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

FORM 10-K

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

For the fiscal year ended December 31, 2017 **Commission File Number: 001-37758**

Moleculin Biotech, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**47-4671997**
(State or Other Jurisdiction of Incorporation or Organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

2575 West Bellfort, Suite 333
Houston, Texas 77054
(713) 300-5160
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Securities registered pursuant to Section 12(b) of the Act:
Common Stock, par value $0.001 per share NASDAQ Capital Market

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 periods as 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 Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☒ NO ☐

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the registrant's voting equity held by non-affiliates of the registrant, computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter, was $32,242,351. In determining the market value of the voting equity held by non-affiliates, securities of the registrant beneficially owned by directors, officers and 10% or greater shareholders of the registrant have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of shares of the registrant's common stock outstanding as of March 16, 2018 was 25,768,861.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of this registrant's definitive proxy statement for its 2018 Annual Meeting of Stockholders to be filed with the SEC no later than 120 days after the end of the registrant's fiscal year are incorporated herein by reference in Part III of this Annual Report on Form 10-K.

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The Securities and Exchange Commission, referred to herein as the SEC, encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. Certain statements that we may make from time to time, including, without limitation, statements contained in this report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995.

We make forward-looking statements under the "Risk Factors," "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other sections of this report. In some cases, you can identify these statements by forward-looking words such as "may," "might," "should," "would," "could," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "potential" or "continue," and the negative of these terms and other comparable terminology. These forward-looking statements, which are subject to known and unknown risks, uncertainties and assumptions about us, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business. These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements. In particular, you should consider the numerous risks and uncertainties described under "Risk Factors."

While we believe we have identified material risks, these risks and uncertainties are not exhaustive. Other sections of this report describe additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very highly regulated, competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible to predict all risks and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of any of these forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We are under no duty to update any of these forward-looking statements after the date of this report to conform our prior statements to actual results or revised expectations, and we do not intend to do so.

Forward-looking statements include, but are not limited to, statements about:

- our ability to obtain additional funding to develop our product candidates;
- the need to obtain regulatory approval of our product candidates;
- the success of our clinical trials through all phases of clinical development;
- our ability to complete our clinical trials in a timely fashion and within our expected budget;
- compliance with obligations under intellectual property licenses with third parties;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to commercialize our product candidates;
- market acceptance of our product candidates;
- competition from existing products or new products that may emerge;
- potential product liability claims;
- our dependency on third-party manufacturers to supply or manufacture our products;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- our ability to adequately support future growth;

and

- our ability to attract and retain key personnel to manage our business effectively.

We caution you not to place undue reliance on the forward-looking statements, which speak only as of the date of this Form 10-K in the case of forward-looking statements contained in this Form 10-K.

PART I

References in this Annual Report on Form 10-K to "MBI" or "the Company", "we", "our" and "us" are used herein to refer to Moleculin Biotech, Inc.

ITEM 1. BUSINESS

Overview

MBI is a clinical-stage pharmaceutical company organized as a Delaware corporation in July 2015 to focus on the development of oncology drug candidates, all of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center, which we refer to as "MD Anderson". MBI has three core drug technologies: a uniquely designed anthracycline (Annamycin), a portfolio of STAT3 inhibitors (WP1066 Portfolio) and a collection of inhibitors of glycolysis (WP1122 Portfolio). Our clinical stage drugs are Annamycin, an anthracycline designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML, and WP1066, an immuno-stimulating STAT3 inhibitor targeting brain tumors, pancreatic cancer and AML. We are also engaged in preclinical development of additional drug candidates, including additional STAT3 inhibitors and compounds targeting the metabolism of tumors through the inhibition of glycolysis.

Our lead drug candidate is liposomal Annamycin, which we refer to as Annamycin, an anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML. Annamycin has been in clinical trials pursuant to an IND, that had been filed with the FDA. Due to a lack of development activity by a prior drug developer, this IND was terminated. To permit the renewed investigation of Annamycin, we submitted a new IND for a Phase I/II trial for the treatment of relapsed or refractory AML in August 2017, which was subsequently allowed by the FDA in September 2017. We have two other drug development projects: (i) one involving a library of small molecules, which we refer to as the WP1066 Portfolio, a collection of STAT3 inhibitors, some of which also have immuno-stimulating capability, targeting brain tumors, pancreatic cancer and AML, and (ii) the WP1122 Portfolio, a library of small molecules targeting the metabolic processes involved in cancer in general and glioblastoma (the most aggressive and most common form of brain tumor) and pancreatic cancer in particular through the inhibition of glycolysis. A physician-sponsored IND for a Phase I trial of WP1066 in patients with recurrent malignant glioma and brain metastasis from melanoma was allowed by the FDA in December 2017. We also continue to sponsor ongoing research at MD Anderson in order to improve and expand our drug development pipeline.

We have been granted royalty-bearing, worldwide, exclusive licenses for the patent and technology rights related to all of our drug technologies, as these patent rights are owned by MD Anderson. The Annamycin drug substance is no longer covered by any existing patent protection, however, we intend to submit patent applications for formulation, synthetic process and reconstitution related to our Annamycin drug product candidate, although there is no assurance that we will be successful in obtaining such patent protection. Independently from potential patent protection, we have received Orphan Drug designation from the FDA for Annamycin for the treatment of AML, which would entitle us to market exclusivity of 7 years from the date of approval of a New Drug Application ("NDA") in the United States. We may then benefit from Orphan Drug exclusivity, during which period FDA generally could not approve another Annamycin product for the same use. We also intend to apply for similar status in the European Union ("EU") where market exclusivity extends to 10 years from the date of Marketing Authorization Application ("MAA"). Separately, the FDA may also grant market exclusivity of 5 years for newly approved new chemical entities (of which Annamycin would be one), but there can be no assurance that such exclusivity will be granted.

With regard to additional potential clinical activity, we submitted in October 2017 a request for Clinical Trial Authorization ("CTA") in Poland which, if allowed, will enable a Phase I/II clinical trial to study Annamycin for the treatment of relapsed or refractory AML in Poland. This will be in addition to the previously announced allowance of our IND in the United States. In December 2017, the Ethics Committee in Poland approved our Phase I/II clinical trial of Annamycin. The CTA remains subject to final approval by the Polish National Office. Furthermore, in September 2017 we engaged a contract research organization ("CRO") to prepare for a proof-of-concept clinical trial in Poland to study our drug candidate WP1220, a part of the WP1066 portfolio, for the topical treatment of cutaneous T-cell lymphoma ("CTCL").

Our Drug Candidates

Annamycin

Our lead product candidate is Annamycin, for which FDA has allowed an IND for a Phase I/II trial for the treatment of relapsed or refractory AML and granted Orphan Drug designation for the treatment of AML. We intend to conduct Phase I/II clinical trials for Annamycin as a monotherapy for the treatment of relapsed or refractory AML in the United States and in Poland.

