchange Act). Yes  No

The aggregate market value of the voting common equity held by non-affiliates of the registrant was approximately \$52.9 million as of December 31, 2016, based on the closing price of the registrant's Common Stock as reported on the NASDAQ Capital Market on such date. For purposes of this calculation, shares of the registrant's common stock held by directors and executive officers have been excluded. This number is provided only for purposes of this Annual Report on Form 10-K and does not represent an admission that any particular person or entity is an affiliate of the registrant.

As of August 30, 2017, there were 36,938,970 shares of the registrant's common stock, par value \$0.00000002 per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain information required by Part III of this Annual Report on Form 10-K is incorporated by reference from the registrant's definitive proxy statement for the annual meeting of stockholders to be held in November 2017, which will be filed with the Securities and Exchange Commission within 120 days after the close of the registrant's fiscal year ended June 30, 2017.

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## Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, includes forward-looking statements, which involve a number of risks and uncertainties. These forward-looking statements can generally be identified as such because the context of the statement will include words such as “may,” “will,” “intend,” “plan,” “believe,” “anticipate,” “expect,” “estimate,” “predict,” “potential,” “continue,” “likely,” or “opportunity,” the negative of these words or other similar words. Similarly, statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. Discussions containing these forward-looking statements may be found, among other places, in “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Annual Report. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Annual Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Annual Report was filed with the Securities and Exchange Commission, or SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, those discussed in “Risk Factors” and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Annual Report. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements to reflect events or circumstances that arise after the filing of this Annual Report or documents incorporated by reference herein that include forward-looking statements.

MEI Pharma, Inc.<sup>®</sup> and our corporate logo are registered service marks of MEI Pharma. Any other brand names or trademarks appearing in this Annual Report are the property of their respective holders.

## PART I

### Item 1. Business

#### Overview

We are an oncology company focused on the clinical development of novel therapies for cancer. Our common stock is listed on the NASDAQ Capital Market under the symbol “MEIP”.

Our business purpose is the development of drugs for the treatment of cancer. Our portfolio of clinical drug candidates includes Pracinostat, an oral histone deacetylase (“HDAC”) inhibitor that is being developed in combination with azacitidine for the treatment of adults with newly diagnosed acute myeloid leukemia (“AML”) who are unfit for intensive chemotherapy, and patients with high or very high-risk myelodysplastic syndrome (“MDS”). In August 2016, we entered into an exclusive worldwide license, development and commercialization agreement with Helsinn Healthcare SA, a Swiss pharmaceutical corporation (“Helsinn”), for Pracinostat in AML, MDS and other potential indications. Our clinical development portfolio also includes ME-401, an oral inhibitor of phosphatidylinositide 3-kinase (“PI3K”) delta being developed for B-cell malignancies, and ME-344, a mitochondrial inhibitor that has shown evidence of clinical activity in refractory solid tumors. We own exclusive worldwide rights to ME-401 and ME-344 without any future milestone or royalty obligations.

#### Clinical Development Programs

##### HDAC Inhibitor Drug Candidate: Pracinostat

In August 2016, the U.S. Food and Drug Administration (“FDA”) granted Breakthrough Therapy Designation for Pracinostat in combination with the hypomethylating agent, azacitidine, for the treatment of patients with newly diagnosed AML who are unfit for intensive chemotherapy. According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

The Breakthrough Therapy Designation is supported by data from a Phase II study of Pracinostat plus azacitidine in elderly patients with newly diagnosed AML who are not candidates for induction chemotherapy. The study showed a median overall survival of 19.1 months and a complete response (CR) rate of 42% (21 of 50 patients). These data compare favorably to a recent international Phase III study of azacitidine (AZA-001; Dombret et al. Blood. 2015 May 18), which showed a median overall survival of 10.4 months with azacitidine alone and a CR rate of 19.5% in a similar patient population. The combination of Pracinostat and azacitidine was generally well tolerated, with no unexpected toxicities. The most common grade 3/4 treatment-emergent adverse events included febrile neutropenia, thrombocytopenia, anemia and fatigue. These results were presented at the American Society of Hematology (“ASH”) Annual Meeting in December 2016.

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In August 2016, we entered into an exclusive license, development and commercialization agreement with Helsinn for Pracinostat in AML, MDS and other potential indications (“Helsinn License Agreement”). Under the terms of the agreement, Helsinn was granted a worldwide exclusive license to develop, manufacture and commercialize Pracinostat, and is primarily responsible for funding its global development and commercialization. As compensation for such grant of rights, we received payments of \$20.0 million, including a \$15.0 million upfront payment and a \$5.0 million payment in March 2017. In addition, we are eligible to receive up to \$444 million in potential regulatory and sales-based milestones, along with royalty payments on the net sales of Pracinostat, which, in the U.S., are tiered and begin in the mid-teens.

In July 2017, the first patient was dosed in a pivotal Phase III study of Pracinostat in combination with azacitidine in adults with newly diagnosed AML who are unfit to receive intensive induction chemotherapy. This randomized, double-blind, placebo-controlled study will enroll approximately 500 eligible patients worldwide. Patients will be randomized 1:1 to receive Pracinostat or placebo with azacitidine as background therapy. The primary endpoint of the study is overall survival. Secondary endpoints include morphologic CR rate, event-free survival (EFS) and duration of CR. Helsinn is responsible for the conduct and funding of this Phase III study.

As part of the Helsinn License Agreement, we are working with Helsinn to determine an optimal dosing regimen of Pracinostat in combination with azacitidine for the treatment of higher risk MDS. In June 2017, the first patient was dosed in a Phase II dose-optimization study of Pracinostat in combination with azacitidine in patients with high and very high risk MDS who are previously untreated with hypomethylating agents. The two-stage study will be conducted at approximately 25 sites and is expected to enroll up to 120 patients. Data from the first stage is expected in the first quarter of 2018. We are responsible for the conduct of this Phase II study, the cost of which will be shared by Helsinn. Helsinn will be responsible for funding any further studies.

### PI3K Delta Drug Candidate: ME-401

In September 2013, we acquired exclusive worldwide rights to ME-401. PI3K delta is a class of drugs that has shown promise in the treatment of B-cell malignancies, but the approved PI3K delta inhibitor idelalisib (marketed as Zydelig®) has shown particular toxicities. We believe this provides an opportunity for development of a differentiated oral drug that can produce therapeutic responses at a safe, effective dose. ME-401 has a distinct chemical structure from certain other PI3K delta inhibitors, including idelalisib. Data presented at the ASH Annual Meeting in December 2012 demonstrated that ME-401 has superior pre-clinical activity compared to idelalisib.

Results from a first-in-human, single ascending dose clinical study of ME-401 in healthy volunteers were presented at the American Association for Cancer Research Annual Meeting in April 2016. The data demonstrated on-target activity at very low plasma concentrations. In addition, the results from the study suggest that ME-401 has the potential for a superior pharmacokinetic and pharmacodynamic profile and an improved therapeutic window compared to idelalisib, with a half-life that supports once-daily dosing.

In May 2017, an independent safety review committee completed its pre-specified review of the first cohort of six evaluable patients in a Phase Ib, open-label, dose-escalation study of ME-401 in relapsed/refractory chronic lymphocytic leukemia (“CLL”) and follicular lymphoma. Based on its review of the safety and efficacy data, the safety review committee declared a minimum biologically effective dose (“mBED”) for ME-401 at the starting dose of 60 mg and recommended escalation to a 120 mg dose cohort. According to the study protocol, the mBED is defined as a dose that is safe and achieves a response in at least three of six patients. To date, there have been no reports of ALT/AST elevations, colitis or pneumonitis, events commonly reported with other drugs in this class. One patient in the study experienced grade 3 neutropenia that was considered related to the study drug; all other adverse events reported were grades 1 or 2. No patients have discontinued due to adverse events or disease progression. We plan to submit full data for presentation at an upcoming scientific meeting.

### Mitochondrial Inhibitor Drug Candidate: ME-344

ME-344 is our isoflavone-derived mitochondrial inhibitor drug candidate. In preclinical studies, ME-344 has been shown to cause cell death in multiple human tumor cell lines, including ovarian cancer stem cells, by interfering with mitochondrial energy generation.

Results from our first-in-human, single-agent Phase I clinical trial of ME-344 in patients with refractory solid tumors were published in the April 1, 2015 issue of *Cancer*. The results indicated that eight of 21 evaluable patients (38%) treated with ME-344 achieved stable disease or better, including five who experienced progression-free survival that was at least twice the duration of their last prior treatment before entry into the study. In addition, one of these patients, a heavily pre-treated patient with small cell lung cancer, achieved a confirmed partial response and remained on study for two years. ME-344 was generally well tolerated at doses equal to or less than 10 mg/kg delivered on a weekly schedule for extended durations. Treatment-related adverse events included nausea, dizziness and fatigue. Dose limiting toxicities were observed at both the 15 mg/kg and 20 mg/kg dose levels, consisting primarily of grade 3 peripheral neuropathy.

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In May 2015, we announced pre-clinical data from a collaboration with the Spanish National Cancer Research Centre in Madrid showing mitochondria-specific effects of ME-344 in cancer cells, including substantially enhanced anti-tumor activity when combined with agents that inhibit the activity of vascular endothelial growth factor (“VEGF”). These data demonstrate that the anti-cancer effects when combining ME-344 with a VEGF inhibitor are due to an inhibition of both mitochondrial and glycolytic metabolism. An investigator-sponsored study of ME-344 in combination with the VEGF inhibitor bevacizumab (marketed as Avastin®) in human epidermal growth factor receptor 2 (“HER2”)-negative breast cancer opened for enrollment in August 2016. This study is now actively dosing patients and interim data are expected in the fourth quarter of 2017.

## **Scientific Overview**

Cancer is a complex disease in which growing tumors employ multiple pathways to maintain their growth advantage. We currently have three clinical-stage development programs, each utilizing a distinct approach to inhibit cancer – epigenetics, cell signaling and cancer metabolism. In each program we have selected a lead drug candidate with a well-defined mechanism of action: Pracinostat, an oral HDAC inhibitor; ME-401, an oral PI3K delta inhibitor; and ME-344, a mitochondrial inhibitor.

### Epigenetics Program: Pracinostat

HDACs, play a key role in epigenetic regulation of gene expression by regulating chromatin structure. Acetylation of positively charged lysine residues present in histone proteins by the histone acetyltransferase (“HATs”) reduces the affinity between histones and negatively charged DNA, resulting in the opening of the chromatin structure. This makes it easier for the transcriptional machinery to access the DNA, enhancing RNA transcription. Conversely, deacetylation by the HDACs closes the chromatin structure leading to a repression of gene transcription. In normal cells, HDACs and HATs together control histone acetylation levels to maintain a balance. In diseases such as cancer, this regulation can be disturbed. HDAC inhibitors cause accumulation of acetylated histones, enhance transcription and result in changes of a variety of cellular responses including differentiation, proliferation, migration, survival and response to metabolic and hypoxic stress. In general, tumor cells are more susceptible than normal cells to the anti-proliferative and pro-apoptotic effects of HDAC inhibitors.

There are currently three HDAC inhibitors, one oral and two injectable, approved by the FDA for the treatment of T-cell lymphoma and a fourth HDAC (oral) approved for multiple myeloma. Other HDAC inhibitors are being evaluated in clinical trials as single agents and in combination for the treatment of various hematologic diseases and solid tumors.

Pracinostat is an orally available, potent HDAC inhibitor with potentially improved physicochemical, pharmaceutical and pharmacokinetic properties when compared to other compounds of this class, including increased bioavailability and increased half-life. Pracinostat has been tested in more than 300 patients in multiple Phase I and Phase II clinical trials and found to be generally well tolerated with manageable side effects often associated with drugs of this class, including fatigue, myelosuppression and gastrointestinal toxicity.

### Signaling Program: ME-401

The PI3K/AKT/mTOR pathway is an important signaling pathway for many cellular functions such as cell survival, cell cycle progression and cellular growth. PI3Ks are a family of enzymes within this pathway that have been shown to play a critical role in the proliferation and survival of certain cancer cells. There are several isoforms of PI3K that are expressed in different types of cells. The PI3K delta isoform is believed to be important for survival of certain B-cell leukemias and lymphomas.

In pre-clinical studies, ME-401 has been found to be a potent and selective oral inhibitor of PI3K delta, with a distinct chemical structure and evidence of improved pre-clinical activity compared to the approved PI3K delta-selective inhibitor, idelalisib. Results from a Phase I first-in-human study of ME-401 showed levels of drug exposure that support the potential for an improved therapeutic window compared to idelalisib, with a half-life that supports once-daily dosing.

### Cancer Metabolism Program: ME-344

Tumor cells often display a high metabolic rate to support cell division and growth. This heightened metabolism requires a continual supply of energy in the form of adenosine triphosphate (“ATP”). The two major sources of ATP are the specialized cellular organelles termed mitochondria and through the metabolism of carbohydrates, proteins and lipids.

ME-344 was identified through a screen of more than 400 new chemical structures originally created based on the central design of naturally occurring plant isoflavones. We believe that some of these synthetic compounds, including our drug candidate ME-344, interact with specific mitochondrial enzyme targets, resulting in the inhibition of ATP generation. When these compounds interact with their target, a rapid reduction in ATP occurs, which leads to a cascade of biochemical events within the cell and ultimately to cell death.

## **Competition**

The marketplace for our drug candidates is highly competitive. A number of other companies have products or drug candidates in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which our drug candidates are being developed. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized sooner. Even if we are successful in developing effective drugs, our drug candidates may not compete successfully with products produced by our competitors.

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Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for us. Many of our competitors developing oncology drugs have significantly greater capital resources, larger research and development staffs and facilities, and greater experience in drug development, regulation, manufacturing, and marketing than we do. They compete with us in recruiting eligible patients to participate in clinical studies and in attracting development and/or commercialization partners. They also license technologies that are competitive with our technologies. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies or our drug candidates obsolete or non-competitive.

### **Intellectual Property**

We own, by assignment, worldwide rights to each of our current drug candidates. Our intellectual property portfolio includes approximately 20 issued U.S. patents, 131 issued foreign patents, 11 pending U.S. patent applications and 38 pending foreign applications.

We have acquired, by assignment, patents and patent applications from S\*Bio Pte Ltd (“S\*Bio”) relating to a family of heterocyclic compounds, which include Pracinostat, that inhibit histone deacetylases. The U.S. Patent and Trademark Office (“USPTO”) has issued six patents covering a number of these heterocyclic-based compounds, including Pracinostat, and their composition of matter, pharmaceutical compositions, and methods of use to treat proliferative diseases. The composition of matter claims covering Pracinostat are projected to expire in May 2028, not including patent term extension. On August 5, 2016, we entered into an exclusive license, development and commercialization agreement with Helsinn. The agreement has a term (the “Term”) commencing on the effective date and continuing, on a country-by-country basis, until the later of the date (i) of expiration of the applicable patents in such country, (ii) of expiration of regulatory exclusivity in such country or (iii) that is 15 years after the first commercial sale in such country. With respect to certain defined “Tier 2” countries, the Term is solely based on 15 years from first commercial sale. During the Term, we granted to Helsinn an exclusive (subject to certain retained rights to perform obligations under the agreement), sublicenseable, payment-bearing, license under and to certain patents and know-how controlled by us to develop, manufacture and commercialize Pracinostat and any pharmaceutical product containing Pracinostat for all human and animal indications.

We have acquired, by assignment, patents and patent applications from Novogen, our former majority shareholder, which relate to a large family of isoflavonoid compounds, including ME-344. The USPTO has issued six patents covering ME-344, including its composition of matter, pharmaceutical compositions and methods of use to treat cancer. The composition of matter and pharmaceutical composition claims covering ME-344 are expected to expire in March 2027 and November 2031, not including patent term extension.

We have acquired by assignment worldwide rights to ME-401 and other related compounds from Pathway Therapeutics, Inc. The USPTO has issued two patents covering the composition of matter and pharmaceutical compositions of ME-401 which are projected to expire in January 2031 and December 2032, not including any patent term extension. There are currently five U.S. and 14 foreign applications for ME-401 and related compounds pending.