We took over the development of Annamycin from a prior drug development company that ceased development work on Annamycin because it believed the clinical data did not support further clinical evaluation of L-Annamycin as a single agent to treat relapsed or refractory adult acute leukemia patients, leading to the termination of its IND by the FDA. The basis for our decision to proceed notwithstanding the prior developer's determination is that we believe the actual clinical data as reported by Dr. Robert Shepard, our Chief Medical Officer and who was the prior developer's Chief Medical Officer at the time of the clinical trials, to the 2009 Annual Meeting of the American Society of Clinical Oncology, and as further reported by the Principal Investigators of the clinical trials in a peer-reviewed journal article (Clin Lymphoma Myeloma Leuk. 2013 August; 13(4): 430-434. doi:10.1016/j.clml.2013.03.015.), supports further clinical evaluation. In addition, the conclusion published in the 2013 Clinical Lymphoma, Myeloma & Leukemia journal article was that "Single agent nanomolecular liposomal annamycin appears to be well-tolerated and [demonstrates] evidence of clinical activity as a single agent in refractory adult ALL." As reported in both the ASCO presentation and the 2013 journal article referenced, the definition of efficacy is based on the following Response Criteria: "Response criteria were achievement of CR defined as ≤5% blasts, granulocyte count of ≥1×109/L, and a platelet count of ≥100×109/L. Partial remission was defined the same as CR, except for the presence of 6% to 25% blasts. Hematologic improvement was defined as for CR but platelet count <100×109/L." The summary of patient response from the 2013 journal article reads: "After determining the MTD, a 10-patient phase IIA was conducted. Eight of the patients completed one cycle of the three days of treatment at the MTD. Of these, five (62%) demonstrated encouraging anti-leukemic activity with complete clearing of circulating peripheral blasts. Three of these subjects also cleared bone marrow blasts with one subsequently proceeding onto successful stem cell transplantation. The other two developed tumor lysis syndrome and unfortunately expired prior to response assessment." In our review of these trials, we confirmed that the activity demonstrated in this summary corresponds with a "Partial remission" as described in the Response Criteria and that the three subjects who "cleared bone marrow blasts" correspond with "CR" (Complete Response).

Market for Annamycin

Leukemia is a cancer of the white blood cells and acute forms of leukemia can manifest quickly and leave patients with limited treatment options. AML is the most common type of acute leukemia in adults. It occurs when a clone of leukemic progenitor white blood cells proliferates in the bone marrow, suppressing the production of normal blood cells. Currently, the only viable option for acute leukemia patients is a bone marrow transplant, also known as a hematopoietic stem cell transplant or "HSCT", which is successful in a significant number of patients. However, in order to qualify for a bone marrow transplant, the patient's leukemia cells must be decreased to a sufficiently low level. This usually began with a therapy referred to as "7+3," which consisted of combining seven injections of Cytarbine with 3 infusions of an anthracycline to induce remission (a complete response, or "CR"). This therapy had not improved since it was first used in the 1970s and we estimate that this induction therapy had a success rate of about 20% to 25%. A revision to this therapy was recently approved in the form of a drug called Vyxeos, which involves combining Cytarabine and an anthracycline (daunorubicin) into a single liposomal injection given 3 times. This improvement appears to have increased the level of CRs to 34% and the overall survival by 3.5 months. Unfortunately, the current clinically approved anthracyclines (including Vyxeos) are cardiotoxic (i.e., can damage the heart), which can limit the dosage amount that may be administered to patients. Additionally, the tumor cells often present de novo or develop resistance to the first line anthracycline, through what is called "multidrug resistance," enabling the tumor cells to purge themselves of the available anthracyclines. Consequently, there remains no effective therapy for inducing remission in the majority of these patients sufficient to enable a curative bone marrow transplant and unfortunately most will succumb quickly to their leukemia. If a patient's leukemia reappears before they can be prepared for a bone marrow transplant, they are considered to have "relapsed." If a patient fails to achieve a sufficient response from the induction therapy to qualify for a bone marrow transplant, they are considered to be "refractory" (resistant to therapy). Together, this group of relapsed and refractory AML patients constitutes our primary focus for treatment with Annamycin and our intent is to pursue FDA approval for Annamycin as a second-line induction therapy for adult relapsed or refractory AML patients.

We believe that pursuing approval as a second line induction therapy for adult relapsed or refractory AML patients is the shortest path to regulatory approval, but we also believe that one of the most important potential uses of Annamycin is in the treatment of children with either AML or ALL (acute lymphoblastic leukemia, which is more common in children). Accordingly, we also intend to pursue approval for pediatric use in these conditions when practicable.

Of the estimated 21,380 U.S. cases of acute myeloid leukemia diagnosed in 2017, an estimated 97% were adult and although exact numbers are not available, we estimate that 70% to 80% (approximately 14,000 to 16,000 patients) were expected to relapse or be resistant to first-line therapy.

Prior Clinical Trials for Annamycin

Annamycin is a liposome formulated anthracycline (also referred to in literature as "L-Annamycin"). It has been tested in 6 prior clinical trials and 114 patients with little to no reported cardiotoxicity and, in the two clinical trials focused on leukemia, with fewer dose-limiting toxicities than are normally expected with doxorubicin (one of the leading first-line anthracyclines used for induction therapy). Each of these trials was conducted by a prior developer of Annamycin, and not by our company. Annamycin demonstrated significant activity in 8 of 16 patients in a Phase I study in adult relapsed or refractory AML and ALL patients, with 6 of 14 patients completely clearing leukemic bone marrow blasts. The reason only 14 (rather than 16) patients were tested for leukemic bone marrow blasts is that 2 of the 16 patients succumbed to their disease before bone marrow testing could be completed. In a 30-patient dose-ranging Phase I/II study in ALL, 3 of 8 patients treated with the maximum tolerable dose cleared their leukemic blasts to a level sufficient to qualify for a bone marrow transplant. One of these patients went on to receive a successful curative bone marrow transplant. The other two of these three patients died of tumor lysis syndrome, a condition resulting from the overloading of their system with the debris from leukemic blast cells destroyed by the induction therapy. Armed with the knowledge of this potential, prophylactic pretreatment intended to protect patients from the effects of tumor lysis syndrome will be deployed where appropriate in future trials. Based on the results of the above clinical trials, we believe Annamycin may be different from currently approved induction therapy drugs in four key ways: (i) it has demonstrated clinical activity in a patient population for whom there are currently no effective therapies, (ii) it appears to be capable of avoiding the "multi-drug resistance" mechanisms that have been associated with limiting the effectiveness of currently approved anthracyclines; (iii) it has been shown to be non-cardiotoxic in animal models and little to no cardiotoxicity has been reported from the use of Annamycin in 114 patients; and (iv) in certain AML cell lines, it has been shown to be more potent than one of the leading approved anthracyclines.

Based on initial conversations with the FDA, because of the serious unmet medical need, we believe Annamycin may qualify for accelerated approval based on our planned clinical trials. In order to facilitate our communication with the FDA, we requested access to and reviewed in detail the available data supporting the dose-ranging Phase I/II clinical trial discussed above, which was conducted by a previous developer of Annamycin. In October 2016, we announced that we had identified some positive findings from this review, which gave rise to a modification of our own clinical development plan. We had indicated that our plan was to conduct a detailed review of the clinical results generated by that prior developer, and then to use those results to reestablish an IND in order to continue clinical trials of Annamycin. However, in the course of our review, we identified that Annamycin may have greater potential for efficacy than we originally believed, based on an unexpected potential opportunity to increase the drug's Maximum Tolerable Dose ("MTD").

In particular, the Dose Limiting Toxicities ("DLTs") reported in the previous trial that led to the establishment of the current MTD of 150 mg/m2 were all from patients who had an unusually high number of induction therapy failures prior to being treated with Annamycin. Specifically, of the three patients in the last clinical trial who experienced these DLTs, one of them had failed nineteen prior induction therapy attempts, another had failed sixteen and the other had failed fifteen before being enrolled in the trial. We concluded from our review of this data that, if the heavily treated patients are excluded from the data set, the MTD may have been higher than the level that was actually set by this previous trial.

Planned Clinical Trials for Annamycin

With the discovery that we may be able to increase our MTD, we adjusted our clinical strategy by adding in a Phase I arm to our trial, which will add expense to our development effort. We believe this change in strategy will add several months to the eventual final approval of the drug, if the drug is approved.