Our success depends in large part on our ability to protect our proprietary technologies, compounds and information, and to operate without infringing the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright, and trademark laws, as well as confidentiality, licensing and other agreements, to establish and protect our proprietary rights. We seek patent protection for our key inventions, including drug candidates we identify, routes for chemical synthesis and pharmaceutical formulations. There is no assurance that any of our pending patent applications will issue, or that any of our patents will be enforceable or will cover a drug or other commercially significant product or method. In addition, we regularly review our patent portfolio to identify patents and patent applications that we deem to have relatively low value to our ongoing business operations for potential abandonment. There is also no assurance that we will correctly identify which of our patents and patent applications should be maintained and which should be abandoned. The term of most of our other current patents commenced, and most of our future patents, if any, will commence, on the date of issuance and terminate 20 years from the earliest effective filing date of the patent application. Because any marketing and regulatory approval for a drug often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on our drug candidates and technologies will likely be substantially less than 20 years.

As most patent applications in the U.S. are maintained as confidential until published by the U.S. Patent and Trademark Office at 18 months from filing for all cases filed after November 29, 2000, or at issue, for cases filed prior to November 29, 2000, we cannot be certain that we, S\*Bio, Novogen or Pathway Therapeutics, Inc. were the first to make the inventions covered by the patents and applications referred to above. Additionally, publication of discoveries in the scientific or patent literature often lags behind the actual discoveries. Moreover, pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of twenty years from the date of such filing except for provisional applications, irrespective of the period of time it may take for such patent to ultimately issue. This may shorten the period of patent protection afforded to therapeutic uses of Pracinostat, ME-401 or ME-344, as patent applications in the biopharmaceutical sector often take considerable time to issue. However, in some countries the patent term may be extended.

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In order to protect the confidentiality of our technology, including trade secrets and know-how and other proprietary technical and business information, we require all of our consultants, advisors and collaborators to enter into agreements that prohibit the use or disclosure of information that is deemed confidential. These agreements also oblige our consultants, advisors and collaborators to assign to us, or negotiate a license to developments, discoveries and inventions made by such persons in connection with their work relating to our products. We cannot be sure that confidentiality will be maintained by those from whom we have acquired technology or disclosure prevented by these agreements. We also cannot be sure that our proprietary information or intellectual property will be protected by these agreements or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive and patents may have been applied for by, and issued to, other parties relating to products competitive with Pracinostat, ME-401 or ME-344. Use of these compounds and any other drug candidates may give rise to claims that they infringe the patents or proprietary rights of other parties, existing now and in the future. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. We cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded.

## **Research and Development**

The objective of our research and development program is the generation of data sufficient to achieve regulatory approval of our drug candidates in one or more dosage forms in major markets such as the U.S., to develop commercially attractive attributes, and/or to allow us to enter into a development and/or commercial relationship with another party. The data are generated by our pre-clinical studies and clinical trial programs.

The key aspects of our research and development program are to provide more complete characterization of the following:

- the relevant molecular targets of action of our drug candidates;
- the relative therapeutic benefits and indications for use of our drug candidates as a monotherapy or as part of combinational therapy with other agents; and
- the most appropriate therapeutic indications and dosage forms for Pracinostat, ME-401 and ME-344.

## **Government Regulation**

### *U.S. Regulatory Requirements*

The FDA, and comparable regulatory agencies in other countries, regulate and impose substantial requirements upon the research, development, pre-clinical and clinical testing, labeling, manufacture, quality control, storage, approval, advertising, promotion, marketing, distribution and export of pharmaceutical products including biologics, as well as significant reporting and record-keeping obligations. State governments may also impose obligations in these areas.

In the U.S., pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and other laws, including in the case of biologics, the Public Health Service Act. We believe, but cannot be certain, that our products will be regulated as drugs by the FDA. The process required by the FDA before drugs may be marketed in the U.S. generally involves the following:

- pre-clinical laboratory evaluations, including formulation and stability testing, and animal tests performed under the FDA’s Good Laboratory Practices regulations to assess pharmacological activity and toxicity potential;
- submission and approval of an Investigational New Drug Application (“IND”), including results of pre-clinical tests, manufacturing information, and protocols for clinical tests, which must become effective before clinical trials may begin in the U.S.;
- obtaining approval of Institutional Review Boards (“IRB”), to administer the products to human subjects in clinical trials;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for the product’s intended use;
- development of manufacturing processes which conform to FDA current Good Manufacturing Practices (“cGMP”), as confirmed by FDA inspection;
- submission of results for pre-clinical and clinical studies, and chemistry, manufacture and control information on the product to the FDA in a New Drug Approval Application (“NDA”); and
- FDA review and approval of a NDA, prior to any commercial sale or shipment of a product.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

The results of the pre-clinical studies, together with initial specified manufacturing information, the proposed clinical trial protocol, and information about the participating investigators are submitted to the FDA as part of an IND, which must become effective before we may begin human clinical trials in the U.S. Additionally, an independent IRB must review and approve each study protocol and oversee conduct of the trial. An IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. If the FDA

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imposes a clinical hold, the IND sponsor must resolve the FDA's concerns before clinical trials can begin. Pre-clinical tests and studies can take several years to complete, and there is no guarantee that an IND we submit based on such tests and studies will become effective within any specific time period, if at all.

Human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase I:* The drug is initially introduced into healthy human subjects or patients and tested for safety and dosage tolerance. Absorption, metabolism, distribution, and excretion testing is generally performed at this stage.
- *Phase II:* The drug is studied in controlled, exploratory therapeutic trials in a limited number of subjects with the disease or medical condition for which the new drug is intended to be used in order to identify possible adverse effects and safety risks, to determine the preliminary or potential efficacy of the product for specific targeted diseases or medical conditions, and to determine dosage tolerance and the optimal effective dose.
- *Phase III:* When Phase II studies demonstrate that a specific dosage range of the drug is likely to be effective and the drug has an acceptable safety profile, controlled, large-scale therapeutic Phase III trials are undertaken at multiple study sites to demonstrate clinical efficacy and to further test for safety in an expanded patient population.

We cannot be certain that we will successfully complete clinical testing of our products within any specific time period, if at all. Furthermore, the FDA, the IRB or we 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.

Results of pre-clinical studies and clinical trials, as well as detailed information about the manufacturing process, quality control methods, and product composition, among other things, are submitted to the FDA as part of a NDA seeking approval to market and commercially distribute the product on the basis of a determination that the product is safe and effective for its intended use. Before approving a NDA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless cGMP compliance is satisfactory. If applicable regulatory criteria are not satisfied, the FDA may deny the NDA or require additional testing or information. As a condition of approval, the FDA also may require post-marketing testing or surveillance to monitor the product's safety or efficacy. Even after a NDA is approved, the FDA may impose additional obligations or restrictions (such as labeling changes, or clinical post-marketing requirements), or even suspend or withdraw a product approval on the basis of data that arise after the product reaches the market, or if compliance with regulatory standards is not maintained. We cannot be certain that any NDA we submit will be approved by the FDA on a timely basis, if at all. Also, any such approval may limit the indicated uses for which the product may be marketed. Any refusal to approve, delay in approval, suspension or withdrawal of approval, or restrictions on indicated uses could have a material adverse impact on our business prospects.

Each NDA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act ("PDUFA"), and its amendments. According to the FDA's fee schedule, the user fee for an application requiring clinical data, such as a NDA, is \$2,038,100. PDUFA also imposes an annual product fee for prescription drugs and biologics (\$97,750), and an annual establishment fee (\$512,200) on facilities used to manufacture prescription drugs and biologics. The FDA adjusts the PDUFA user fees on an annual basis. A written request can be submitted for a waiver for the application fee for the first human drug application that is filed by a small business, but there are no waivers for product or establishment fees. We are not at the stage of development with our products where we are subject to these fees, but they are significant expenditures that may be incurred in the future and must be paid at the time of application submissions to the FDA.

Satisfaction of FDA requirements typically takes several years. The actual time required varies substantially, based upon the type, complexity, and novelty of the pharmaceutical product, among other things. Government regulation imposes costly and time-consuming requirements and restrictions throughout the product life cycle and may delay product marketing for a considerable period of time, limit product marketing, or prevent marketing altogether. Success in pre-clinical or early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from pre-clinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit, or prevent marketing approval. Even if a product receives marketing approval, the approval is limited to specific clinical indications. Further, even after marketing approval is obtained, the discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

After product approval, there are continuing significant regulatory requirements imposed by the FDA, including record-keeping requirements, obligations to report adverse side effects in patients using the products, and restrictions on advertising and promotional activities. Quality control and manufacturing procedures must continue to conform to cGMPs, and the FDA periodically inspects facilities to assess cGMP compliance. Additionally, post-approval changes in ingredient composition, manufacturing processes or facilities, product labeling, or other areas may require submission of a NDA Supplement to the FDA for review and approval. New indications will require additional clinical studies and submission of a NDA Supplement. Failure to comply with FDA regulatory requirements may result in an enforcement action by the FDA, including Warning Letters, product recalls, suspension or revocation of product approval, seizure of product to prevent distribution, impositions of injunctions prohibiting product manufacture or distribution, and civil and criminal penalties. Maintaining compliance is costly and time-consuming. We cannot be certain that we, or our present or future suppliers or third-party manufacturers, will be able to comply with all FDA regulatory requirements, and potential consequences of noncompliance could have a material adverse impact on our business prospects.

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The FDA's policies may change, and additional governmental regulations may be enacted that could delay, limit, or prevent regulatory approval of our products or affect our ability to manufacture, market, or distribute our products after approval. Moreover, increased attention to the containment of healthcare costs in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on our business. Our ability to commercialize future products will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers, and other third-party payers. European Union member states and U.S. government and other third-party payers increasingly are attempting to contain healthcare costs by consideration of new laws and regulations limiting both coverage and the level of reimbursement for new drugs. Our failure to obtain coverage, an adequate level of reimbursement, or acceptable prices for our future products could diminish any revenues we may be able to generate. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Our activities also may be subject to state laws and regulations that affect our ability to develop and sell our products. We are also subject to numerous federal, state, and local laws relating to such matters as safe working conditions, clinical, laboratory, and manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future, and the failure to comply may have a material adverse impact on our business prospects.

The FDCA includes provisions designed to facilitate the development and expedite the review of drugs and biological products intended for treatment of serious or life-threatening conditions that demonstrate the potential to address unmet medical needs for such conditions. These provisions set forth a procedure for designation of a drug as a "fast track product". The fast track designation applies to the combination of the product and specific indication for which it is being studied. A product designated as fast track is ordinarily eligible for additional programs for expediting development and review, but products that are not in fast track drug development programs may also be able to take advantage of these programs. These programs include priority review of NDAs and accelerated approval. Drug approval under the accelerated approval regulations may be based on evidence of clinical effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. A post-marketing clinical study will be required to verify clinical benefit, and other restrictions to assure safe use may be imposed. We do not currently have fast track designation for any of our clinical programs. If we should seek such designation for any of our programs, however, we cannot be assured that it will be granted by the FDA.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a sponsor may obtain marketing exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or if new clinical studies were required to support the marketing application for the drug. This marketing exclusivity prevents a third party from obtaining FDA approval for an identical or nearly identical drug under an Abbreviated New Drug Application or a "505(b)(2) New Drug Application". The statute also allows a patent owner to obtain an extension of applicable patent terms for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval, with a five year maximum patent extension. We cannot be certain that we will be able to take advantage of either the patent term extension or marketing exclusivity provisions of these laws.

The Best Pharmaceuticals for Children Act ("BPCA"), signed into law on January 4, 2002, was reauthorized and amended by the FDA Amendments Act of 2007 ("FDAAA"). The reauthorization of BPCA provides an additional six months of patent protection to NDA applicants that conduct acceptable pediatric studies of new and currently-marketed drug products for which pediatric information would be beneficial, as identified by the FDA in a Pediatric Written Request. The Pediatric Research Equity Act ("PREA"), signed into law on December 3, 2003, also was reauthorized and amended by the FDAAA. The reauthorization of PREA requires that most applications for drugs and biologics include a pediatric assessment (unless waived or deferred) to ensure the drugs' and biologics' safety and effectiveness in children. Such pediatric assessment must contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective. The pediatric assessments can only be deferred provided there is a timeline for the completion of such studies. The FDA may waive (partially or fully) the pediatric assessment requirement for several reasons, including if the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed. The Food and Drug Administration Safety and Innovation Act signed into law on July 9, 2012, permanently renewed and strengthened BPCA and PREA.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances. Pracinostat has been granted orphan drug designation by the FDA for the treatment of AML, but it may not receive orphan designation for other indications. Our other products may not be eligible for orphan drug status or be designated as orphan drugs. Even if designated as orphan drugs, our products may not be approved before other applications or granted orphan drug exclusivity if approved.

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### *Foreign Regulatory Requirements*

Outside the U.S., our ability to market our products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with FDA regulation, described above.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or a national procedure. Under the centralized procedure, a single application to the European Medicines Agency (“EMA”) leads to an approval granted by the European Commission which permits the marketing of the product throughout the EU. The centralized procedure is mandatory for certain classes of medicinal products, but optional for others. For example, all medicinal products developed by certain biotechnological means, and those developed for cancer and other specified diseases and disorders, must be authorized via the centralized procedure. We assume that the centralized procedure will apply to our products that are developed by means of a biotechnology process or are intended for treatment of cancer. The national procedure is used for products that are not required to be authorized by the centralized procedure. Under the national procedure, an application for a marketing authorization is submitted to the competent authority of one member state of the EU. The holders of a national marketing authorization may submit further applications to the competent authorities of the remaining member states via either the decentralized or mutual recognition procedure. The decentralized procedure enables applicants to submit an identical application to the competent authorities of all member states where approval is sought at the same time as the first application, while under the mutual recognition procedure, products are authorized initially in one member state, and other member states where approval is sought are then requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. Both the decentralized and mutual recognition procedures should take no longer than 90 days, but if one member state makes an objection, which under the legislation can only be based on a possible risk to human health, the application will be automatically referred to the Committee for Medicinal Products for Human Use (“CHMP”) of the EMA. If a referral for arbitration is made, the procedure is suspended. However, member states that have already approved the application may, at the request of the applicant, authorize the product in question without waiting for the result of the arbitration. Such authorizations will be without prejudice to the outcome of the arbitration. For all other concerned member states, the opinion of the CHMP, which is binding, could support or reject the objection or alternatively could reach a compromise position acceptable to all EU countries concerned. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

As with FDA approval, we may not be able to secure regulatory approvals in Europe in a timely manner, if at all. Additionally, as in the U.S., post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved in Europe, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

The conduct of clinical trials in the European Union is governed by the European Clinical Trials Directive (2001/20/EC), which was implemented in May 2004. This Directive governs how regulatory bodies in member states control clinical trials. No clinical trial may be started without a clinical trial authorization granted by the national competent authority and favorable ethics approval. New legislation to revise and replace the European Clinical Trials Directive is currently proposed by the European Commission and is under consideration by European Union institutions.

Accordingly, there is a marked degree of change and uncertainty both in the regulation of clinical trials and in respect of marketing authorizations which we face for our products in Europe.

### **Manufacturing**

We do not have the facilities or capabilities to commercially manufacture any of our drug candidates. We are and expect to continue to be dependent on contract manufacturers for supplying our existing and future candidates for clinical trials and commercial scale manufacturing of our candidates in accordance with regulatory requirements, including current Good Manufacturing Practices. Contract manufacturers may utilize their own technology, technology developed by us, or technology acquired or licensed from third parties. FDA approval of the manufacturing procedures and the site will be required prior to commercial distribution.

### **Employees**

As of June 30, 2017, we had 25 employees, seven of whom hold a Ph.D. or M.D. degree. Other personnel resources are used from time to time as consultants or third party service organizations on an as-needed basis. All members of our senior management team have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced personnel, but there can be no assurance that we will be able to attract and retain the individuals needed. None of our employees are represented by a collective bargaining agreement, nor have we experienced work stoppages. We believe that our relations with our employees are good.

### **Available Information**

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website at [www.meipharma.com](http://www.meipharma.com) as soon as reasonably practicable after they are electronically filed with, or furnished to, the Securities and Exchange Commission.

## Item 1A. Risk Factors

*Investment in our securities involves a high degree of risk. You should consider carefully the risks described below, together with other information in this Annual Report and other public filings, before making investment decisions regarding our securities. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.*

### Risks Related to Our Business and Industry

***We will need substantial additional funds to progress the clinical trial program for our drug candidates, and to develop new compounds. The actual amount of funds we will need will be determined by a number of factors, some of which are beyond our control.***

We will need substantial additional funds to progress the clinical trial program for our drug candidates and to develop any additional compounds. The factors that will determine the actual amount of funds that we will need to progress the clinical trial programs may include, but are not limited to, the following:

- the therapeutic indications for use being developed;
- the clinical trial endpoint required to achieve regulatory approval;
- the number of clinical trials required to achieve regulatory approval;
- the number of sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients who participate in the trials and the rate that they are recruited;
- the number of treatment cycles patients complete while they are enrolled in the trials;
- costs and potential difficulties encountered in manufacturing sufficient drug product for the trials; and
- the efficacy and safety profile of the product.

We have been opportunistic in our efforts to obtain cash, and we expect to continue to evaluate various funding alternatives from time to time. If we obtain additional funding, it may adversely affect the market price of our common stock and may be dilutive to existing stockholders. If we are unable to obtain additional funds on favorable terms or at all, we may be required to cease or reduce our operations. We may sell additional shares of common stock, and securities exercisable for or convertible into shares of our common stock, to satisfy our capital and operating needs; however, such transactions will be subject to market conditions and there can be no assurance any such transactions will be completed.

***If Helsinn does not satisfy its obligations under our collaboration agreement or if they terminate the collaboration agreement, we may not be able to develop or commercialize Pracinostat.***

In August 2016, we entered into an exclusive license, development and commercialization agreement with Helsinn to collaborate on the global development, manufacturing and commercialization of Pracinostat. In connection with this agreement, we granted to Helsinn certain rights regarding the use of our patents and technology with respect to Pracinostat. Helsinn will be primarily responsible for the global development of Pracinostat and, subject to certain exceptions, will be solely responsible for all costs related thereto, and will also be solely responsible for the global commercialization of Pracinostat and shall be solely responsible for the costs related thereto.

Helsinn might not fulfill all of its obligations under the agreement. Our ability to receive revenue from Pracinostat is dependent upon Helsinn's efforts. If Helsinn fails to devote adequate resources or otherwise does not successfully develop and commercialize Pracinostat, we may not receive the future milestone payments or royalties provided for in the agreement. In addition, under certain circumstances, including our failure to satisfy our obligations under the agreement, Helsinn has the right to terminate the agreement.

We could also become involved in disputes with Helsinn, which could lead to delays in or termination of the agreement and time-consuming and expensive litigation or arbitration.

If Helsinn is unwilling or unable to fulfill its obligations or if the agreement is terminated, we may lack sufficient resources to develop and commercialize Pracinostat on our own and may be unable to reach agreement with a suitable alternative collaborator. The failure to develop and commercialize Pracinostat would have a material adverse effect on our business, operating results, prospects and financial condition.

***Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators.***

Negative conditions in the U.S. or global economy, including financial markets, may adversely affect our business and the business of current and prospective vendors, licensees and collaborators, and others with whom we do or may conduct business. The duration and severity of these conditions is uncertain. If negative economic conditions occur, we may be unable to secure funding to sustain our operations or to find suitable collaborators to advance our internal programs, even if we achieve positive results from our drug development programs.

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### ***We are a clinical research and development stage company and are likely to incur operating losses for the foreseeable future.***

You should consider our prospects in light of the risks and difficulties frequently encountered by clinical research stage and developmental companies. We have incurred net losses of \$174.3 million from our inception through June 30, 2017, including net income of \$2.7 million for the year ended June 30, 2017, and net losses of \$20.9 million and \$32.7 million for the years ended June 30, 2016 and 2015, respectively. We anticipate that we will incur operating losses and negative operating cash flow for the foreseeable future. We have not yet commercialized any drug candidates and cannot be sure that we will ever be able to do so, or that we may ever become profitable.

### ***The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.***

Pre-clinical studies and Phase I and Phase II clinical trials are an expensive and uncertain process that may take years to complete. Pre-clinical studies and Phase I and Phase II clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. Favorable results in early studies or trials may not be repeated in later studies or trials, including ongoing pre-clinical studies and large-scale Phase III clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing pre-clinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Pre-clinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

### ***Final approval by regulatory authorities of our drug candidates for commercial use may be delayed, limited or prevented, any of which would adversely affect our ability to generate operating revenues.***

We will not generate any operating revenue until we successfully commercialize one of our drug candidates. Currently, we have drug candidates at different stages of development, and each will need to successfully complete a number of clinical studies and obtain regulatory approval before potential commercialization.

The preclinical and clinical development, manufacturing, labeling, packaging, storage, recordkeeping, export, marketing and distribution, and other possible activities relating to our drug candidates are subject to extensive regulation by the FDA and other regulatory agencies. Failure to comply with applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions that may negatively impact the approval of one or more of our drug candidates or otherwise negatively impact our business.

Neither collaborators, licensees nor we are permitted to market a drug candidate in the United States until the particular drug candidate is approved for marketing by the FDA. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an IND application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. Regulatory approval of an NDA is not guaranteed. The number and types of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. Despite the time and expense exerted in preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including but not limited to, the following:

- a drug candidate may not be deemed adequately safe or effective for an intended use;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA's interpretation and our interpretation of data from preclinical studies and clinical trials may differ significantly;
- our or our contractors' or collaborators' failure to comply with applicable FDA and other regulatory requirements, including those identified in other risk factors;
- the FDA may not approve the manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new regulations; or
- the FDA may not accept an NDA or other submission due to, among other reasons, the content or formatting of the submission.

Our preclinical and clinical data, other information and procedures relating to a drug candidate may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop.

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Additionally, any of the following factors may serve to delay, limit or prevent the final approval by regulatory authorities of our drug candidates for commercial use, including, but not limited to:

- Pracinostat, ME-401, and ME-344 are in various stages of development, and we or our licensees will need to conduct significant clinical testing to demonstrate safety and efficacy of these drug candidates before applications for marketing can be filed with the FDA, or with the regulatory authorities of other countries;
- development and testing of product formulation, including identification of suitable excipients, or chemical additives intended to facilitate delivery of our drug candidates;
- it may take us many years to complete the testing of our drug candidates, and failure can occur at any stage of this process; and
- negative or inconclusive results or adverse medical events during a clinical trial could cause us to delay or terminate our development efforts.

The successful development of any of these drug candidates is uncertain and, accordingly, we may never commercialize any of these drug candidates or generate significant revenue.

### ***Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.***

We intend to have our drug candidates marketed outside the United States. In order to market our products in many non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. To date, we have not filed for marketing approval for any of our drug candidates and may not receive the approvals necessary to commercialize our drug candidates in any market.

The approval procedure varies among countries and may include all of the risks associated with obtaining FDA approval. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval, and additional clinical trials, testing and data review may be required. We may not obtain foreign regulatory approvals on a timely basis, if at all. Additionally, approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could limit commercialization of our products, reduce our ability to generate profits and harm our business.

### ***Even if we or our licensees receive regulatory approval to commercialize our drug candidates, our ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of our control.***

Even if our drug candidates obtain regulatory approval, resulting products may not gain market acceptance among physicians, patients, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such products will depend on a number of factors, including, but not limited to, the following:

- timing of market introduction of our drugs and competitive drugs;
- actual and perceived efficacy and safety of our drug candidates;
- prevalence and severity of any side effects;
- potential or perceived advantages or disadvantages over alternative treatments;
- potential post-marketing commitments imposed by regulatory authorities, such as patient registries;
- strength of sales, marketing and distribution support;
- price of our future products, both in absolute terms and relative to alternative treatments;
- the effect of current and future healthcare laws on our drug candidates; and
- availability of coverage and reimbursement from government and other third-party payers.

If any of our drugs are approved and fail to achieve market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability.

### ***If any products we develop become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, our ability to successfully commercialize our products will be impaired.***

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payers to contain or reduce the costs of health care through various means. We expect a number of federal, state and foreign proposals to control the cost of drugs through government regulation. We are unsure of the impact that the potential repeal of recent health care reform legislation may have on our business or what actions federal, state, foreign and private payers may take or reforms that may be implemented in the future. Therefore, it is difficult to predict the effect of any potential reform on our business. Our ability to commercialize our drug candidates successfully will depend, in part, on the extent to which reimbursement for the cost of such drug candidates and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the United States, private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, particularly for indications for which there is no current effective

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treatment or for which medical care typically is not sought. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in research and development. If adequate coverage and reimbursement levels are not provided by government and third-party payers for use of our products, our products may fail to achieve market acceptance without a substantial reduction in price or at all and our results of operations will be harmed.

### ***Even if our drug candidates obtain regulatory approval, we and our collaborators will be subject to ongoing government regulation.***

Even if regulatory authorities approve any of our drug candidates, the manufacture, marketing and sale of these drugs will be subject to strict and ongoing regulation. Compliance with such regulations may consume substantial financial and management resources and expose us and our collaborators to the potential for other adverse circumstances. For example, a regulatory authority can place restrictions on the sale or marketing of a drug in order to manage the risks identified during initial clinical trials or after the drug is on the market. A regulatory authority can condition the approval for a drug on costly post-marketing follow-up studies. Based on these studies, if a regulatory authority does not believe that the drug demonstrates a clinical benefit to patients or an acceptable safety profile, it could limit the indications for which a drug may be sold or revoke the drug's marketing approval. In addition, identification of certain side effects either during clinical trials or after a drug is on the market may result in reformulation of a drug, additional preclinical and clinical trials, labeling changes, termination of ongoing clinical trials or withdrawal of approval. Any of these events could delay or prevent us from generating revenue from the commercialization of these drugs and cause us to incur significant additional costs.

### ***We may not be able to establish the contractual arrangements necessary to develop, market and distribute our drug candidates.***

A key part of our business plan is to establish contractual relationships with third parties to package, market and distribute our drug candidates. There is no assurance that we will be able to negotiate commercially acceptable licensing or other agreements for the future exploitation of our drug candidates, including continued clinical development, manufacture or marketing. If we are unable to successfully contract for these services, or if arrangements for these services are terminated, we may have to delay our commercialization program which will adversely affect our ability to generate operating revenues.

### ***Our commercial opportunity will be reduced or eliminated if competitors develop and market products that are more effective, have fewer side effects or are less expensive than our drug candidates.***

The development of drug candidates is highly competitive. A number of other companies have products or drug candidates that have either been approved or are in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which our drug candidates are being developed. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized sooner. Even if we are successful in developing effective drugs, our compounds may not compete successfully with products produced by our competitors.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for us. Many of our competitors developing oncology drugs have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us and our service providers, to recruit qualified personnel, and with us to attract partners for joint ventures and to license technologies that are competitive with us. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies or our drug candidates obsolete or non-competitive.

### ***We rely on third parties to conduct our clinical trials and many of our pre-clinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our drug candidates may not advance in a timely manner or at all.***

In the course of our pre-clinical testing and clinical trials, we rely on third parties, including laboratories, investigators, clinical contract research organizations ("CROs"), and manufacturers, to perform critical services for us. For example, we rely on third parties to conduct our clinical trials and many of our pre-clinical studies, which are required to be conducted consistent with regulations on Good Laboratory Practice, or GLP. CROs are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with us. In addition, if such third parties fail to perform their obligations in compliance with our clinical trial protocols or GCPs, our clinical trials may not meet regulatory requirements or may need to be repeated. As a result of our dependence on third parties, we may face delays or failures outside of our direct control. These risks also apply to the development activities of collaborators, and we do not control their research and development, clinical trial or regulatory activities.

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***We will depend on third party suppliers and contract manufacturers for the manufacturing of our drug candidates and have no direct control over the cost of manufacturing our drug candidates. Increases in the cost of manufacturing our drug candidates would increase our costs of conducting clinical trials and could adversely affect our future profitability.***

We do not intend to manufacture our drug candidates ourselves, and we will rely on third parties for our drug supplies both for clinical trials and for commercial quantities in the future. We have taken the strategic decision not to manufacture active pharmaceutical ingredients (“API”) for our drug candidates, as these can be more economically supplied by third parties with particular expertise in this area. We have identified contract facilities that are registered with the FDA, have a track record of large scale API manufacture, and have already invested in capital and equipment. We have no direct control over the cost of manufacturing our drug candidates. If the cost of manufacturing increases, or if the cost of the materials used increases, these costs will be passed on to us, making the cost of conducting clinical trials more expensive. Increases in manufacturing costs could adversely affect our future profitability if we are unable to pass all of the increased costs along to our customers.

Further, we, along with our contract manufacturers, are required to comply with FDA requirements for cGMPs, related to product testing, quality assurance, manufacturing and documentation. Our contract manufacturers may not be able to comply with the applicable FDA regulatory requirements. They may be required to pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture our drug candidates and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP, we may experience manufacturing errors resulting in defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business. Not complying with FDA requirements could result in a product recall, or prevent commercialization of our drug candidates and delay our business development activities. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and potentially civil and/or criminal penalties depending on the matter.

***Our business strategy may include entry into additional collaborative or license agreements. We may not be able to enter into collaborative or license agreements or may not be able to negotiate commercially acceptable terms for these agreements.***

Our current business strategy may include the entry into additional collaborative or license agreements for the development and commercialization of our drug and drug candidates. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators or licensees and require significant time and resources. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators or licensees, we compete with numerous other third parties with product opportunities as well as the collaborators’ or licensees’ own internal product opportunities. We may not be able to consummate collaborative or license agreements, or we may not be able to negotiate commercially acceptable terms for these agreements.

If we do enter into such arrangements, we could be dependent upon the subsequent success of these other parties in performing their respective responsibilities and the cooperation of our partners. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators’ resources that will be devoted to researching our product candidates pursuant to our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us.

Under agreements with any collaborators or licensees we may work with in the future, we may rely significantly on them to, among other activities:

- fund research and development activities with us;
- pay us fees upon the achievement of milestones; and
- market for or with us any commercial products that result from our collaborations.

If we do not consummate collaborative or license agreements, we may use our financial resources more rapidly on our drug development efforts, continue to defer certain development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business prospects. Further, we may not be successful in overseeing any such collaborative arrangements. If we fail to establish and maintain necessary collaborative or license relationships, our business prospects could suffer.

***We rely on acquisitions or licenses from third parties to expand our pipeline of drug candidates.***

We are not presently engaged in drug discovery activities. In order to expand our pipeline of drug candidates for future development, we may need to purchase or in-license any such drug candidates. The success of this strategy depends in large part on the combination of our regulatory and development capabilities and expertise and our ability to identify, select and acquire or in-license clinically-enabled product candidates on terms that are acceptable to us. Identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical expertise, and we have limited experience in identifying and integrating any acquired product candidates into our current infrastructure. Efforts to do so may not result in the actual acquisition or in-license of a particular drug candidate, potentially resulting in a diversion of our management’s time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects may be limited.

***We face a risk of product liability claims and claims may exceed our insurance limits.***

Our business exposes us to the risk of product liability claims. This risk is inherent in the manufacturing, testing and marketing of human therapeutic products. Our product liability insurance coverage is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities, or claims may exceed our insurance limits. If we cannot or do not sufficiently insure against potential product liability claims, we may be exposed to significant liabilities, which may materially and adversely affect our business development and commercialization efforts.

***Our efforts will be seriously jeopardized if we are unable to retain and attract key employees.***

Our success depends on the continued contributions of our principal management, development and scientific personnel. We face competition for such personnel, and we believe that risks and uncertainties related to our business, including the timing and risk associated with research and development, our available and anticipated cash resources, and the volatility of our stock price, may impact our ability to hire and retain key and other personnel. The loss of services of our Chief Executive Officer or other key employees could adversely impact our operations and ability to generate or raise additional capital.

***Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers.***

Laws and regulations affecting public companies, including rules adopted by the SEC and by NASDAQ, may result in increased costs to us. These laws, rules and regulations could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as executive officers. We cannot estimate accurately the amount or timing of additional costs we may incur to respond to these laws, rules and regulations.

***If we fail to establish and maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which would adversely affect our consolidated operating results, our ability to operate our business, and our stock price, and could result in litigation or similar actions.***

Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause the trading price of our common stock to fall dramatically. Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with accounting standards generally accepted in the United States of America ("U.S. GAAP"). A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the company will be detected.

We cannot be certain that the actions we have taken to ensure we have adequate internal controls over financial reporting will be sufficient. In future periods, if the process required by Section 404 of the Sarbanes-Oxley Act reveals any material weaknesses or significant deficiencies, the correction of any such material weaknesses or significant deficiencies could require remedial measures which could be costly and time-consuming. In addition, in such a case, we may be unable to produce accurate financial statements on a timely basis. Any associated accounting restatement could create a significant strain on our internal resources and cause delays in our release of quarterly or annual financial results and the filing of related reports, increase our costs and cause management distraction. Any of the foregoing could cause investors to lose confidence in the reliability of our consolidated financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

***Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.***

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, as well as personally identifiable information of clinical trial participants and employees. Similarly, our third-party providers possess certain of our sensitive protected health data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. 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 compliance with the Health Insurance Portability and Accountability Act of 1996 and recently enacted laws in a majority of states requiring security breach notification.