Because the prior developer of Annamycin allowed their IND to lapse, we were required to submit a new IND for continued clinical trials with Annamycin. We filed our IND application for Annamycin, with the clinical strategy of increasing the MTD mentioned above, on February 10, 2017. In subsequent discussions with us, FDA requested certain revisions to the protocol, additional information, and additional data related to Chemistry, Manufacturing and Controls ("CMC"). We made the requested revisions to the protocol, and included the CMC data in our re-submission of the IND in August 2017 and the FDA allowed this IND in September 2017.

In August 2017, we met with the European Medicines Agency ("EMA") to discuss a CTA in Europe for the study of Annamycin for the treatment of AML. As a result of that meeting, we decided to proceed with an application in October 2017 for a CTA for Annamycin in Poland. Unlike in the United States, the process for beginning a clinical trial in Poland requires a hospital contract before a request for CTA can be made. We obtained the required hospital contract, which allowed the formal request for Polish approval. In December 2017, the Ethics Committee in Poland approved our Phase I/II trial of Annamycin for the treatment of relapsed or refractory AML. A final approval is required by the Polish National Office. In March we received requests for and provided additional information to the Polish National Office. We expect a response from the Polish National Office in the first half of 2018 and at the earliest mid-April 2018. The start of clinical trials in Poland remains subject to

confirmation and approval of the CTA by the Polish National Office. We can provide no assurance that we will receive such confirmation on a timely basis, if at all.

We have appointed a CRO in both the United States and Poland. In addition, we continue to recruit and contract clinics both in the United States and Poland. In the US, we have one site - University Hospitals Cleveland Medical Center ("UHCMC") - recruiting patients and active with drug ready to provide treatments. A patient has been enrolled with anticipated treatment to occur in the near term. We can provide no assurance treatment will occur on a timely basis, if at all.

On March 21, 2017, we received notice that FDA had granted Orphan Drug designation for Annamycin for the treatment of AML, effective March 20, 2017.

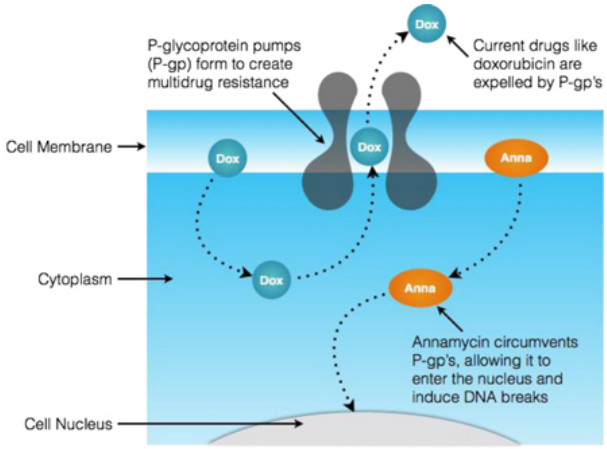
Little to No Cardiotoxicity

One of the key dose-limiting toxicities associated with currently available anthracyclines (including the anthracycline in Vyxeos) is their propensity to induce life-threatening heart damage. This is especially problematic for pediatric leukemia patients whose life spans can be severely shortened by the very induction therapy designed to cure them of acute leukemia. In the animal model relied upon by the FDA as an indicator of human cardiotoxicity, the non-liposomal (free) form of Annamycin has been shown to be significantly less likely than doxorubicin to create heart lesions in mice, and the liposomal formulation (L-Annamycin) has been shown in these same models to have reduced cardiotoxicity to the point where it is unlikely to cause harm to human patients. This possible lack of human cardiotoxicity means L-Annamycin may be able to be used more aggressively in helping patients achieve remission. This would be especially valuable in the case of pediatric acute leukemia (both AML and ALL) where long-term survival can be greatly impacted by cardiotoxicity. In our current Phase I/II trial for Annamycin, we will collect data to further validate the design intent of Annamycin to have little or no cardiotoxicity. Unless otherwise noted, all of our references to Annamycin refer to the liposomal form (L-Annamycin).

Circumventing Multidrug Resistance

In addition to cardiotoxicity, the effectiveness of currently approved anthracyclines is limited by their propensity for succumbing to "multidrug resistance," whereby transmembrane proteins acting as transporters (one type of which is referred to as a "P-glycoprotein pump") develop on the outer surface of cells to expel drugs like anthracyclines as a natural defense mechanism. The dosing of current therapies cannot be increased in an attempt to overcome multidrug resistance because of the likelihood of cardiotoxicity and other serious side effects. This limitation prevents adequate dosing of current anthracyclines to produce lasting remission in most patients. A laboratory study has suggested that Annamycin may resist being expelled by P-glycoprotein pumps and other similar tested multidrug resistance transporters, which may mean the drug circumvents multidrug resistance. This characteristic has been shown in pre-clinical testing to allow for higher drug uptake in diseased cells, which we believe could allow for more effective induction therapy with less risk to the patient.

In order for anthracyclines to provide effective induction therapy, they must be allowed to accumulate in leukemic cells sufficiently to enter the cell's nucleus, where they damage the cell's DNA and induce apoptosis (cell death). As induction therapy progresses, however, the targeted cells can develop a natural defense mechanism to prevent the anthracycline activity. The graphic below provides a simplified depiction of the formation of a P-glycoprotein pump on the outer surface (membrane) of a leukemic cell. As typical anthracyclines enter the cell, they are attracted to such pumps and are expelled (referred to as "efflux") before they can accumulate sufficiently to serve their purpose. In contrast, Annamycin appears to avoid such pumps, thereby being allowed to accumulate sufficiently to destroy the leukemia cell despite the presence of the multidrug resistance mechanisms.



The WP1066 Portfolio

We have a license agreement with MD Anderson pursuant to which we have been granted a royalty-bearing, worldwide, exclusive license for the patent and technology rights related to our WP1066 Portfolio and its close analogs, molecules targeting the modulation of key oncogenic transcription factors.

Clinical Testing of WP1066 Portfolio

In vitro testing has shown a high level of activity for WP1066 against a wide range of solid tumors, and *in vivo* testing has shown significant activity against head and neck, pancreatic, stomach, and renal cancers, as well as metastatic melanoma and glioblastoma, among others. *In vivo* testing in mouse tumor models has shown that WP1066 inhibits tumor growth, blocks angiogenesis (a process that leads to the formation of blood vasculature needed for tumor growth) and increases survival.

With respect to our WP1066 Portfolio, we collaborated with a clinician at MD Anderson who submitted an IND for WP1066 treatment of brain tumors to the FDA. In December 2017, the FDA allowed this application for a Phase I trial of WP1066 in patients with recurrent malignant glioma and brain metastasis from melanoma.

This Phase I trial with WP1066 drug will receive $2 million in private grant funding at MD Anderson which is in addition to two Specialized Programs of Research Excellence or (SPORE) peer reviewed grants awarded by the National Cancer Institute. We believe the rigorous peer-review process applied to SPORE grant applications represents an important additional measure of independent assessment and validation of the research connected with our approach to using WP1066/STAT3 for the treatment of cancer. The grants described here do not flow through Moleculin's financial statements, but instead are applied to the cost of preclinical and clinical activities at and conducted by MD Anderson.

We estimate that this physician-sponsored Phase I trial will begin treating patients in the first half of 2018. However, as this is a physician-sponsored clinical trial, we have limited influence on the process in beginning clinical trials and, as such, any disruptions to this process may delay the treatment of patients with WP1066, which may delay the commencement of this trial beyond the first half of 2018.