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Thus, any access, disclosure or other loss of information, including our data being breached at our partners or third-party providers, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disrupt our operations and damage our reputation, which could adversely affect our business.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste. Even if we contract with third parties for the disposal of these materials and waste, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

### **Risks Relating to Our Intellectual Property**

***Our commercial success is dependent, in part, on obtaining and maintaining patent protection and preserving trade secrets, which cannot be guaranteed.***

Patent protection and trade secret protection are important to our business and our future will depend, in part on our ability to maintain trade secret protection, obtain patents and operate without infringing the proprietary rights of others both in the United States and abroad. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents or to protect our trade secrets. Such litigation could result in substantial costs and diversion of our management's attention.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. In August 2012, we acquired patents and patent applications related to Pracinostat from S\*Bio. In September 2013, we acquired patents and patent applications related to ME-401 from Pathway Therapeutics, Inc. Additionally, prior to the Isoflavone Transaction, Novogen had applied for patents in a number of countries with respect to the use of their isoflavone compounds, including ME-344. We acquired both issued patents and pending patent applications related to ME-344 from Novogen in relation to our Isoflavone-based compounds, which we previously licensed from Novogen. The patent applications may not proceed to grant or may be amended to reduce the scope of protection of any patent granted. The applications and patents may also be opposed or challenged by third parties. Our commercial success will depend, in part, on our ability to obtain and maintain effective patent protection for our compounds and their use in treating, preventing, or curing cancer, and to successfully defend patent rights in those technologies against third-party challenges. As patent applications in the United States are maintained in secrecy until published or issued and as publication of discoveries in the scientific or patent literature often lag behind the actual discoveries, we cannot be certain that we, S\*Bio, Novogen, or Pathway Therapeutics, Inc. were the first to make the inventions covered by the pending patent applications or issued patents referred to above or that we or they were the first to file patent applications for such inventions. Additionally, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. We cannot be sure that, should any patents issue, we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that should patents issue, they will be of commercial value to us, or that private parties, including competitors, will not successfully challenge our patents or circumvent our patent position in the United States or abroad.

***Claims by other companies that we infringe on their proprietary technology may result in liability for damages or stop our development and commercialization efforts.***

The pharmaceutical industry is highly competitive and patents have been applied for by, and issued to, other parties relating to products competitive with the compounds that we have acquired. Therefore, Pracinostat, ME-401 and ME-344 and any other drug candidates may give rise to claims that they infringe the patents or proprietary rights of other parties existing now and in the future.

Furthermore, to the extent that we or our consultants or research collaborators use intellectual property owned by others in work performed for us, disputes may also arise as to the rights in such intellectual property or in resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties.

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We have contracted formulation development and manufacturing process development work for our product candidates. This process has identified a number of excipients, or additives to improve drug delivery, which may be used in the formulations. Excipients, among other things, perform the function of a carrier of the active drug ingredient. Some of these identified excipients or carriers may be included in third party patents in some countries. We intend to seek a license if we decide to use a patented excipient in the marketed product or we may choose one of those excipients that does not have a license requirement.

We cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded.

***We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Many of our employees and the employees of Helsinn and third parties upon which we rely to conduct our clinical trials were previously employed at universities or at other biotechnology or pharmaceutical companies, some of which may be competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants, advisors and collaborators who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

***We may be subject to substantial costs stemming from our defense against third-party intellectual property infringement claims.***

Third parties may assert that we are using their proprietary information without authorization. Third parties may also have or obtain patents and may claim that technologies licensed to or used by us infringe their patents. If we are required to defend patent infringement actions brought by third parties, or if we sue to protect our own patent rights, we may be required to pay substantial litigation costs and managerial attention may be diverted from business operations even if the outcome is not adverse to us. In addition, any legal action that seeks damages or an injunction to stop us from carrying on our commercial activities relating to the affected technologies could subject us to monetary liability and require us or any third party licensors to obtain a license to continue to use the affected technologies. We cannot predict whether we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms or at all.

## **Risks Related to Securities Markets and Investment in Our Stock**

***The trading price of the shares of our common stock has been and may continue to be highly volatile and could decline in value and we may incur significant costs from class action litigation.***

The trading price of our common stock could be highly volatile in response to various factors, many of which are beyond our control, including, but not limited to, the following:

- failure to successfully develop our drug candidates;
- design, results and timing of clinical trials and preclinical studies;
- announcements of technological innovations by us or our competitors;
- new products introduced or announced by us or our competitors;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in operating results;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology, pharmaceutical and genomics industries;
- instability in the stock market as a result of current or future domestic and global events;
- changes in the market valuations of similar companies;
- the liquidity of any market for our securities; and
- threatened or actual delisting of our common stock from a national stock exchange.

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Equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. In addition, changes in economic conditions in the U.S., Europe or globally, particularly in the context of current global events, could impact upon our ability to grow profitably. Adverse economic changes are outside our control and may result in material adverse impacts on our business or our results of operations. These broad market and industry factors may materially affect the market price of shares of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources.

***Future sales of our common stock, including common stock issued upon exercise of outstanding warrants or options, may depress the market price of our common stock and cause stockholders to experience dilution.***

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, including upon exercise of outstanding warrants or stock options, or upon issuance of shares related to restricted stock units ("RSUs"), and any subsequent sales of such shares. As of June 30, 2017, we had outstanding warrants issued in our December 2012 private placement exercisable to purchase 3,230,202 shares of common stock at an exercise price of \$3.12 per share, which expire in December 2017. We also had outstanding options to purchase 4,259,083 shares of common stock and RSUs representing the right to receive 744,179 shares of common stock. We may seek additional capital through one or more additional equity transactions in the future; however, such transactions will be subject to market conditions and there can be no assurance any such transactions will be completed. If we sell shares in the future, the prices at which we sell these future shares will vary, and these variations may be significant. Stockholders will experience significant dilution if we sell these future shares at prices significantly below the price at which previous stockholders invested.

***Because we do not intend to pay, and have not paid, any cash dividends on our shares of common stock, our stockholders will not be able to receive a return on their shares unless the value of our common stock appreciates and they sell their shares.***

We have never paid or declared any cash dividends on our common stock, and we intend to retain any future earnings to finance the development and expansion of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Therefore, our stockholders will not be able to receive a return on their investment unless the value of our common stock appreciates and they sell their shares.

***We will have broad discretion over the use of the net proceeds from any exercise of outstanding warrants and options.***

We will have broad discretion to use the net proceeds to us upon any exercise of outstanding warrants and options, and investors in our stock will be relying on the judgment of our board of directors and management regarding the application of these proceeds. Although we expect to use a substantial portion of the net proceeds from any exercise of the warrants and options for general corporate purposes and progression of our clinical trial programs, we have not allocated these net proceeds for specific purposes.

***We are authorized to issue blank check preferred stock, which could adversely affect the holders of our common stock.***

Our restated certificate of incorporation allows us to issue blank check preferred stock with rights potentially senior to those of our common stock without any further vote or action by the holders of our common stock. The issuance of a class of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our shares, or making a change in control of the Company more difficult.

***Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price.***

Sales of our stock by our executive officers and directors, or the perception that such sales may occur, could adversely affect the market price of our stock. Our executive officers and directors may sell stock in the future, either as part, or outside, of trading plans under Rule 10b5-1 under the Securities Exchange Act of 1934, as amended.

### **Item 1B. Unresolved Staff Comments**

None.

### **Item 2. Properties**

We have leased approximately 13,700 square feet of office space, located at 3611 Valley Centre Drive, Suite 500, San Diego, California 92130. The location houses our executive and administrative offices. The lease commenced in July 2017 and expires in May 2020. The monthly rental rate is approximately \$44,000 per month over the term of the lease, plus a pro rata share of certain building expenses.

### **Item 3. Legal Proceedings**

None.

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**Item 4. Mine Safety Disclosures**

Not applicable.

**PART II**

**Item 5. Market for the Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock is listed on the NASDAQ Capital Market under the symbol “MEIP”. The following table sets forth, for the periods indicated, the high and low sale prices of our common stock for each quarterly period within the two most recent fiscal years.

	Prices	
	High \$	Low \$
Year Ended June 30, 2017		
First Quarter	2.28	1.32
Second Quarter	1.89	1.34
Third Quarter	1.88	1.40
Fourth Quarter	2.50	1.48
Year Ended June 30, 2016		
First Quarter	2.08	1.47
Second Quarter	2.12	1.52
Third Quarter	1.67	0.87
Fourth Quarter	1.80	1.23

**Holders**

As of August 30, 2017, there were 36,938,970 shares of our common stock outstanding and 1,146 holders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

For a discussion of outstanding warrants and other securities exercisable for or convertible into shares of our common stock, see Note 6 and 7 under Item 8 in this Annual Report.

**Dividends**

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain all available funds and future earnings, if any, to support operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

**Securities authorized for issuance under equity compensation plans**

The table below shows, as of June 30, 2017, information for equity compensation plans previously approved by stockholders and for compensation plans not previously approved by stockholders.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	5,003,262	\$ 3.21	5,096,693
Equity compensation plans not approved by security holders	—	—	—
<b>Total</b>	<b>5,003,262</b>	<b>\$ 3.21</b>	<b>5,096,693</b>

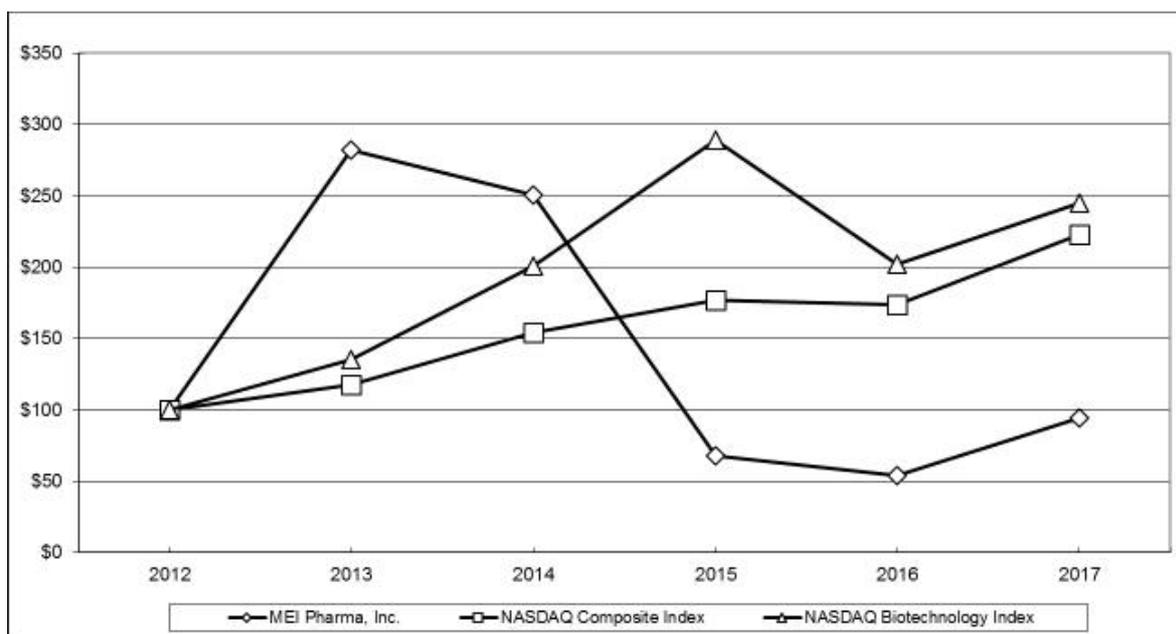
- (1) Consists of 4,259,083 shares of common stock issuable upon exercise of options and 744,179 shares of common stock issuable upon vesting of RSUs, in each case, granted or that may be granted under the MEI Pharma, Inc. Amended and Restated 2008 Stock Omnibus Equity Compensation Plan (“the Plan”), under which 10,186,000 shares of common stock are authorized for issuance. The Plan provides for the grant of options and/or other stock-based or stock-denominated awards to our non-employee directors, officers, employees and advisors. The weighted-average exercise price presented is the weighted-average exercise price of vested and unvested options. The RSUs have no exercise price. For purposes of determining the number of shares available for future grant, there were 344,179 RSUs outstanding as of June 30, 2017 which are calculated as 1.25 shares of common stock under the terms of the Plan.

### Performance graph

The graph below compares the cumulative five-year total return on our common stock from July 1, 2012, through June 30, 2017, to the cumulative total return over such period for (i) the NASDAQ Composite Index and (ii) the NASDAQ Biotechnology Index. The graph assumes the investment of \$100 on July 1, 2012, with the reinvestment of dividends, although dividends have not been declared on our common stock, and is calculated according to the Securities and Exchange Commission’s methodology. We caution that the stock price performance shown in the graph may not be indicative of future stock price performance. The graph, including each of the graph lines, was provided by Zacks Investment Research, Inc.

*This information, including the graph below, is not deemed to be “soliciting material” or to be “filed” with the Securities and Exchange Commission, or subject to the Securities and Exchange Commission’s proxy rules, other than as provided in such rules, or to the liabilities of Section 18 of the Securities Exchange Act of 1934, and shall not be deemed incorporated by reference into any prior or subsequent filing by us under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that we specifically incorporate it by reference into any such filing.*

**COMPARISON OF FIVE-YEAR CUMULATIVE TOTAL RETURN**



### Item 6. Selected Financial Data

The following Selected Financial Data should be read in conjunction with “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Item 8. Financial Statements and Supplementary Data” included below in this Annual Report.

The following table presents our selected historical condensed financial data. The condensed statements of operations data for fiscal years ended June 30, 2017, 2016 and 2015 and the condensed balance sheet data as of June 30, 2017 and 2016 are derived from our audited financial statements included elsewhere in this Annual Report. The condensed statements of operations data for the fiscal years ended June 30, 2014 and 2013 and the condensed balance sheet data as of June 30, 2015, 2014 and 2013 are derived from our audited financial statements that are not included in this Annual Report.

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	Years Ended June 30,				
	2017	2016	2015	2014	2013
	(In thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Revenues:					
License revenue	\$ 20,880	\$ —	\$ —	\$ —	\$ —
Research and development revenue	2,369	—	—	—	—
Total revenues	23,249	—	—	—	—
Operating expenses:					
Cost of research and development revenue	5,000	—	—	—	—
Research and development	7,237	13,403	23,823	19,331	6,084
General and administrative	8,628	7,601	8,948	7,897	5,138
Total operating expenses	20,865	21,004	32,771	27,228	11,222
Income (loss) from operations	2,384	(21,004)	(32,771)	(27,228)	(11,222)
Other income, net	286	142	77	80	36
Net income (loss)	\$ 2,670	\$ (20,862)	\$ (32,694)	\$ (27,148)	\$ (11,186)
Net income (loss) per share, basic	\$ 0.07	\$ (0.61)	\$ (1.16)	\$ (1.35)	\$ (1.10)
Net income (loss) per share, diluted	\$ 0.07	\$ (0.61)	\$ (1.16)	\$ (1.35)	\$ (1.10)
Shares used to calculate net income (loss) per share					
Basic	36,813	34,400	28,204	20,061	10,161
Diluted	36,938	34,400	28,204	20,061	10,161
	As of June 30,				
	2017	2016	2015	2014	2013
	(In thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 53,565	\$ 45,918	\$ 63,779	\$ 48,793	\$ 35,573
Total assets	55,704	47,164	64,750	49,808	36,547
Total liabilities	4,866	5,512	4,959	4,616	1,675
Accumulated deficit	(174,331)	(177,001)	(156,139)	(123,445)	(96,297)
Total stockholders' equity	55,704	41,652	59,791	45,192	34,872

### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with "Item 8. Financial Statements and Supplementary Data" included below in this Annual Report. Operating results are not necessarily indicative of results that may occur in future periods.

This discussion and analysis contains forward-looking statements that involve a number of risks, uncertainties and assumptions. Actual results may differ materially from those anticipated in the forward-looking statements as a result of many factors including, but not limited to, those set forth under "Cautionary Statement About Forward-Looking Statements" and "Risk Factors" in Item 1A. included above in this Annual Report. All forward-looking statements included in this Annual Report are based on the information available to us as of the time we file this Annual Report, and except as required by law, we undertake no obligation to update publicly or revise any forward-looking statements.

### Overview and Recent Developments

Our business purpose is the development of drugs for the treatment of cancer. Our portfolio of clinical drug candidates includes Pracinostat, an oral HDAC inhibitor that is being developed in combination with azacitidine for the treatment of adults with newly diagnosed AML who are unfit for intensive chemotherapy, and patients with high or very high-risk MDS. In August 2016, we entered into an exclusive worldwide license, development and commercialization agreement with Helsinn for Pracinostat in AML, MDS and other potential indications. Our clinical development portfolio also includes ME-401, an oral inhibitor of PI3K delta being developed for B-cell malignancies, and ME-344, a mitochondrial inhibitor that has shown evidence of clinical activity in refractory solid tumors. We own exclusive worldwide rights to ME-401 and ME-344.

We have an accumulated deficit of \$174.3 million as of June 30, 2017, and may incur substantial net losses in the future as we advance our research and development programs. We expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. We may need additional financing to fund our operations in the future, including the continued development of our lead drug candidates.

## Clinical Development Programs

### Pracinostat

In August 2016, the FDA granted Breakthrough Therapy Designation for Pracinostat in combination with azacitidine for the treatment of patients with newly diagnosed AML who are unfit for intensive chemotherapy. The Breakthrough Therapy Designation is supported by data from a Phase II study of Pracinostat plus azacitidine in elderly patients with newly diagnosed AML who are not candidates for induction chemotherapy. The study showed a median overall survival of 19.1 months and a CR rate of 42% (21 of 50 patients). The combination of Pracinostat and azacitidine was generally well tolerated, with no unexpected toxicities. The most common grade 3/4 treatment-emergent adverse events included febrile neutropenia, thrombocytopenia, anemia and fatigue.

In August 2016, we entered into the Helsinn License Agreement. Under the terms of the agreement, Helsinn was granted a worldwide exclusive license to develop, manufacture and commercialize Pracinostat, and is primarily responsible for funding its global development and commercialization. As compensation for such grant of rights, we received payments of \$20.0 million, including a \$15.0 million upfront payment and a \$5.0 million payment in March 2017. In addition, we are eligible to receive up to \$444 million in potential regulatory and sales-based milestones, along with royalty payments on the net sales of Pracinostat, which, in the U.S., are tiered and begin in the mid-teens.

In July 2017, the first patient was dosed in a pivotal Phase III study of Pracinostat in combination with azacitidine in adults with newly diagnosed AML who are unfit to receive intensive induction chemotherapy. The randomized, double-blind, placebo-controlled study will enroll approximately 500 eligible patients worldwide. The primary endpoint of the study is overall survival. Secondary endpoints include morphologic CR rate, EFS and duration of CR. Helsinn is responsible for the conduct and funding of this Phase III study.

In June 2017, the first patient was dosed in a Phase II dose-optimization study of Pracinostat in combination with azacitidine in patients with high and very high risk MDS who are previously untreated with hypomethylating agents. The two-stage study will be conducted at approximately 25 sites and is expected to enroll up to 120 patients. Data from the first stage is expected in the first quarter of 2018. We are responsible for the conduct of this Phase II study, the cost of which will be shared by Helsinn. Helsinn will be responsible for funding any further studies.

### ME-401

Results from a first-in-human, single ascending dose clinical study of ME-401 in healthy volunteers were presented at the American Association for Cancer Research Annual Meeting in April 2016. The data demonstrated on target activity at very low plasma concentrations. In addition, the results from the study suggest that ME-401 has the potential for a superior pharmacokinetic and pharmacodynamics profile and an improved therapeutic window compared to idelalisib, with a half-life that supports once-daily dosing.

In May 2017, an independent safety review committee completed its pre-specified review of the first cohort of six evaluable patients in a Phase Ib, open-label, dose-escalation study of ME-401 in relapsed/refractory CLL and follicular lymphoma. Based on its review of the safety and efficacy data, the safety review committee declared a mBED for ME-401 at the starting dose of 60 mg and recommended escalation to a 120 mg dose cohort. To date there have been no reports of ALT/AST elevations, colitis or pneumonitis, events commonly reported with other drugs in this class. One patient in the study experienced grade 3 neutropenia that was considered related to the study drug; all other adverse events reported were grades 1 or 2. No patients have discontinued due to adverse events or disease progression. We plan to submit full data for presentation at an upcoming scientific meeting.

### ME-344

Results from our first-in-human, single-agent Phase I clinical trial of ME-344 in patients with refractory solid tumors were published in the April 1, 2015 issue of *Cancer*. The results indicated that eight of 21 evaluable patients (38%) treated with ME-344 achieved stable disease or better, including five who experienced progression-free survival that was at least twice the duration of their last prior treatment before entry into the study. In addition, one of these patients, a heavily pre-treated patient with small cell lung cancer, achieved a confirmed partial response and remained on study for two years. ME-344 was generally well tolerated at doses equal to or less than 10 mg/kg delivered on a weekly schedule for extended durations. Treatment-related adverse events included nausea, dizziness and fatigue. Dose limiting toxicities were observed at both the 15 mg/kg and 20 mg/kg dose levels, consisting primarily of grade 3 peripheral neuropathy.

In May 2015, we announced pre-clinical data from a collaboration with the Spanish National Cancer Research Centre in Madrid showing mitochondria-specific effects of ME-344 in cancer cells, including substantially enhanced anti-tumor activity when combined with a VEGF inhibitor. These data demonstrate that the anti-cancer effects when combining ME-344 with a VEGF inhibitor are due to an inhibition of both mitochondrial and glycolytic metabolism. An investigator-sponsored study of ME-344 in combination with the VEGF inhibitor bevacizumab (marketed as Avastin®) in HER2-negative breast cancer opened for enrollment in August 2016. This study is now actively dosing patients and interim data are expected in the fourth quarter of 2017.

## Equity Transactions

### *Shelf Registration Statement*

In May 2017, we filed a shelf registration statement on Form S-3 with the SEC (“shelf registration statement”). The shelf registration statement was declared effective by the SEC in May 2017 and permits us to sell, from time to time, up to \$150.0 million of common stock, preferred stock and warrants. As of June 30, 2017, there is \$150.0 million aggregate value of securities available under the shelf registration statement.

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### *Helsinn Equity Investment*

On August 5, 2016, we entered into a Common Stock Purchase Agreement with Helsinn Investment Fund SA (the “Helsinn Equity Agreement”). Pursuant to the terms of the Helsinn Equity Agreement, we issued 2,616,431 shares of common stock on August 16, 2016 in exchange for a \$5.0 million investment. Under the multiple-element arrangement accounting guidance, we allocated \$0.8 million of the investment as additional consideration related to the revenues under the Helsinn License Agreement. (See Note 2 to the Financial Statements included in Item 8 of this Annual Report.) The transaction was exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended.

### *Underwritten Registered Offerings*

In December 2014, we completed an underwritten registered offering of 11,500,000 shares of our common stock at a price per share of \$4.00. We received net proceeds of \$43.1 million associated with the offering, after costs of \$2.9 million.

## **Critical Accounting Policies and Management Estimates**

Management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

### *Revenue Recognition:*

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. The Company considers a variety of factors in determining the appropriate method of accounting under its license agreements, including whether the various elements can be separated and accounted for individually as separate units of accounting.

### *Multiple Element Arrangements*

Deliverables under an arrangement will be separate units of accounting, provided (i) a delivered item has value to the customer on a standalone basis; and (ii) the arrangement includes a general right of return relative to the delivered item, and delivery or performance of the undelivered item is considered probable and substantially in the Company’s control.

We account for revenue arrangements with multiple elements by separating and allocating consideration according to the relative selling price of each deliverable. If an element can be separated, an amount is allocated based upon the relative selling price of each element. We determine the relative selling price of a separate deliverable using the price it charges other customers when it sells that element separately. If the element is not sold separately and third party pricing evidence is not available, we will use our best estimate of selling price.

### *License Fee Revenue*

Non-refundable, up-front fees that are not contingent on any future performance by us and require no consequential continuing involvement on our part are recognized as revenue when the license term commences and the licensed data, technology or product is delivered. We defer recognition of non-refundable upfront license fees if it has continuing performance obligations, without which the licensed data, technology, or product has no utility to the licensee separate and independent of its performance under the other elements of the applicable arrangement. The specific methodology for the recognition of the revenue is determined on a case-by-case basis according to the facts and circumstances of the applicable agreement.

### *Research and Development Revenue*

Research and development revenue represents ratable recognition of fees allocated to research and development activities. We defer recognition of research and development revenue until the performance of the related research and development activities has occurred.

### *Expenses:*

#### *Cost of Research and Development Revenue*

Cost of research and development revenue primarily includes external costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials, and internal compensation and related personnel expenses to support our research and development revenue.

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### *Clinical Trials Expenses*

Estimates have been used in determining the expenses under certain clinical trial contracts where services have been performed but not yet invoiced. Generally, the costs associated with clinical trial contracts are based on the number of patients in each trial, the service contracts associated with clinical sites, service providers and drug development contracts. The length of time before actual amounts can be determined will vary, and are therefore estimated based on enrollment of subjects, the length of drug administration cycles, the completion of trials and other events.

### *Share-Based Compensation*

Share-based compensation expense for employees and directors is recognized in the statement of operations based on estimated amounts, including the grant date fair value and the expected service period. For stock options, we estimate the grant date fair value using a Black-Scholes valuation model, which requires the use of multiple subjective inputs including estimated future volatility, expected forfeitures and the expected term of the awards. We estimate our expected future volatility based on our stock's historical price volatility. Our stock's future volatility may differ from our estimated volatility at the grant date. For RSU equity awards, we estimate the grant date fair value using our closing stock price on the date of grant. Share-based compensation recorded in our statement of operations is based on awards expected to ultimately vest and has been reduced for estimated forfeitures. Our estimated forfeiture rates may differ from actual forfeiture rates which would affect the amount of expense recognized during the period. We recognize the value of the awards over the awards' requisite service or performance periods. The requisite service period is generally the time over which our share-based awards vest. Unrecognized compensation expense as of June 30, 2017 related to non-vested stock options and RSUs totalled \$1.1 million and \$0.3 million, respectively. Such compensation expense is expected to be recognized over weighted-average periods of 1.6 years and 1.1 years, respectively.

## **Results of Operations**

### **Comparison of Years Ended June 30, 2017 and 2016**

**License Revenue:** We recognized license revenue of \$20.9 million for the year ended June 30, 2017 compared to no license revenue for the year ended June 30, 2016. The license revenue resulted from the completion of the performance obligations related to the upfront license fees in accordance with the Helsinn License Agreement.

**Research and Development Revenue:** We recognized research and development revenue of \$2.4 million for the year ended June 30, 2017 compared to no research and development revenue for the year ended June 30, 2016. The research and development revenue resulted from the recognition of fees allocated to research and development activities in accordance with the Helsinn License Agreement.

### **Expenses:**

The following is a summary of our research and development expenses, including cost of research and development revenue, to supplement the more detailed discussions below. The dollar values in the following table are in thousands.

Research and development expenses	Years Ended June 30,	
	2017	2016
Pracinostat	\$ 4,501	\$ 3,405
ME-401	2,565	3,041
ME-344	65	1,972
Other	5,106	4,985
Total research and development expenses	<u>\$12,237</u>	<u>\$13,403</u>

**Cost of Research and Development Revenue:** We recognized cost of research and development revenue of \$5.0 million for the year ended June 30, 2017 compared to no cost of research and development revenue for the year ended June 30, 2016. The cost of research and development revenue includes external costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials, and internal compensation and related personnel expenses to support our research and development revenue. All costs of research and development revenue relate to expenses incurred in connection with our development activities in accordance with the Helsinn License Agreement.

**Research and Development:** Research and development expenses consist primarily of clinical trial costs (including payments to CROs), pre-clinical study costs, cost to manufacture our drug candidates for non-clinical and clinical studies, and salaries and other personnel costs. Research and development expenses decreased \$6.2 million to \$7.2 million for the year ended June 30, 2017 compared to \$13.4 million for the year ended June 30, 2016. The decrease was primarily due to a reduction of \$2.5 million in costs associated with clinical trials for Pracinostat pursuant to the Helsinn License Agreement whereby Helsinn is primarily responsible for the costs to continue the development of Pracinostat. Additionally, costs related to our other clinical trials decreased by \$1.0 million and the cost of drug manufacturing for Pracinostat decreased by \$0.7 million.

**General and Administrative:** General and administrative expenses increased by \$1.0 million to \$8.6 million for the year ended June 30, 2017 compared to \$7.6 million for the year ended June 30, 2016. The increase primarily relates to higher levels of professional services expenses related to the Helsinn License Agreement.

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**Other income or expense:** We received interest on cash, cash equivalents and short-term investments of \$287,000 for the year ended June 30, 2017 and \$143,000 for the year ended June 30, 2016. The increase was due to higher yields on investments during the year ended June 30, 2017 compared to the year ended June 30, 2016.

### Comparison of Years Ended June 30, 2016 and 2015

The following is a summary of our research and development expenses to supplement the more detailed discussions below. The dollar values in the following table are in thousands.

Research and development expenses	Years Ended June 30,	
	2016	2015
Pracinostat	\$ 3,405	\$12,933
ME-401	3,041	2,258
ME-344	1,972	3,214
Other	4,985	5,418
Total research and development expenses	<u>\$13,403</u>	<u>\$23,823</u>

**Research and Development:** Research and development expenses consist primarily of clinical trial costs (including payments to CROs), pre-clinical study costs, cost to manufacture our drug candidates for non-clinical and clinical studies, and salaries and other personnel costs. Research and development expenses decreased \$10.4 million to \$13.4 million for the year ended June 30, 2016 compared to \$23.8 million for the year ended June 30, 2015. The decrease was primarily due to a reduction of \$7.1 million in costs associated with Phase II clinical trials for Pracinostat related to MDS, a \$1.6 million decrease in costs related to our other clinical trials and a \$1.1 million decrease in drug manufacturing for Pracinostat.

**General and Administrative:** General and administrative expenses decreased by \$1.3 million to \$7.6 million for the year ended June 30, 2016 compared to \$8.9 million for the year ended June 30, 2015. The decrease primarily relates to lower levels of share-based compensation expense.

**Other income or expense:** We received interest on cash, cash equivalents and short-term investments of \$143,000 for the year ended June 30, 2016 and \$78,000 for the year ended June 30, 2015. The increase was due to higher yields on investments during the year ended June 30, 2016 compared to the year ended June 30, 2015.

### New Accounting Pronouncements

See Note 1 to the Financial Statements included in Item 8 of this Annual Report.

### Off-Balance Sheet Arrangements

We do not currently have any off-balance sheet arrangements.

### Liquidity and Capital Resources

We have accumulated losses of \$174.3 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of June 30, 2017, we had \$53.6 million in cash and cash equivalents and short-term investments, which we believe will be sufficient to fund our operations into calendar year 2019. Our current business operations are focused on continuing the clinical development of our drug candidates. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. To date, we have obtained cash and funded our operations primarily through equity financings. In order to continue the development of our drug candidates, at some point in the future we expect to pursue one or more capital transactions, whether through the sale of equity securities, license agreements or entry into strategic partnerships.

### Sources and Uses of Our Cash

Net cash provided by operations for the year ended June 30, 2017 was \$3.5 million compared to net cash used in operations of \$17.9 million in the year ended June 30, 2016 due to license fee revenues earned from the Helsinn License Agreement, as described above. Net cash used in operations for the year ended June 30, 2016 was \$17.9 million compared to \$28.1 million in the year ended June 30, 2015 due to a decrease in expenses incurred for research and development and general and administrative costs as described above.

Net cash used in investing activities for the year ended June 30, 2017 was \$10.0 million compared to \$10.0 million provided by investing activities for the year ended June 30, 2016. The change was primarily due to higher purchases of short-term investments in 2016 compared to 2017, net of maturities. Net cash provided by investing activities for the year ended June 30, 2016 was \$10.0 million compared to \$10.1 million used in investing activities for the year ended June 30, 2015. The increase was primarily due to lower purchases of short-term investments in 2015 compared to 2016, net of maturities.