An analog of WP1066, referred to as WP1220, was previously the subject of an IND (WP1220 was referred to as “MOL4239” for purposes of this IND) related to use of the molecule in the topical treatment of psoriasis. Clinical trials were commenced on WP1220 in the US, but were terminated early due to limited efficacy in the topical treatment of psoriatic plaques. Notwithstanding its limitations in treating psoriasis, our pre-clinical research in multiple cutaneous T-cell lymphoma (“CTCL”) cell lines has suggested that WP1220 may be effective in inhibiting CTCL. Based on this data, we are collaborating with a Polish drug development company, Dermin, which has received Polish government grant money to develop WP1220 in Poland for the topical treatment of early stage CTCL patients. CTCL is a potentially deadly form of skin cancer for which there are limited treatment options.

In September 2017, we engaged a CRO to prepare a proof-of-concept clinical trial in Poland to study WP1220 for the topical treatment of CTCL.

We also conducted a Phase II clinical trial for WP1066 for the topical treatment of psoriasis, using a longer treatment period as compared with the WP1220 psoriasis trial, however this trial was terminated early as a significant number of patients experienced a non-permanent worsening of their psoriatic plaques after extended use of the drug, suggesting that its use as a topical agent for non-life-threatening diseases such as psoriasis will require further study to optimize dosing and scheduling regimens.

Scientific Rationale for WP1066 Portfolio

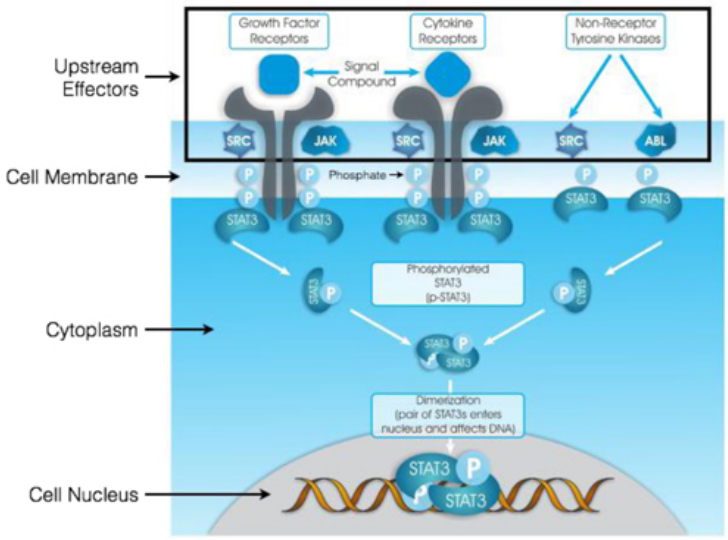
Cellular biology depends upon signaling mechanisms to regulate functions such as cell growth, death and adaptation. Signal "transduction" is such a mechanism that converts an upstream stimulus to a cell into a specific cellular response. Signal transduction starts with a signal to a receptor or via a compound capable of passing through the cell membrane and ends with a change in cell function. The end result of this signal is often the activation of "transcription," whereby genetic information is expressed and, in the case of oncogenic transcription, disease processes are initiated or maintained.

Receptors span the cell membrane, with part of the receptor outside and part inside the cell. When a chemical signal represented by a specific protein binds to the outer portion of the receptor, it conveys another signal inside the cell. Often there is a cascade of signals within the cell, wherein an upstream inducer starts a chain of events that resembles a domino effect. Collectively, this sequence is referred to as a "signaling pathway." Eventually, the signal creates a change in the cell function by changing the expression of specific genes and production of specific proteins within the cell, and again, in the case of tumor development, such expression results in unwanted oncogenic processes.

Importantly, while normal healthy cell function relies on signaling mechanisms, diseases are capable of co-opting these mechanisms with negative consequences. Oncogenic processes (including inflammation and proliferation) depend upon signaling pathways that are responsible for coordinating functions such as cell growth, survival and cell differentiation. A particular class of proteins referred to as Signal Transducers and Activators of Transcription (such proteins are "STATs") regulates the process of disease cell survival and proliferation, angiogenesis and immune system function and is persistently activated in a large number of human inflammatory processes and in hyper-proliferating diseases. Because certain of these proteins are known to be co-opted by tumor cells, we refer to them as "oncogenic transcription factors," of which certain STATs are a subset.

Some STATs, such as STAT3, can be activated by any one of many different upstream inducers, making them very difficult to target by blocking just one or more of these upstream inducers. We believe that blocking a targeted STAT directly rather than via its multiple upstream inducers should result in greater efficacy with lower toxicity.

In the diagram shown below, any one of many different pathways (categorized as Growth Factor Receptors, Cytokine Receptors and Non-Receptor Tyrosine Kinases) triggers the activation of STAT3 proteins in a process called "phosphorylation". In this process, phosphates attach to corresponding receptors on STAT3 and, eventually, two phosphorylated STAT3 proteins ("p-STAT3") bind together in a pair referred to as a "dimer." Once the dimer is formed, it enters the cell nucleus and triggers gene transcription. Conversely, if we reduce the presence of p-STAT3 before dimers can be formed, we can prevent the triggering of gene transcription and effectively inhibit the disease process.



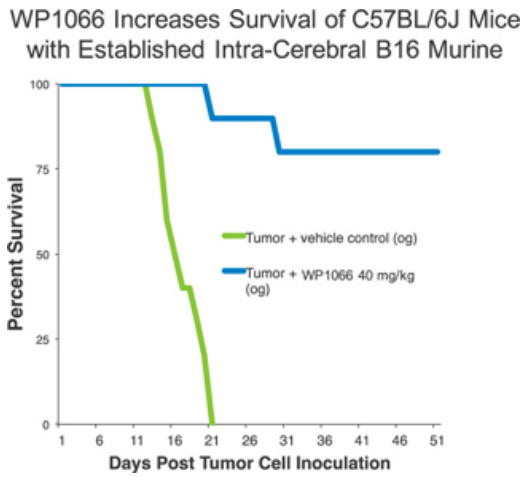
The upstream effectors shown in the above diagram (SRC, JAK and ABL) are just some of those capable of activating STAT3 once they themselves are activated by a variety of signal compounds. The complexity and diversity of pathways capable of activating STAT3 make it very difficult to develop effective drugs that attempt to target the upstream effectors. Furthermore, many of these upstream pathways are necessary for normal healthy cell function, so blocking them indiscriminately can lead to unwanted toxicities.

Published research has identified STAT3 as a master regulator of a wide range of tumors and linked STAT3 activation with the progression of these tumors. For this reason, it is believed that direct inhibition of p-STAT3 may be an effective way to reduce or eliminate the progression of these diseases.

Many research efforts have been directed toward development of specific methods to control activation of STAT3, but most have focused on targeting the upstream effectors of these pathways like growth factors, cytokines, and specific kinases including Janus kinases ("JAKs"). However, we believe that the multifactorial nature of the activation of STAT3 limits the effectiveness of such upstream approaches. Because the activity of p-STAT3 is a final and determinative step in triggering unwanted transcription, we believe it is preferable to inhibit p-STAT3 more directly and independently from upstream effectors.

We believe the WP1066 Portfolio represents a novel class of agents capable of hitting multiple targets, including p-STAT3, regardless of their upstream method of activation. Numerous preclinical tests involving a wide range of tumor cells suggest that by inhibiting the presence of p-STAT3, WP1066 directly attacks tumor cells. We believe the effectiveness of WP1066 is not only the result of attacking tumors directly, but also indirectly by stimulating the immune system, increasing the patient's natural ability to fight off tumor development. STAT1 is believed to stimulate T-cell activity and thereby the immune system responsible for fighting tumors. WP1066 has been shown to increase the activity of STAT1 at the same time it inhibits the activity of p-STAT3. We believe this dual activity makes WP1066 a uniquely promising oncology drug candidate, although we recognize that substantial additional preclinical and clinical research remains to be done, and may not bear out these early results and our optimism.