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There was \$4.2 million provided by financing activities during the year ended June 30, 2017 compared with no cash provided by financing activities during the year ended June 30, 2016. Cash raised during the year ended June 30, 2017 reflected the equity investment by Helsinn. There was no cash provided by financing activities during the year ended June 30, 2016 compared with \$43.1 million during the year ended June 30, 2015. Cash raised during the year ended June 30, 2015 reflected \$43.1 million in net proceeds received from the issuance of common stock.

### *Contractual Obligations*

We have contracted with various consultants and third parties to assist us in pre-clinical research and development and clinical trials work for our leading drug compounds. The contracts are terminable at any time, but obligate us to reimburse the providers for any time or costs incurred through the date of termination. Additionally, we have employment agreements with certain of our current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances.

We have leased approximately 13,700 square feet of office space, located at 3611 Valley Centre Drive, San Diego, California 92130. The location houses our executive and administrative offices. The lease commenced in June 2017 and expires in May 2020. The monthly rental rate is approximately \$44,000 over the remaining lease term, plus a pro rata share of certain building expenses. The remaining contractual obligation is \$1.5 million.

### *License Agreement*

In September 2012, we entered into a license agreement with CyDex Pharmaceuticals, Inc. (“CyDex”). Under the license agreement, CyDex granted to us an exclusive, nontransferable license to intellectual property rights relating to Captisol® for use with our two isoflavone-based drug compounds. We agreed to pay to CyDex a non-refundable license issuance fee, future milestone payments, and royalties at a low, single-digit percentage rate on future sales of our approved drugs utilizing Captisol. Contemporaneously with the license agreement, CyDex and us entered into a commercial supply agreement pursuant to which we agreed to purchase 100% of our requirements for Captisol from CyDex. We may terminate both the license agreement and the supply agreement for convenience at any time upon 90 days’ prior written notice.

### *S\*Bio Asset Purchase*

In August 2012, we entered into a definitive asset purchase agreement with S\*Bio, pursuant to which we agreed to acquire certain assets comprised of intellectual property and technology including rights to Pracinostat, in exchange for \$500,000 of common stock. On August 22, 2012, we completed the asset purchase and issued 195,756 shares of common stock to S\*Bio. We also agreed to make certain milestone payments to S\*Bio based on the achievement of certain clinical, regulatory and net sales-based milestones, as well as to make certain contingent earnout payments to S\*Bio. Milestone payments will be made to S\*Bio up to an aggregate amount of \$75.2 million if certain U.S., E.U. and Japanese regulatory approvals are obtained and if certain net sales thresholds are met in North America, the E.U. and Japan. The first milestone payment of \$200,000 in cash plus \$500,000 payable in cash or in shares of our common stock will be due upon the first dosing of a patient in a Phase III clinical trial or other pivotal trial, for any indication. Subsequent milestone payments will be due upon certain regulatory approvals and sales-based events. In July 2017, the first patient was dosed in a Phase III study of Pracinostat in AML. As of June 30, 2017, we have accrued \$700,000 for payment of the first milestone. In August 2017, we issued 166,527 shares and paid \$200,000 in cash to S\*Bio.

## **Item 7a. Quantitative and Qualitative Disclosures about Market Risk**

### **Interest Rate Risk**

Our exposure to market interest rates relates primarily to the investments of cash balances and short-term investments. We have cash reserves held in U.S. dollars and we place funds on deposit with financial institutions, which are readily available. Our short-term investments consist solely of U.S. government securities with a maturity of three to twelve months.

We place our cash deposits with high credit quality financial institutions and by policy limit the amount of credit exposure to any one corporation or bank. These deposits are in excess of the Federal Deposit Insurance Corporation (“FDIC”) insurance limits. We are adverse to principal loss and we ensure the safety and preservation of our invested funds by limiting default risk, market risk and reinvestment risk. We seek to mitigate default risk by depositing funds with high credit quality financial institutions, by limiting the amount of credit exposure to any one corporation or bank, by purchasing short-term investments consisting of U.S. government securities, and by positioning our portfolio to respond appropriately to a significant reduction in a credit rating of any such financial institution.

We do not consider the effects of interest rate movements to be a material risk to our financial condition.

## **Item 8. Financial Statements and Supplementary Data**

### **MEI Pharma, Inc.**

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Report of Independent Registered Public Accounting Firm

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Statements of Cash Flows

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders  
MEI Pharma, Inc.  
San Diego, California

We have audited the accompanying balance sheets of MEI Pharma, Inc. (the “Company”) as of June 30, 2017 and 2016 and the related statements of operations, stockholders’ equity, and cash flows for each of the three years in the period ended June 30, 2017. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of MEI Pharma, Inc. at June 30, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2017, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), MEI Pharma, Inc.’s internal control over financial reporting as of June 30, 2017, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated September 4, 2017 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP  
San Diego, California  
September 4, 2017

**MEI PHARMA, INC.**  
**BALANCE SHEETS**  
(In thousands, except per share amounts)

	<b>June 30,</b>	
	<b>2017</b>	<b>2016</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,458	\$ 10,837
Short-term investments	45,107	35,081
Total cash, cash equivalents and short-term investments	53,565	45,918
Prepaid expenses and other current assets	1,758	831
Total current assets	55,323	46,749
Intangible assets, net	331	366
Property and equipment, net	50	49
Total assets	<u>\$ 55,704</u>	<u>\$ 47,164</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 585	\$ 1,079
Accrued liabilities	3,285	4,433
Deferred revenues	996	—
Total current liabilities	4,866	5,512
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100 shares authorized; none outstanding	—	—
Common stock, \$0.00000002 par value; 113,000 shares authorized; 36,772 and 34,156 shares issued and outstanding at June 30, 2017 and 2016, respectively.	—	—
Additional paid-in-capital	225,169	218,653
Accumulated deficit	(174,331)	(177,001)
Total stockholders' equity	50,838	41,652
Total liabilities and stockholders' equity	<u>\$ 55,704</u>	<u>\$ 47,164</u>

*See accompanying notes to financial statements.*

**MEI PHARMA, INC.**  
**STATEMENTS OF OPERATIONS**  
(In thousands, except per share amounts)

	Years Ended June 30,		
	2017	2016	2015
Revenues:			
License revenue	\$20,880	\$ —	\$ —
Research and development revenue	2,369	—	—
	<u>23,249</u>	<u>—</u>	<u>—</u>
Operating expenses:			
Cost of research and development revenue	5,000	—	—
Research and development	7,237	13,403	23,823
General and administrative	8,628	7,601	8,948
Total operating expenses	<u>20,865</u>	<u>21,004</u>	<u>32,771</u>
Income (loss) from operations	2,384	(21,004)	(32,771)
Other income (expense):			
Interest and dividend income	287	143	78
Income tax expense	(1)	(1)	(1)
Net income (loss)	<u>\$ 2,670</u>	<u>\$ (20,862)</u>	<u>\$ (32,694)</u>
Net income (loss) per share, basic	<u>\$ 0.07</u>	<u>\$ (0.61)</u>	<u>\$ (1.16)</u>
Net income (loss) per share, diluted	<u>\$ 0.07</u>	<u>\$ (0.61)</u>	<u>\$ (1.16)</u>
Shares used in computing net income (loss) per share:			
Basic	<u>36,813</u>	<u>34,400</u>	<u>28,204</u>
Diluted	<u>36,938</u>	<u>34,400</u>	<u>28,204</u>

*See accompanying notes to financial statements.*

**MEI PHARMA, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
(In thousands)

	Common Shares	Additional paid in capital	Accumulated Deficit	Total Stockholders' Equity
<b>Balance at June 30, 2014</b>	21,607	\$168,637	\$ (123,445)	\$ 45,192
Net loss	—	—	(32,694)	(32,694)
Issuance of common stock	11,500	43,070	—	43,070
Exercise of warrants	1,049	—	—	—
Share-based compensation expense	—	4,223	—	4,223
<b>Balance at June 30, 2015</b>	34,156	215,930	(156,139)	59,791
Net loss	—	—	(20,862)	(20,862)
Share-based compensation expense	—	2,723	—	2,723
<b>Balance at June 30, 2016</b>	34,156	218,653	(177,001)	41,652
Net income	—	—	2,670	2,670
Issuance of common stock	2,616	4,212	—	4,212
Share-based compensation expense	—	2,304	—	2,304
<b>Balance at June 30, 2017</b>	<u>36,772</u>	<u>\$225,169</u>	<u>\$ (174,331)</u>	<u>\$ 50,838</u>

*See accompanying notes to financial statements.*

**MEI PHARMA, INC.**  
**STATEMENTS OF CASH FLOWS**  
(In thousands)

	Year Ended June 30,		
	2017	2016	2015
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 2,670	\$(20,862)	\$(32,694)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Share-based compensation	2,304	2,723	4,223
Depreciation and amortization	85	58	64
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(927)	(329)	(5)
Accounts payable	(494)	216	(845)
Accrued liabilities	(1,148)	337	1,188
Deferred revenue	996	—	—
Net cash provided by (used in) operating activities	<u>3,486</u>	<u>(17,857)</u>	<u>(28,069)</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(51)	(4)	(15)
Purchases of short-term investments	(60,123)	(55,238)	(70,077)
Proceeds from maturity of short-term investments	50,097	65,214	60,036
Net cash (used in) provided by investing activities	<u>(10,077)</u>	<u>9,972</u>	<u>(10,056)</u>
<b>Cash flows from financing activities:</b>			
Net proceeds from issuance of common stock	4,212	—	43,070
Net cash provided by financing activities	<u>4,212</u>	<u>—</u>	<u>43,070</u>
Net (decrease) increase in cash and cash equivalents	(2,379)	(7,885)	4,945
Cash and cash equivalents at beginning of the period	10,837	18,722	13,777
Cash and cash equivalents at end of the period	<u>\$ 8,458</u>	<u>\$ 10,837</u>	<u>\$ 18,722</u>
<b>Supplemental cash flow information:</b>			
Income taxes paid	<u>\$ (1)</u>	<u>\$ (1)</u>	<u>\$ (1)</u>

*See accompanying notes to financial statements.*

**MEI PHARMA, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**June 30, 2017**

**Note 1. The Company and Summary of Significant Accounting Policies**

**The Company**

We are an oncology company focused on the clinical development of novel therapies for cancer. Our common stock is listed on the NASDAQ Capital Market under the symbol “MEIP”. We were incorporated in December 2000 as a wholly-owned subsidiary of Novogen Limited (“Novogen”). In December 2012, Novogen distributed to its shareholders substantially all of its MEI Pharma common stock.

Our business purpose is the development of drugs for the treatment of cancer. Our portfolio of drug candidates includes Pracinostat, an oral HDAC inhibitor that is being developed in combination with azacitidine for the treatment of adults with newly diagnosed AML who are unfit for intensive chemotherapy, and patients with high or very high-risk MDS. In August 2016, we entered into the Helsinn License Agreement for Pracinostat in AML, MDS and other potential indications. Our clinical development portfolio also includes ME-401, an oral inhibitor of PI3K delta currently in a Phase Ib study in patients with relapsed/refractory CLL or follicular lymphoma, and ME-344, a mitochondrial inhibitor currently in an investigator-sponsored clinical study in combination with bevacizumab for the treatment of HER2-negative breast cancer. We own exclusive worldwide rights to ME-401 and ME-344.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials. The commercial opportunity will be reduced or eliminated if competitors develop and market products that are more effective, have fewer side effects or are less expensive than our drug candidates. We will need substantial additional funds to progress the clinical trial programs for the drug candidates ME-401 and ME-344, and to develop new compounds. The actual amount of funds that will be needed are determined by a number of factors, some of which are beyond our control. Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators.

**New Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers*. The standard provides companies with a single model for accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific revenue guidance. The core principle of the model is to recognize revenue when control of the goods or services transfers to the customer, as opposed to recognizing revenue when the risks and rewards transfer to the customer under the existing revenue guidance. The guidance permits companies to either apply the requirements retrospectively to all prior periods presented, or apply the requirements in the year of adoption, through a cumulative adjustment. In August 2015, the FASB issued ASU 2015-14, *Deferral of the Effective Date*, which defers the required adoption date of ASU 2014-09 by one year. As a result of the deferred effective date, ASU 2014-09 will be effective for us in our first quarter of fiscal 2019. The following ASUs were subsequently issued by the FASB to clarify the implementation guidance in some areas and add practical expedients: In March 2016, ASU 2016-08, *Revenue from Contracts with Customers, Principal versus Agent Considerations*; in April 2016, ASU 2016-10, *Revenue from Contracts with Customers, Identifying Performance Obligations and Licensing*; in May 2016, ASU 2016-11, *Revenue from Contracts with Customers and Derivatives and Hedging—Rescission of SEC Guidance*; and ASU 2016-12, *Revenue from Contracts with Customers—Narrow Scope Improvements and Practical Expedients*. We are in the process of evaluating the transition method that will be elected and the impact of adoption on our financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties About an Entity’s Ability to Continue as a Going Concern* (“ASU 2014-15”). The standard requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date the financial statements are issued and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. Certain disclosures will be required if conditions give rise to substantial doubt about an entity’s ability to continue as a going concern. ASU 2014-15 applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016. We adopted this standard for the quarter ended December 31, 2016, and have applied the guidance in ASU 2014-15 to assess our ability to continue as a going concern. We have concluded that we do not have any issues related to our ability to continue as a going concern.

In February 2016, the FASB issued ASU 2016-02 *Leases*, which introduces the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous guidance. The new standard establishes a right-of-use (“ROU”) model that requires a lessee to record an ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. The new standard is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years with early adoption permitted. We are evaluating the impact that the adoption of this standard will have on our financial statements.

In March 2016, the FASB issued ASU 2016-09 *Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. We are evaluating the impact that the adoption of this standard will have on our financial statements.

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In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation: Scope of Modification Accounting*, which provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. This ASU does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions or award classification and would not be required if the changes are considered non-substantive. The amendments of this ASU are effective in the first quarter of fiscal 2018, with early adoption permitted. The adoption of ASU 2017-09 is not expected to have an impact on our financial statements.

### **Use of Estimates**

The preparation of 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 disclosures made in the accompanying notes to the financial statements. We use estimates that affect the reported amounts (including assets, liabilities and expenses) and related disclosures. Actual results could materially differ from those estimates.

### **Cash and Cash Equivalents**

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less when purchased. Cash is maintained at financial institutions and, at times, balances may exceed federally insured limits. We have never experienced any losses related to these balances.

### **Short-Term Investments**

Investments that have maturities of greater than three months but less than one year are classified as short-term investments. As of June 30, 2017 and 2016, our short-term investments consisted of \$45.1 million and \$35.1 million, respectively, in U.S. government securities. The short-term investments held as of June 30, 2017 and 2016 had maturity dates of less than one year, are considered to be "held to maturity" and are carried at amortized cost. Due to the short-term maturities of these instruments, the amortized cost approximates the related fair values. As of June 30, 2017 and 2016, the gross holding gains and losses were immaterial.

### **Fair Value of Financial Instruments**

The carrying amounts of financial instruments such as cash equivalents, short-term investments and accounts payable approximate the related fair values due to the short-term maturities of these instruments. We invest our excess cash in financial instruments which are readily convertible into cash, such as money market funds and U.S. government securities.

The fair value of financial assets and liabilities is measured under a three-tier fair value hierarchy as follows: Level 1 fair value is determined from observable, quoted prices in active markets for identical assets or liabilities. Level 2 fair value is determined from quoted prices for similar items in active markets or quoted prices for identical or similar items in markets that are not active. Level 3 fair value is determined using the entity's own assumptions about the inputs that market participants would use in pricing an asset or liability. Cash equivalents, where applicable, and short-term investments are classified as Level 1 as defined by the fair value hierarchy.

### **Intangible Assets**

Intangible assets consist of patents acquired from S\*Bio in August 2012, relating to a family of heterocyclic compounds that inhibit HDACs. Capitalized amounts are amortized on a straight-line basis over the expected life of the intellectual property of 14 years from the date of acquisition. The carrying values of intangible assets are periodically reviewed to determine if the facts and circumstances suggest that a potential impairment may have occurred. Results of operations for the years ended June 30, 2017, 2016 and 2015 do not reflect any write-downs associated with the potential impairment of intangible assets.

### **Property and Equipment**

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (generally three to seven years) using the straight-line method. Leasehold improvements are stated at cost and are amortized over the shorter of the estimated useful lives of the assets or the lease term.