We believe the combination of the direct and indirect effects of WP1066 may ultimately be shown to provide significant tumor suppression and increased survival in a number of *in vitro* cancer models. Below is one example of an animal model suggesting an increase in survival by treating mice with metastatic melanoma with WP1066.



Recent Developments in the WP1066 Portfolio

In February 2018, we announced that, pursuant to our continued collaboration with MD Anderson we had developed and licensed what we believe, based on preclinical testing, is a potential breakthrough - WP1732, a new molecule in the WP1066 portfolio - in our effort to develop a new cancer treatment that selectively kills highly resistant tumors. We believe this new discovery could improve our ability to treat a broader range of the most difficult cancers, and especially pancreatic cancer. Specifically, we have preclinical data to suggest this new molecule is capable of controlling a process known as 'ubiquitination' to block the activated form of STAT3, an important oncogenic transcription factor.

In developing our current lead STAT3 inhibitor, WP1066, for brain tumors, we have focused on its oral bioavailability and brain uptake but at the same time we have continued to expand this portfolio by creating alternative inhibitors with increased bioavailability and altered tissue and organ distribution that are not affected by first-pass metabolism. The lead molecule resulting from this new discovery - WP1732 - not only appears to share the same key mechanistic properties with WP1066, it has markedly different organ distribution and its dramatically increased solubility makes it ideal for administration via standard IV injection. In addition, preclinical testing has also shown that WP1732's properties make it a promising candidate for treating pancreatic cancer, one of the most resistant and deadly forms of cancer.

We have begun planning and performing the necessary pre-clinical work required to submit an IND for WP1732.

The WP1122 Portfolio

We have a license agreement with MD Anderson pursuant to which we have been granted a royalty-bearing, worldwide, exclusive license for the patent and technology rights related to our WP1122 Portfolio and similar molecules targeting the treatment of glioblastoma multiforme (“GBM”) and related central nervous system malignancies.

We believe this technology has the potential to target a wide variety of solid tumors, which eventually become resistant to all treatments, and thereby provide a large and important opportunity for novel drugs. Notwithstanding this potential, we are focused on the treatment of central nervous system malignancies and especially GBM. Although less prevalent than some larger categories of solid tumors, cancers of the central nervous system are particularly aggressive and resistant to treatment. The prognosis for such patients can be particularly grim and the treatment options available to their physicians are among the most limited of any cancer.

The American Cancer Society has estimated 23,770 new cases of brain and other nervous system cancers will occur in the United States in 2016, resulting in 16,050 deaths. Despite the severity and poor prognosis of these tumors, there are few FDA-approved drugs on the market.

We have preliminary preclinical data for WP1122, including *in vitro* activity against cancer cell lines, as well as data on survival of animals subjected to xenografts of human brain tumors, including data regarding biodistribution and pharmacokinetics. In non-optimal doses and treatment regimes, WP1122 performed equal to or better than the current market leader, temozolomide and provided for superior survival for animals treated in combination with temozolomide.

Notwithstanding these early results, we recognize that substantial additional preclinical and clinical research remains to be done, and may not support these initial findings or their translation into activity in humans.

Scientific Rationale for WP1122

Science has recognized that many cancer cells have a unique metabolism, distinct from that of normal cells. Dubbed the "Warburg Effect" after its discoverer, tumors rely preferentially on glycolysis for the metabolism of glucose, even in the presence of abundant oxygen, for energy (adenosine triphosphate ("ATP") production. This alternative form of energy production makes cancer cells as much as 17 times more dependent on glucose than normal cells.

The fundamental mechanism for imaging actively growing tumors using positron emission tomography ("PET scans") is the Warburg Effect. A radiolabeled glucose decoy called F18DG accumulates disproportionately in tumors because of their dramatically increased rate of glucose uptake and accumulation.

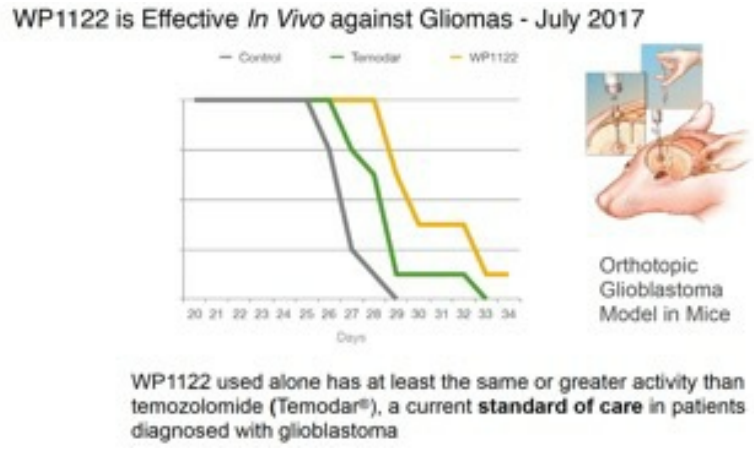
Researchers have theorized that if a tumor's access to glucose could be blocked, the tumor could be starved out of existence. Previous attempts at targeting the metabolism of tumor cells have failed due to the rapid metabolism and short half-life (minutes) of the drugs being investigated. Efforts to target tumor metabolism in the brain were further thwarted by the inability to get glycolytic inhibitors into the brain in sufficient/therapeutic amounts due to the presence of what is called the "blood brain barrier."

We believe WP1122 has the potential for developing into a technology platform for enabling increased cellular uptake, increased drug half-life and, importantly, an increased ability to cross the blood brain barrier, enabling greater uptake in the brain. Our approach was inspired by the same principle that distinguishes morphine from heroin. Heroin is chemically the diacetyl ester of morphine. While morphine has a limited ability to cross the blood brain barrier (making it a good candidate for pain killing without impairing mental function), its diacetyl form, heroin, has the ability to accumulate in the brain by 10 to 100 times more than morphine. Once across the blood brain barrier, the acetyl groups are cleaved off by natural enzyme esterases, leaving pure morphine to accumulate in the brain. Similarly, we believe, based on pre-clinical testing, that WP1122, the diacetyl form of a glucose analog and decoy known as "2-DG," crosses the blood brain barrier where its acetyl groups are cleaved off, allowing the resulting 2-DG to accumulate in the brain at a much higher rate than free 2-DG can do by itself.

Adding to the difficulty in getting free 2-DG in circulation (reaching a sufficient plasma level) and to cross the blood brain barrier in therapeutic quantities is the relatively short half-life of 2-DG. The free form of 2-DG is rapidly metabolized causing typically observed 2-DG plasma levels to be generally lower than desired to achieve sufficient therapeutic potential.
In contrast, WP1122 -generated 2-DG has significantly increased half-life and observed levels of 2-DG in plasma are substantially higher, making it much more feasible to deliver 2-DG to tumors in quantities adequate to produce a therapeutic effect. In addition, based on preliminary data, we believe WP1122 may represent an improvement to current PET scan diagnostics techniques because of its unique ability to reach tumors protected by the blood brain barrier in greater amounts than the glucose decoys currently used for PET scans. Significant additional development is required to determine if these findings are valid and if they will translate into the desired activity in humans.

In October 2016, we announced promising initial results of the preclinical toxicology work on WP1122, our unique inhibitor of glucose metabolism, an important driver of glycolytic brain tumor progression and survival. We view this as an important step toward future clinical trials for WP1122. We indicated that preliminary escalating single dose toxicity testing in mice (oral administration) was successfully completed and even at the highest possible dose, no toxic death was observed. In multiple therapeutic doses, WP1122 was well tolerated during intense twice-daily oral dosing.