## Revenue Recognition

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. The Company considers a variety of factors in determining the appropriate method of accounting under its license agreements, including whether the various elements can be separated and accounted for individually as separate units of accounting.

### *Multiple Element Arrangements*

Deliverables under an arrangement will be separate units of accounting, provided (i) a delivered item has value to the customer on a standalone basis; and (ii) the arrangement includes a general right of return relative to the delivered item, and delivery or performance of the undelivered item is considered probable and substantially in the Company's control.

We account for revenue arrangements with multiple elements by separating and allocating consideration according to the relative selling price of each deliverable. If an element can be separated, an amount is allocated based upon the relative selling price of each element. We determine the relative selling price of a separate deliverable using the price we charge other customers when we sell that element separately. If the element is not sold separately and third party pricing evidence is not available, we will use our best estimate of selling price.

### *License Fee Revenue*

Non-refundable, up-front fees that are not contingent on any future performance by us and require no consequential continuing involvement on our part are recognized as revenue when the license term commences and the licensed data, technology or product is delivered. We defer recognition of non-refundable upfront license fees if it has continuing performance obligations, without which the licensed data, technology, or product has no utility to the licensee separate and independent of its performance under the other elements of the applicable arrangement. The specific methodology for the recognition of the revenue is determined on a case-by-case basis according to the facts and circumstances of the applicable agreement.

### *Research and Development Revenue*

Research and development revenue represents ratable recognition of fees allocated to research and development activities. We defer recognition of research and development revenue until the performance of the related research and development activities has occurred.

### *Cost of Research and Development Revenue*

Cost of research and development revenue primarily includes external costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials, and internal compensation and related personnel expenses to support our research and development revenue. All cost of research and development revenue relate to expenses incurred in connection with our development activities in accordance with the Helsinn License Agreement.

## Research and Development Costs

Research and development costs are expensed as incurred and include costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third-party contractors, are a significant component of research and development expenses. We accrue research and development costs based on work performed. In determining the amount to accrue, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events. Costs incurred related to the purchase of in-process research and development for early-stage products or products that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

## License Fees

Costs incurred related to the licensing of products that have not yet received regulatory approval to be marketed, or that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

## Share-based Compensation

Share-based compensation expense for employees and directors is recognized in the statement of operations based on estimated amounts, including the grant date fair value and the expected service period. For stock options, we estimate the grant date fair value using a Black-Scholes valuation model, which requires the use of multiple subjective inputs including estimated future volatility, expected forfeitures and the expected term of the awards. We estimate the expected future volatility based on the stock's historical price volatility. The stock's future volatility may differ from our estimated volatility at the grant date. For RSU equity awards, we estimate the grant date fair value using our closing stock price on the date of grant. Share-based compensation recorded in the statement of operations is based on the awards expected to ultimately vest and has been reduced for estimated forfeitures. The estimated forfeiture rates may differ from actual forfeiture rates which would affect the amount of expense recognized during the period. We recognize the value of the awards over the awards' requisite service or performance periods. The requisite service period is generally the time over which the share-based awards vest.

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### Interest and Dividend Income

Interest on cash balances is recognized when earned. Dividend income is recognized when the right to receive the payment is established.

### Income Taxes

Our income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to tax credits and loss carryforwards and to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of June 30, 2017 and 2016, we have established a valuation allowance to fully reserve our net deferred tax assets. Tax rate changes are reflected in income during the period such changes are enacted. Changes in our ownership may limit the amount of net operating loss carry-forwards that can be utilized in the future to offset taxable income.

The FASB Topic on Income Taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There were no unrecognized tax benefits as of June 30, 2017 and 2016.

### Net Income (Loss) Per Share

Basic and diluted net income (loss) per share are computed using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of common stock subject to repurchase or forfeiture for the years ended June 30, 2017, 2016 and 2015.

Shares used in calculating net income (loss) per share was determined as follows (in thousands):

	Years ended June 30,		
	2017	2016	2015
Weighted average shares outstanding	36,435	34,156	28,093
Effect of vested restricted stock units	378	244	111
Weighted average shares used in calculating basic earnings per share	36,813	34,400	28,204
Effect of potentially dilutive common shares from equity awards	125	—	—
Weighted average shares used in calculating diluted earnings per share	36,938	34,400	28,204
Potentially dilutive shares excluded from calculation due to anti-dilutive effect	7,377	6,628	6,533

Because we were in a net loss position for the years ended June 30, 2016 and 2015, we excluded stock options, warrants, unvested RSUs and convertible preferred stock from our calculation of diluted net loss per share, and our diluted net loss per share for such years was the same as our basic net loss per share. For the years ended June 30, 2017, 2016 and 2015, we did not have any items that would be classified as other comprehensive income or losses.

### Note 2. Helsinn License Agreement

In August 2016, we entered into the Helsinn License Agreement. Under the terms of the agreement, Helsinn was granted a worldwide exclusive license to develop, manufacture and commercialize Pracinostat, and is primarily responsible for funding its global development and commercialization. As compensation for such grant of rights, we received payments of \$20.0 million, including a \$15.0 million upfront payment and a \$5.0 million payment in March 2017. In addition, we are eligible to receive up to \$444 million in potential regulatory and sales-based milestones, along with royalty payments on the net sales of Pracinostat, which, in the U.S., are tiered and begin in the mid-teens.

We determined that the exclusive license, development and commercialization agreement represents a multiple-element arrangement for purposes of revenue recognition. We identified the following elements, based upon deliverables under the agreement: (i) worldwide license and transfer of technology and data; (ii) completion of the conduct of certain identified clinical trials related to Pracinostat; (iii) coordination of services provided by third-party vendors related to research and development activities, for which Helsinn has agreed to reimburse such third-party expenses; and (iv) the conduct of the POC study, for which Helsinn has agreed to share third-party expenses. The license was determined to represent a separate element as it has stand-alone value and is not dependent upon the performance of the research and development activities. The research and development elements, related to the conduct of clinical trials and services provided by third-party vendors, were determined to represent separate elements as they primarily represent pass through of services performed by third parties and therefore are sold separately by other vendors. We allocated the proceeds related to the agreement to the units of accounting using the relative selling price method. We determined the estimated selling price for the license using an income approach. We determined the estimated selling price for the research and development elements based on estimated fulfillment costs plus a normal profit margin. Revenue of \$20.9 million related to the

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license was recognized during the year ended June 30, 2017. Revenues related to the research and development elements of the arrangement are recognized based on the proportional performance of each research and development activity. Research and development revenues are recognized on a gross basis as we are the primary obligor and have discretion in supplier selection.

Contemporaneously with the Helsinn License Agreement, we entered into the Helsinn Equity Agreement in August 2016, with Helsinn Investment Fund SA (the "Purchaser"). Pursuant to the terms of the Helsinn Equity Agreement, the Purchaser agreed to purchase and we agreed to issue a number of shares of our common stock determined by dividing \$5,000,000 by the volume weighted-average price for shares of our common stock for the 10-trading-day-period beginning on August 1, 2016 and ending on August 12, 2016 (the "VWAP"), rounded to the nearest whole share. The VWAP was \$1.911 per share. Accordingly, on August 16, 2016, we issued 2,616,431 shares of common stock. The multiple-element arrangements guidance contains a presumption that separate contracts entered into at or near the same time with the same entity or related parties were negotiated together and should be evaluated as a single agreement. Therefore, the difference between the VWAP of \$1.911 per share and the closing price of our common stock on August 5, 2016 of \$1.61 per share, totaling \$0.8 million, has been allocated as additional consideration related to the revenue elements.

### Note 3. Intangible Assets

Intangible assets consisted of the following, in thousands:

	June 30,	
	2017	2016
S*Bio Patents – Gross	\$ 500	\$ 500
S*Bio Patents – Accumulated amortization	(169)	(134)
Intangible assets, net	<u>\$ 331</u>	<u>\$ 366</u>

Amortization expense of intangible assets for the years ended June 30, 2017, 2016 and 2015 was \$35,000, \$35,000 and \$34,000, respectively. We expect to record amortization of \$35,000 per year through 2026 for our S\*Bio patents.

### Note 4. Property and Equipment

Property and equipment consisted of the following, in thousands:

	June 30,	
	2017	2016
Furniture and equipment	\$ 95	\$127
Less: accumulated depreciation	(45)	(78)
Property and equipment, net	<u>\$ 50</u>	<u>\$ 49</u>

Depreciation expense of property and equipment for the years ended June 30, 2017, 2016 and 2015 was \$50,000, \$23,000 and \$30,000, respectively.

### Note 5. Accrued Liabilities

Accrued liabilities consisted of the following, in thousands:

	June 30,	
	2017	2016
Accrued pre-clinical and clinical trial expenses	\$1,334	\$2,816
Accrued compensation and benefits	1,546	1,342
Accrued legal and professional services expenses	267	215
Other	138	60
Total accrued liabilities	<u>\$3,285</u>	<u>\$4,433</u>

### Note 6. Stockholders' Equity

#### Equity Transactions

##### *Shelf Registration Statement*

In May 2017, we filed a shelf registration statement on Form S-3 with the SEC ("shelf registration statement"). The shelf registration statement was declared effective by the SEC in May 2017. The shelf registration statement permits us to sell, from time to time, up to \$150.0 million of common stock, preferred stock and warrants. As of June 30, 2017, there is \$150.0 million aggregate value of securities available under the shelf registration statement.

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### *Helsinn Equity Investment*

On August 5, 2016, we entered into the Helsinn Equity Agreement. Pursuant to the terms of the Helsinn Equity Agreement, we issued 2,616,431 shares of common stock on August 16, 2016 in exchange for a \$5.0 million investment. Under the multiple-element arrangement accounting guidance, we allocated \$0.8 million of the investment as additional consideration related to the revenues under the Helsinn License Agreement (Note 2). The transaction was exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended.

### *Underwritten Registered Offerings*

In December 2014, we completed an underwritten registered offering of 11,500,000 shares of our common stock at a price per share of \$4.00. We received net proceeds of \$43.1 million associated with the offering, after costs of \$2.9 million.

## **Description of Capital Stock**

Our total authorized share capital is 113,100,000 shares consisting of 113,000,000 shares of common stock, \$0.00000002 par value per share, and 100,000 shares of preferred stock, \$0.01 par value per share.

### *Common Stock*

The holders of common stock are entitled to one vote per share. In the event of a liquidation, dissolution or winding up of the our affairs, holders of the common stock will be entitled to share rateably in all our assets that are remaining after payment of the our liabilities and the liquidation preference of any outstanding shares of preferred stock. All outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of holders of common stock are subject to any series of preferred stock that we have issued or that we may issue in the future. The holders of common stock have no pre-emptive rights and are not subject to future calls or assessments by us.

### *Preferred Stock*

Our Board of Directors has the authority to issue up to 100,000 shares of preferred stock with par value of \$.01 per share in one or more series and to fix the rights, preferences, privileges and restrictions in respect of that preferred stock, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption (including sinking fund provisions), redemption prices and liquidation preferences, and the number of shares constituting such series and the designation of any such series, without future vote or action by the stockholders. Therefore, the board without the approval of the stockholders could authorize the issue of preferred stock with voting, conversion and other rights that could affect the voting power, dividend and other rights of the holders of shares or that could have the effect of delaying, deferring or preventing a change of control. There were no shares of preferred stock outstanding as of June 30, 2017 or 2016.

### *Warrants*

As of June 30, 2017, there were outstanding warrants to purchase 3,230,202 shares of our common stock at an exercise price of \$3.12 per share, which expire in December 2017, issued in conjunction with our December 2012 private placement.

## **Note 7. Share-based Compensation**

We use equity-based compensation programs to provide long-term performance incentives for our employees. These incentives consist primarily of stock options and RSUs. In December 2008, we adopted the MEI Pharma, Inc. 2008 Stock Omnibus Equity Compensation Plan ("2008 Plan"), as amended and restated in 2011, 2013 and 2016, under which 10,186,000 shares of common stock are authorized for issuance. The 2008 Plan provides for the grant of options and/or other stock-based or stock-denominated awards to our non-employee directors, officers, employees and advisors. As of June 30, 2017, there were 5,096,693 shares available for future grant under the 2008 Plan.

Total share-based compensation expense for all stock awards consists of the following, in thousands:

	Years Ended June 30,		
	2017	2016	2015
Research and development	\$ 839	\$1,871	\$1,030
General and administrative	1,465	852	3,193
Total share-based compensation	<u>\$2,304</u>	<u>\$2,723</u>	<u>\$4,223</u>

### *Stock Options*

Stock options granted to employees vest ratably each month for a period of 36 months, or vest 25% one year from the date of grant and ratably each month thereafter for a period of 36 months and expire either five years or ten years from the date of grant. Stock options granted to directors vest ratably each month for periods ranging from seven to 36 months from the date of grant and expire either five years or ten years from the date of grant. As of June 30, 2017, there were a total of 4,259,083 options outstanding.

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A summary of our stock option activity and related data follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 30, 2016	2,827,172	\$ 4.29		
Granted	1,709,583	1.41		
Forfeited / Cancelled	(222,865)	1.76		
Expired	(54,807)	9.13		
Outstanding at June 30, 2017	<u>4,259,083</u>	<u>\$ 3.21</u>	<u>6.6</u>	<u>\$ 2,644,191</u>
Vested and exercisable at June 30, 2017	<u>2,239,490</u>	<u>\$ 4.37</u>	<u>5.0</u>	<u>\$ 930,673</u>

No stock option exercises occurred during the years ended June 30, 2017, 2016 and 2015. As of June 30, 2017, the aggregate intrinsic value of outstanding options is calculated as the difference between the exercise price of the underlying options and the closing price of our common stock of \$2.39 on that date. The total fair value of options that vested during the years ended June 30, 2017, 2016 and 2015 was \$2.4 million, \$3.1 million and \$2.6 million, respectively.

A summary of our nonvested stock option activity:

	Number of Options	Weighted-Average Grant Date Fair Value
Nonvested at June 30, 2016	1,464,217	\$ 2.69
Granted	1,709,583	1.15
Forfeited	(222,865)	1.44
Vested	(931,342)	2.60
Nonvested at June 30, 2017	<u>2,019,593</u>	<u>\$ 1.57</u>

Unrecognized compensation expense related to non-vested stock options totalled \$1.1 million as of June 30, 2017. Such compensation expense is expected to be recognized over a weighted-average period of 1.6 years. As of June 30, 2017, we expect all outstanding options to vest.

We use a Black-Scholes valuation model to estimate the grant date fair value of stock options. To calculate these fair values, the following weighted-average assumptions were used:

	Years ended June 30,		
	2017	2016	2015
Risk-free interest rate	1.3%	1.7%	1.6%
Expected life (years)	5.9	5.8	5.0
Expected volatility	107.4%	116.7%	115.9%
Dividend yield	0.0%	0.0%	0.0%
Weighted-average grant date fair value	\$ 1.15	\$ 1.35	\$ 4.81

### Restricted Stock Units

In March 2013, the Compensation Committee of the Board of Directors granted 400,000 RSUs to our Chief Executive Officer, Dr. Daniel P. Gold. Each RSU represents the contingent right to receive one share of our common stock. One-third of the RSUs vested on August 30, 2014, one-third vested on August 30, 2015, and the remaining one-third vested on August 30, 2016. The shares underlying the RSUs will be delivered to Dr. Gold on the earliest to occur of (i) March 29, 2018, (ii) Dr. Gold's death, disability or separation from service from us for any reason, or (iii) a change in our control. The fair value of the RSUs on the date of grant was \$3.5 million. The grant date fair value per unit was \$8.63. In June 2016, we granted 364,726 RSUs to employees. Each RSU represents the contingent right to receive one share of our common stock. The RSUs were subject to performance criteria that were met in August 2016. The RSUs will vest in August 2018. The fair value of the RSUs was measured at \$1.61 per unit on the date the performance criteria were met. Under the terms of the 2008 Plan, each of these RSUs is calculated as 1.25 shares of common stock for purposes of determining the number of shares available for future grant. There were forfeitures of 18,835 RSUs during the year ended June 30, 2017, and 344,179 unvested RSUs were outstanding as of June 30, 2017. As of June 30, 2017, unrecognized compensation expense related to the unvested portion of our RSUs was approximately \$0.3 million and is expected to be recognized over approximately 1.1 years.

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### **Note 8. Commitments and Contingencies**

We have contracted with various consultants and third parties to assist it in pre-clinical research and development and clinical trials work for our leading drug compounds. The contracts are terminable at any time, but obligate us to reimburse the providers for any time or costs incurred through the date of termination. We also have employment agreements with certain of our current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances.