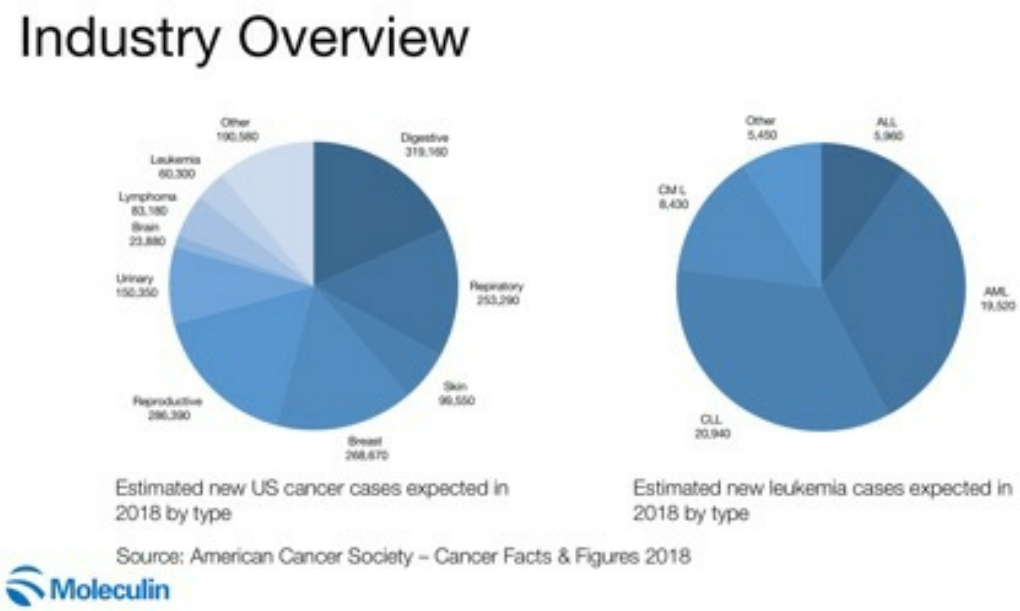
In June 2017, we announced the discovery of a metabolic inhibitor with the potential to treat pancreatic cancer. In pre-clinical testing, WP1234, a modification to WP1122, has shown improved in-vitro drug characteristics and a 20 to 50-fold greater ability to kill pancreatic cancer cell lines when compared with WP1122. We know that pancreatic cancer thrives even in a reduced oxygen environment, and is highly dependent on glycolysis to proliferate and survive. We believe WP1234 may be a promising drug candidate to be studied for the treatment of pancreatic cancer.



Pancreatic cancer is still considered largely untreatable, so even modest gains in treating this disease could represent a significant clinical benefit. In pre-clinical testing, WP1234 improves on known inhibitors for glycolysis by increasing drug circulation time, which should increase the potential for drug uptake by and destruction of tumor cells. We intend to pursue development opportunities with WP1234 for the treatment of pancreatic cancer and compare its activity with our other inhibitors, including WP1122.

Overview of the market for our oncology drugs

Cancer is the second leading cause of death in the United States behind heart disease. In 2016, an estimated 15.5 million people in the United States were living with a past or current diagnosis of cancer and, in 2018, the National Institutes of Health estimated that nearly 1.7 million new cases will be diagnosed and over 600,000 Americans will die from cancer.



Source: American Cancer Society - Cancer Facts & Figures 2018

Digestive, reproductive, breast and respiratory cancers comprise 65% of expected cancer diagnoses in 2018, while cancers like leukemia and brain tumors are considered “rare diseases.” Leukemia in particular, can be divided into acute, chronic and other, with acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (“AML”) comprising 26,900 of the estimated 60,300 new cases expected in the United States in 2018.

The worldwide cancer drug business has been estimated to represent approximately $100 billion in annual sales. Our lead drug candidate, Annamycin, is in a class of drugs referred to as anthracyclines, which are chemotherapy drugs designed to destroy the DNA of targeted cancer cells. The most common approved anthracyclines are daunorubicin and doxorubicin and, prior to the expansion of their generic equivalents, annual revenues generated from anthracyclines have been estimated in the range of $600 million. Acute leukemia is one of a number of cancers that are treated with anthracyclines. One industry report estimates that annual drug revenues generated from the demand for AML-related therapies in the United States, United Kingdom, France, Germany, Italy and Spain were in the range of $151 million in 2012, and we believe that this number may increase if and when improved AML treatments are available.

Our other two active development projects have applications (among others) in the treatment of brain tumors, another rare disease for which there are few available treatments. The leading brain tumor drug is temozolomide, a drug introduced under the brand name Temodar. In 2012, one industry source reported annual revenues of approximately $882 million for Temodar before the expiration of its patent protection, at which point generic versions of the drug began to enter the market and reduce prices.

The Orphan Drug Act and other legislative initiatives provide incentives, including market exclusivity and accelerated approval pathways, for companies that pursue the development of treatments for rare diseases and serious diseases for which there are few or no acceptable available treatment alternatives. Over the last 10 years, an increasing number of companies have begun using these designations to obtain new drug approvals for drugs where patent coverage has expired and/or where accelerated approval appears possible. An IMS Health report estimated that, in 2013, the sale of drugs with full or partial Orphan Drug exclusivity represented approximately $29 billion in revenue. We consider obtaining Orphan Drug exclusivity and accelerated approval to be an important part of our development strategy for our drug candidates. Notwithstanding these potential opportunities, we can provide no assurance that our drugs will receive Orphan Drug designation (other than Annamycin, which recently received such designation) or, if approved, exclusivity or any other special designation that could, among other things, provide for accelerated approval.

Our License Agreements

Sponsored Research Agreements with MD Anderson

On January 9, 2017, we amended our Sponsored Laboratory Study Agreement with MD Anderson whereby we paid $302,500 in 2017, and the agreement was extended to October 31, 2018. On December 4, 2017, we extended this Agreement until October 31, 2019 for a total of payments of $346,687 spread over that period of time. Of this amount, $236,687 was paid in the first quarter of 2018. The final payment of $110,000 is due on July 31, 2018.

Annamycin

As of August 2015, we obtained the rights and obligations of Annamed under a June 2012 Patent and Technology Development and License Agreement by and between Annamed and Dermin (the “Annamed Agreement”). Therefore, certain intellectual property rights, including rights, if any, covering the potential drug product, Annamycin have been licensed to Dermin and Dermin has been granted a royalty-bearing, exclusive license to manufacture, have manufactured, use, import, offer to sell and/or sell products in the field of human therapeutics under the licensed intellectual property in the countries of Poland, Ukraine, Czech Republic, Hungary, Romania, Slovakia, Belarus, Lithuania, Latvia, Estonia, Netherlands, Turkey, Belgium, Switzerland, Austria, Sweden, Greece, Portugal, Norway, Denmark, Ireland, Finland, Luxembourg, Iceland, Kazakhstan, Russian Federation, Uzbekistan, Georgia, Armenia, Azerbaijan and Germany (“Annamed licensed territories”). We are obligated to develop and provide a dossier containing data related to the licensed subject matter to Dermin. In consideration, Dermin will pay a royalty for the sale of any licensed product in the Annamed licensed territories and pay all out-of-pocket expenses incurred by us in filing, prosecuting and maintaining the licensed patents for which the license has been granted. Dermin also agrees to provide a percentage of certain consideration that Dermin receives pursuant to sublicense agreements. On June 29, 2017, the Company entered into an agreement with MD Anderson licensing certain technology related to the method of preparing Liposomal Annamycin. The agreement includes a one-time license documentation fee of $40,000, annual maintenance fees of $25,000 until the first sale of drug and has the following the milestone payments: (i) commencement of Phase III Study for first licensed drug/product - $125,000; (ii) submission of the first NDA within the United States - $175,000; and (iii) receipt of first marketing approval for sale of a license product in the United States - $225,000.