We have leased approximately 13,700 square feet of office space, located at 3611 Valley Centre Drive, San Diego, California 92130. The location houses our executive and administrative offices. The lease commenced in June 2017 and expires in May 2020. The monthly rental rate is approximately \$44,000 over the remaining lease term, plus a pro rata share of certain building expenses. The remaining contractual obligation is \$1.5 million.

#### *Asset Purchase Agreement*

In August 2012, we entered into a definitive asset purchase agreement with S\*Bio, pursuant to which we agreed to acquire certain assets comprised of intellectual property and technology including rights to Pracinostat, in exchange for \$500,000 of common stock. On August 22, 2012, we completed the asset purchase and issued 195,756 shares of common stock to S\*Bio. We have also agreed to make certain milestone payments to S\*Bio based on the achievement of certain clinical, regulatory and net sales-based milestones, as well as to make certain contingent earnout payments to S\*Bio. Milestone payments will be made to S\*Bio up to an aggregate amount of \$75.2 million if certain U.S., E.U. and Japanese regulatory approvals are obtained and if certain net sales thresholds are met in North America, the E.U. and Japan. The first milestone payment of \$200,000 plus shares of our common stock having a value of \$500,000 will be due upon the first dosing of a patient in a Phase III clinical trial or other pivotal trial, for any indication. Subsequent milestone payments will be due upon certain regulatory approvals and sales-based events. In July 2017, the first patient was dosed in a Phase III study of Pracinostat in AML. As of June 30, 2017, we have accrued \$700,000 for payment of the first milestone. In August 2017, we issued 166,527 shares and paid \$200,000 in cash to S\*Bio.

#### *License Agreement*

In September 2012, we entered into a license agreement with CyDex Pharmaceuticals, Inc. ("CyDex"). Under the license agreement, CyDex granted to us an exclusive, nontransferable license to intellectual property rights relating to Captisol® for use with our two isoflavone-based drug compounds. We agreed to pay to CyDex a non-refundable license issuance fee, future milestone payments, and royalties at a low, single-digit percentage rate on future sales of our approved drugs utilizing Captisol. Contemporaneously with the license agreement, CyDex and us entered into a commercial supply agreement pursuant to which we agreed to purchase 100% of our requirements for Captisol from CyDex. We may terminate both the license agreement and the supply agreement for convenience at any time upon 90 days' prior written notice. As of June 30, 2017, we have not accrued any amounts for potential future payments.

### **Note 9. Segment Information**

We have one operating segment, the development of pharmaceutical compounds. All of our assets and liabilities were located in the United States of America as of June 30, 2017, 2016 and 2015.

### **Note 10. Income Taxes**

Pre-tax income (loss) consists of the following jurisdictions (in thousands):

	Years ended June 30,		
	2017	2016	2015
Domestic	\$2,670	\$(20,862)	\$(32,694)
Foreign	—	—	—
Pre-tax loss	<u>\$2,670</u>	<u>\$(20,862)</u>	<u>\$(32,694)</u>

The reconciliation of income tax computed at the U.S. federal statutory tax rates to income tax expense is as follows (in thousands):

	Years Ended June 30,					
	2017		2016		2015	
	\$	%	\$	%	\$	%
Tax (expense) benefit at U.S. statutory rates	\$ (908)	34%	\$ 7,093	34%	\$ 11,116	34%
State tax	(158)	6%	1,215	6%	1,906	6%
Other	(208)	8%	(356)	(2)%	(475)	(2)%
Capital loss carryover expiration	(26,382)	988%	—	0%	—	0%
Decrease (increase) in valuation allowance	27,655	(1,036)%	(7,953)	(38)%	(12,548)	(38)%
	<u>\$ (1)</u>	<u>0%</u>	<u>\$ (1)</u>	<u>0%</u>	<u>\$ (1)</u>	<u>0%</u>

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Deferred tax liabilities and assets are comprised of the following (in thousands):

	June 30,	
	2017	2016
Deferred tax assets:		
Tax carried forward losses	\$ 7,886	\$ 7,730
Share-based payments	5,621	4,904
Consultant and other accruals	325	145
Fixed and intangible assets	29,660	32,484
Compensation accruals	630	545
Capital lease obligation	413	—
Capital loss carryforward	—	26,382
Total deferred tax assets	44,535	72,190
Valuation allowance for deferred tax assets	(44,535)	(72,190)
Net deferred tax assets and liabilities	\$ —	\$ —

We evaluate the recoverability of the deferred tax assets and the amount of the required valuation allowance. Due to the uncertainty surrounding the realization of the tax deductions in future tax returns, we have recorded a valuation allowance against our net deferred tax assets as of June 30, 2017 and 2016. At such time as it is determined that it is more likely than not that the deferred tax assets will be realized, the valuation allowance would be reduced.

We had federal and state net operating loss carryforwards of approximately \$20.1 million and \$17.8 million as of June 30, 2017. The federal and state net operating losses will begin to expire in 2022 and 2029, respectively. We also had federal and state capital loss carryforwards of approximately \$66.2 million that expired in 2017.

Our ability to utilize our net operating loss carryforwards may be substantially limited due to ownership changes that have occurred or that could occur in the future under Section 382 of the Internal Revenue Code and similar state laws. During 2017, we completed a study to analyze whether one or more ownership changes have occurred and determined that two such ownership changes did occur. Although these changes currently limit the use of some of our net operating losses, all of the net operating losses will be available for utilization before they expire.

None of our prior income tax returns have been selected for examination by a major taxing jurisdiction; however, the statutes of limitations for various filings remain open. The oldest filings subject to potential examination for federal, state, and foreign purposes are 2014 and 2013, respectively. If we utilize a net operating loss related to a closed year, the statute for that year would re-open. We have not reduced any tax benefit on our financial statements due to uncertain tax positions as of June 30, 2017 and we are not aware of any circumstance that would significantly change this result through the end of fiscal year 2018. To the extent we incur income-tax related penalties or interest, we will recognize them as additional income tax expense.

### Note 11. Selected Quarterly Financial Information (Unaudited)

The following table presents our unaudited quarterly results of operations for the years ended June 30, 2017 and 2016 (in thousands, except per share amounts).

	Quarters Ended			
	June 30, 2017	March 31, 2017	December 31, 2016	September 30, 2016
Total revenues	\$ 449	\$ 4,505	\$ 17,199	\$ 1,096
Net income (loss)	(4,343)	(602)	11,885	(4,270)
Basic income (loss) per share	(0.12)	(0.02)	0.32	(0.12)
Diluted income (loss) per share	(0.12)	(0.02)	0.32	(0.12)

	Quarters Ended			
	June 30, 2016	March 31, 2016	December 31, 2015	September 30, 2015
Revenues	\$ —	\$ —	\$ —	\$ —
Net loss	(5,770)	(5,371)	(5,101)	(4,620)
Basic loss per share	(0.17)	(0.16)	(0.15)	(0.13)
Diluted loss per share	(0.17)	(0.16)	(0.15)	(0.13)

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures**

*(a) Disclosure Controls and Procedures*

At the end of the period covered by this Annual Report on Form 10-K, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Securities Exchange Act of 1934 (“Exchange Act”) is accumulated and communicated to the issuer’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that the information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

A control system no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within the Company are detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

*(b) Management’s Annual Report on Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a – 15(f) under the Exchange Act. Our internal control was designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Management maintains a comprehensive system of controls intended to ensure that transactions are executed in accordance with management’s authorization, assets are safeguarded and financial records are reliable. Management also takes steps to ensure that information and communication flows are effective, and to monitor performance, including performance of internal control procedures.

Management assessed the effectiveness of our internal control over financial reporting as of June 30, 2017, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, management believes that our internal control over financial reporting is effective as of June 30, 2017.

There were no changes in internal control over financial reporting during the quarter ended June 30, 2017, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

The effectiveness of our internal control over financial reporting as of June 30, 2017 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report which is included herein.

**Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders  
MEI Pharma, Inc.  
San Diego, California

We have audited MEI Pharma, Inc.'s internal control over financial reporting as of June 30, 2017, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). MEI Pharma, Inc.'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, "Item 9A, Management's Annual 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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit 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.

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.

In our opinion, MEI Pharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of June 30, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of MEI Pharma, Inc. as of June 30, 2017 and 2016, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended June 30, 2017 and our report dated September 4, 2017 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP  
San Diego, California  
September 4, 2017

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**Item 9B. Other Information**

Not applicable.

**PART III**

**Item 10. Directors and Executive Officers of the Registrant**

**Code of Ethics**

We have adopted a Code of Business and Ethics policy that applies to our directors and employees (including our principal executive officer and our principal financial officer), and have posted the text of our policy on our website (www.meipharma.com). In addition, we intend to promptly disclose (i) the nature of any amendment to the policy that applies to our principal executive officer and principal financial officer and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

The other information required by this item is incorporated herein by reference to our proxy statement for the fiscal year ended June 30, 2017 (the "Proxy Statement").

**Item 11. Executive Compensation**

The information required by this item is incorporated herein by reference to the Proxy Statement.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this item is incorporated herein by reference to the Proxy Statement.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this item is incorporated herein by reference to the Proxy Statement.

**Item 14. Principal Accountant Fees and Services.**

The information required by this item is incorporated herein by reference to the Proxy Statement.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

**(a) 1. Financial Statements**

Reference is made to the Financial Statements under Item 8 in Part II hereof.

**2. Financial Statement Schedules**

The Financial Statement Schedules have been omitted either because they are not required or because the information has been included in the financial statements or the notes thereto included in this Annual Report on Form 10-K.

**3. Exhibits**

**Exhibit Index**

- 3.1 [Restated Certificate of Incorporation \(incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 filed on September 25, 2003 \(Reg. No. 333-109129\)\)](#).
- 3.2 [Certificate of Amendment to the Restated Certificate of Incorporation \(incorporated by reference to Exhibit 3.1.1 to the Registrant's Current Report on Form 8-K filed on March 31, 2010 \(File No. 000-50484\)\)](#).
- 3.3 [Certificate of Amendment to the Restated Certificate of Incorporation \(incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on December 19, 2012 \(File No. 000-50484\)\)](#).
- 3.4 [Certificate of Ownership and Merger \(incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on July 2, 2012 \(File No. 000-50484\)\)](#).
- 3.5 [Certificate of Designation of Series A Convertible Preferred Stock of Marshall Edwards, Inc. \(incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on May 11, 2011 \(File No. 000-50484\)\)](#).
- 3.6 [Certificate of Designation of Series B Preferred Stock of Marshall Edwards, Inc. \(incorporated by reference to Exhibit 4 to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 18, 2011 \(File No. 000-50484\)\)](#).
- 3.7 [Second Amended and Restated Bylaws \(incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 4, 2017 \(File No. 000-50484\)\)](#).
- 4.1 [Specimen Stock Certificate \(incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed on October 31, 2003 \(Reg. No. 333-109129\)\)](#).
- 4.2 [Form of Warrant \(incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on November 5, 2012 \(File No. 000-50484\)\)](#).
- 10.1 [Employment letter dated April 23, 2010, between Marshall Edwards, Inc. and Daniel Gold \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 26, 2010 \(File No. 000-50484\)\)](#).
- 10.2 [Employment letter dated June 1, 2011, between Marshall Edwards, Inc. and Robert D. Mass \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 2, 2011 \(File No. 000-50484\)\)](#).
- 10.3 [Employment letter dated March 6, 2014, between MEI Pharma, Inc. and David M. Urso \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 8, 2014 \(File No. 000-50484\)\)](#).
- 10.4 [Employment letter dated February 1, 2017, between MEI Pharma, Inc. and Brian G. Drazba \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 3, 2017 \(File No. 000-50484\)\)](#).
- 10.5 [MEI Pharma, Inc. Amended and Restated 2008 Stock Omnibus Equity Compensation Plan \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 2, 2016 \(File No. 000-50484\)\)](#).
- 10.6 [Form of Indemnification Agreement \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 29, 2011 \(File No. 000-50484\)\)](#).
- 10.7 [Asset Purchase Agreement, dated as of August 7, 2012, between MEI Pharma, Inc. and S\\*Bio Pte Ltd. \(incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on August 8, 2012 \(File No. 000-50484\)\)](#).
- 10.8\*\* [License Agreement, dated September 28, 2012, between Cydex Pharmaceuticals, Inc. and the Company \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 13, 2012 \(File No. 000-50484\)\)](#).
- 10.9\*\* [Supply Agreement, dated September 28, 2012, between Cydex Pharmaceuticals, Inc. and the Company \(incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 13, 2012 \(File No. 000-50484\)\)](#).

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10.10**	<a href="#"><u>License, Development and Commercialization Agreement, dated August 5, 2016, by and between the Company and Helsinn Healthcare SA (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q/A filed on February 16, 2017 (File No. 000-50484)).</u></a>
10.11	<a href="#"><u>Common Stock Purchase Agreement, dated as of August 5, 2016, by and between MEI Pharma, Inc. and Helsinn Investment Fund SA (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 9, 2016 (File No. 000-50484)).</u></a>
23.1	<a href="#"><u>Consent of Independent Registered Accounting Firm*</u></a>
31.1	<a href="#"><u>Certification of Chief Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934*</u></a>
31.2	<a href="#"><u>Certification of Chief Financial Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934*</u></a>
32.1	<a href="#"><u>Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934*</u></a>
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

(\*) Filed herewith.

(\*\*) Portions of this exhibit have been redacted pursuant to a confidential treatment request filed with the Securities and Exchange Commission.

### **Item 16. Form 10-K Summary**

None.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on September 4, 2017.

MEI PHARMA, INC.  
A Delaware Corporation

By: /s/ Daniel P. Gold  
Daniel P. Gold  
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities indicated on September 4, 2017.

<u>Signatures</u>	<u>Title</u>
By: <u>/s/ Daniel P. Gold</u> Daniel P. Gold	President, Chief Executive Officer and Director (Principal Executive Officer)
By: <u>/s/ Brian G. Drazba</u> Brian G. Drazba	Secretary, Chief Financial Officer (Principal Financial and Accounting Officer)
By: <u>/s/ Christine A. White</u> Christine A. White	Chairman
By: <u>/s/ William D. Rueckert</u> William D. Rueckert	Director
By: <u>/s/ Charles V. Baltic</u> Charles V. Baltic	Director
By: <u>/s/ Thomas C. Reynolds</u> Thomas C. Reynolds	Director
By: <u>/s/ Nicholas Glover</u> Nicholas Glover	Director
By: <u>/s/ Kevan Clemens</u> Kevan Clemens	Director

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

MEI Pharma, Inc.  
San Diego, CA

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File Nos. 333-217645, 333-186070, 333-184011, 333-174789, 333-146453, and 333-136440) and Form S-8 (File Nos. 333-216103, 333-213278, 333-201703, 333-179591, 333-174790, 333-169719, and 333-156985) of MEI Pharma, Inc. of our reports dated September 4, 2017, relating to the financial statements and the effectiveness of MEI Pharma, Inc.'s internal control over financial reporting, which appear in this Form 10-K.

/s/ BDO USA, LLP

San Diego, California  
September 4, 2017

**CERTIFICATION**

I, Daniel P. Gold, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended June 30, 2017 of MEI Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 4, 2017

/s/ Daniel P. Gold

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Daniel P. Gold  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION**

I, Brian G. Drazba, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended June 30, 2017 of MEI Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 4, 2017

/s/ Brian G. Drazba

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Brian G. Drazba  
Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION**

Each of the undersigned hereby certifies, for the purposes of Section 1350 of Chapter 63 of Title 18 of the U.S. Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his capacity as an officer of MEI Pharma, Inc. (“MEI Pharma”) that, to his knowledge, this Annual Report on Form 10-K of MEI Pharma, for the year ended June 30, 2017, fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of MEI Pharma.

Date: September 4, 2017

/s/ Daniel P. Gold

Daniel P. Gold  
Chief Executive Officer  
(Principal Executive Officer)

/s/ Brian G. Drazba

Brian G. Drazba  
Chief Financial Officer  
(Principal Financial Officer)

These certifications accompanying the report to which they relate, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of MEI Pharma under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent MEI Pharma specifically incorporates it by reference.

A signed original of this written statement required by Section 906 has been provided to MEI Pharma and will be retained by MEI Pharma and furnished to the Securities and Exchange Commission or its staff upon request.