WP1066 Portfolio

The rights and obligations to a June 2010 Patent and Technology License Agreement entered into by and between Moleculin LLC and MD Anderson (the “Moleculin Agreement”) have been assigned to us. Therefore, we have obtained a

royalty-bearing, worldwide, exclusive license to intellectual property rights, including patent rights, related to our WP1066 drug product candidate. In consideration, we must make payments to MD Anderson including an up-front payment, milestone payments and minimum annual royalty payments for sales of products developed under the license agreement. Annual maintenance fee payments will no longer be due upon marketing approval in any country of a licensed product. One-time milestone payments are due upon commencement of the first Phase III study for a licensed product within the United States, Europe, China or Japan; upon submission of the first NDA for a licensed product in the United States; and upon receipt of the first marketing approval for sale of a licensed product in the United States. The rights we have obtained pursuant to the assignment of the Moleculin Agreement are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the U.S. government. The agreement, as amended, has the following the milestone payments: (i) commencement of Phase III Study for first licensed drug/product within the United States, Europe, China or Japan - $150,000; (ii) submission of the first NDA within the United States - $500,000; and (iii) receipt of first marketing approval for sale of a license product in the United States - $600,000.

We entered into an out-licensing agreement with Houston Pharmaceuticals, Inc. ("HPI"), pursuant to which we have granted certain intellectual property rights to HPI, including rights covering the potential drug candidate, WP1066 ("HPI Out-Licensing Agreement"). Under the HPI Out-Licensing Agreement, we must make quarterly payments totaling $0.75 million for the first twelve quarters following the effective date of the HPI Out-Licensing Agreement, or May 2, 2016, in consideration for the right to development data related to the development of licensed products. Notwithstanding our obligation to make the foregoing payments, the HPI Out-Licensing Agreement does not obligate HPI to conduct any research or to meet any milestones. Upon payment in the amount of $1.0 million to HPI within three years of the effective date of the HPI Out-Licensing Agreement we will regain all rights to the licensed subject matter and rights to any and all development data and any regulatory submissions including any IND, NDA or ANDA related to the licensed subject matter and can end the license without any other obligation other than the aforementioned quarterly payments. In the event that we do not exercise our right to regain our rights to the licensed subject matter within three years of the effective date of the HPI Out-Licensing Agreement, the license granted to HPI shall convert to an exclusive license upon HPI's written notice and we shall be obligated to transfer all existing data relating to licensed subject matter including any development data and any IND to HPI.

In February 2018, we entered into a license agreement covering a new group of molecules recently discovered in connection with research we have been sponsoring at MD Anderson Cancer Center called WP1732, a part of the WP1066 Portfolio. In consideration, we must make payments to MD Anderson including an up-front payment, license documentation fee, annual maintenance fee, milestone payments and minimum annual royalty payments for sales of products developed under the license agreement. Under the agreement, annual maintenance fees are $10,000 on the effective date of the agreement and increase by $5,000 per year up to a maximum of $50,000 per year. Under the agreement, we are required to make royalty payments ranging from 3% to 5% of Net Sales, depending on the intended use, each quarter upon the commencement of sales, with a minimum of $200,000 per year. Additional payments are due upon the commencement of a Phase II study ($150,000), submission of an New Drug Application ($500,000), and the receipt of marketing approval of a licensed product ($600,000).

WP1122 Portfolio

The rights and obligations to an April 2012 Patent and Technology License Agreement entered into by and between IntertechBio and MD Anderson (the "IntertechBio Agreement") have been assigned to us. Therefore, we have obtained a royalty-bearing, worldwide, exclusive license to intellectual property, including patent rights, related to our WP1122 Portfolio and to our drug product candidate, WP1122. In consideration, we must make payments to MD Anderson including an up-front payment, license documentation fee, annual maintenance fee, milestone payments and minimum annual royalty payments for sales of products developed under the license agreement. Under the agreement, annual maintenance fees are $10,000 on the first anniversary of the effective date of the agreement, $20,000 on the second anniversary of the effective date of the agreement, $40,000 on the third anniversary of the effective date of the agreement, $60,000 on the fourth anniversary of the effective date of the agreement, $80,000 on the fifth anniversary of the effective date of the agreement and $100,000 on the sixth anniversary of the effective date of the agreement, except that such payments will no longer be due upon the first sale of a licensed product. Under the assignment, we agreed to make a minimum annual royalty payment in the amount of $200,000 for the first anniversary following the first sale of a licensed product, $400,000 for the second anniversary following the first sale of a licensed product, and $600,000 for the third year following the first sale of a licensed product.

One-time milestone payments are due as follows: 1) Upon commencement of a Phase II study for a licensed product - $200,000; 2) Upon commencement of a Phase III study for a licensed product - $250,000; 3) Upon filing of a New Drug Application ("NDA") for a licensed product - $400,000; and 4) Upon receipt of market approval for sale of a licensed product - $500,000. The rights we have obtained pursuant to the assignment of the IntertechBio Agreement are made subject to the rights

of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the U.S. government.

Corporate History

We were founded in 2015 by Walter Klemp (our chairman and CEO), Dr. Don Picker (our Chief Science Officer) and Dr. Waldemar Priebe of MD Anderson (Chairman of our Scientific Advisory Board) in order to combine and consolidate development efforts that include several MD Anderson oncology technologies. Dr. Priebe is a Professor of Medicinal Chemistry in the Department of Experimental Therapeutics, Division of Cancer Medicine, at the University of Texas MD Anderson Cancer Center. This effort began with the acquisition of the Annamycin development project from AnnaMed, Inc., or AnnaMed, followed by the acquisition of the license rights to the WP1122 Portfolio from IntertechBio Corporation, or IntertechBio. Further, we undertook an effort to gain control of the WP1066 Portfolio, which culminated with the merger of Moleculin, LLC and MBI and the establishment of a co-development agreement with Houston Pharmaceuticals, Inc., or HPI, coincident with our IPO.

AnnaMed, a company controlled by Mr. Klemp, was formed in 2012 to take over the development of Annamycin from a prior drug development company. In 2012, AnnaMed out-licensed development rights in a limited territory to a Polish special purpose drug development company called Dermin in exchange for Dermin's development work based on its successful effort to obtain Polish government grant funding to assist in the development of Annamycin. In August 2015, we entered into a rights transfer agreement with AnnaMed pursuant to which, in exchange for our common stock, AnnaMed agreed to transfer any and all data it had regarding the development of Annamycin and the Annamycin IND, including all trade secrets, know-how, confidential information and other intellectual property rights held by AnnaMed.

IntertechBio was formed in 2009 to license and begin development on the WP1122 Portfolio. The WP1122 Portfolio was also out-licensed to Dermin, which was awarded a Polish government grant to assist in drug development efforts. In August 2015, IntertechBio agreed to assign all license rights to us in exchange for our common stock. Drs. Priebe and Picker are shareholders of IntertechBio and control the voting and dispositive power over the shares of our common stock held by IntertechBio.

Moleculin, LLC was formed in 2006 and had been working to develop the WP1066 Portfolio it licensed from MD Anderson. As a part of the formation of Moleculin, LLC, an agreement was reached with HPI to limit Moleculin, LLC's development efforts to uses in dermatology only, leaving non-dermatology indications to HPI.

Prior to our IPO, Moleculin, LLC was merged with and into our company. Dr. Priebe, Mr. Klemp and Dr. Picker were members of Moleculin, LLC and received shares of our common stock as a result of the merger. In addition, Mr. Klemp and Dr. Picker were members of the board of Moleculin, LLC. The merger agreement contains mutual representations and warranties between the parties. Pursuant to the merger agreement, we agreed for a period of six years to indemnify and hold harmless each present and former director and/or officer of Moleculin, LLC whom Moleculin, LLC would have had the power to indemnify under Delaware law that is made a party or threatened to be made a party to any threatened, pending or completed proceeding or claim by reason of the fact that he or she was a director or officer of the Moleculin, LLC prior to the effective time of the merger and arising out of actions or omissions of the indemnified party in any such capacity occurring at or prior to the effective time of the merger against any losses or damages reasonably incurred in connection with any claim. To our knowledge, no such proceeding or claim exists or has been threatened on the date hereof and Moleculin, LLC made representations to this effect in the merger agreement as of the date of such agreement. As additional consideration payable to the Moleculin, LLC unit holders, we agreed pursuant to the merger agreement that if drugs for dermatology indications are successfully developed by us (or our successors) using any of the Existing IP Assets, then the Moleculin, LLC unit holders, in the aggregate, will be entitled to receive a 2.5% royalty on the net revenues generated by such drugs. Any such net revenues would include a deduction for license fees or royalty obligations payable to MD Anderson for such Existing IP Assets. The merger agreement defined "Existing IP Assets" to mean all intellectual property, licensed by us and Moleculin, LLC as of the time of the merger, including, without limitation, the intellectual property licensed from MD Anderson under the Patent and Technology License Agreement entered into by and between IntertechBio Corporation and MD Anderson dated April 2, 2012, as amended, and the Patent and Technology License Agreement dated June 21, 2010, as amended, between MD Anderson and Moleculin, LLC, but excluding any intellectual property relating to Annamycin. The right to receive the contingent royalty payments described herein are for drugs developed only for dermatology indications, and do not include drugs developed for any other indications. We have no obligation of any nature to pursue the development of any drugs for dermatology indications.

Prior to our IPO, we entered into a co-development agreement with HPI whereby HPI is continuing its grant-funded research and making all resulting data available for our use in exchange for a development fee. We may buy HPI out of its co-development rights in the WP1066 Portfolio at our option. Please see the section "Business - License Agreements" for a

description of our agreement with HPI. Drs. Priebe and Picker are shareholders of HPI, and Dr. Priebe has the voting and dispositive power over the shares of our common stock held by HPI.

Competition

We operate in a highly competitive segment of the pharmaceutical market, which market is highly competitive as a whole. We face competition from numerous sources including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors may have significantly greater financial, product development, manufacturing and marketing resources. Additionally, many universities and private and public research institutes are active in cancer research, and some may be in direct competition with us. We may also compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The unmet medical need for more effective cancer therapies is such that oncology drugs are, by far, the leading class of drugs in development. These include a wide array of products against cancer targeting many of the same indications as our drug candidates. While the introduction of newer targeted agents may result in extended overall survival, induction therapy regimens are likely to remain a cornerstone of cancer treatment in the foreseeable future.

There are a number of established therapies that may be considered competitive for the cancer indications for which we intend to develop our lead product, Annamycin. A key consideration when treating AML patients is whether the patient is suitable for intensive therapy. The standard of care for the treatment of newly diagnosed AML patients who can tolerate intensive therapy is cytarabine in combination with an anthracycline (e.g., doxorubicin or daunorubicin), typically referred to as a “7+3” regimen. For some patients, primarily those less than 60 years of age, a stem cell transplant could also be considered if the induction regimen is effective in attaining a CR (Complete Response). The 7+3 regimen of cytarabine in combination with an anthracycline has been the standard of care for decades. A patient not suitable for intensive therapy may be offered the option for low-intensity therapy such as low-dose cytarabine, azacitidine or decitabine. It should be noted that, in the United States, these are not approved by the FDA for the treatment of AML patients and there remains no effective therapy for these patients or for relapsed or refractory AML, with the exception of some recently approved targeted therapies that have demonstrated a low level of activity for limited subgroups of AML patients. The initial focus for Annamycin development is in patients for whom the standard induction regimen has failed. Also, several major pharmaceutical companies and biotechnology companies are aggressively pursuing new cancer development programs for the treatment of AML.

A number of attempts have been made or are under way to provide an improved treatment for AML. Celator Pharmaceuticals reported Phase III clinical trial results for a new combined formulation of cytarabine and daunorubicin (commonly used induction therapy drugs) they call Vyxeos. This new liposome formulation provides a 5:1 ratio of cytarabine and daunorubicin in each of three injections. When compared with patients receiving 7 injections of cytarabine and 3 injections of daunorubicin (traditional 7+3 induction therapy), patients receiving Vyxeos achieved an average increase in overall survival of approximately 3.5 months (9.5 months compared with 6 months). Despite this extension of overall survival, Vyxeos did not reduce the toxic side effects of daunorubicin (including cardiotoxicity) and it failed to qualify a significant majority of patients for curative bone marrow transplant. With these results, Jazz Pharmaceuticals acquired Celator in 2016 and recently obtained FDA approval, making Vyxeos the new first line standard of care for the treatment of AML

Drugs attempting to target a subset of AML patients who present with specific gene mutations, such as one referred to as FLT3, have recently received FDA approval, but by definition serve only subsets of the AML population. Other targeted therapies are currently in clinical trials, as well as other approaches that include immunotherapy relying on other biomarkers, other attempts at improved chemotherapy and alternative approaches to radiation therapy. Other approaches to improve the effectiveness of induction therapy are in early stage clinical trials and, although they do not appear to address the underlying problems with anthracyclines, we can provide no assurance that such improvements, if achieved, would not adversely impact the need for improved anthracyclines. A modified version of doxorubicin designed to reduce cardiotoxicity is in clinical trials for the treatment of sarcoma and, although this drug does not appear to address multidrug resistance and is not currently intended for the treatment of acute leukemia, we can provide no assurance that it will not become a competitive alternative to Annamycin. Although we are not aware of any other single agent therapies in clinical trials that would directly compete against Annamycin in the treatment of relapsed and refractory AML, we can provide no assurance that such therapies are not in development, will not receive regulatory approval and will reach market before our drug candidate Annamycin. In addition, any such competing therapy may be more effective and/or cost-effective than ours.

Government Regulation

Government authorities in the US, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. The pharmaceutical drug product candidates that we develop must be approved by the FDA before they may be marketed and distributed.

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug, and Cosmetic Act, and implementing regulations. Pharmaceutical products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA and related enforcement activity could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a pharmaceutical product may be marketed in the US generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;

- Submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical studies may begin;

- Performance of adequate and well-controlled human clinical studies according to the FDA's current good clinical practices ("GCP"), to establish the safety and efficacy of the proposed pharmaceutical product for its intended use;

- Submission to the FDA of an NDA for a new pharmaceutical product;

- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the pharmaceutical product is produced, to assess compliance with current good manufacturing practices ("cGMP"), to assure that the facilities, methods and controls are adequate to preserve the pharmaceutical product's identity, strength, quality and purity;

- Potential FDA audit of the preclinical and clinical study sites that generated the data in support of the NDA; and

- FDA review and approval of the NDA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals, and continued compliance are inherently uncertain.

Before testing any compounds with potential therapeutic value in humans, the pharmaceutical product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the pharmaceutical product candidate. These early proof-of-principle studies are done using sound scientific procedures and thorough documentation. The conduct of the single and repeat dose toxicology and toxicokinetic studies in animals must comply with federal regulations and requirements including good laboratory practices. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA has concerns and notifies the sponsor. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. If resolution cannot be reached within the 30-day review period, either the FDA places the IND on clinical hold or the sponsor withdraws the application. The FDA may also impose clinical holds on a pharmaceutical product candidate at any time before or during clinical studies for various reasons. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate such clinical study.

Clinical studies involve the administration of the pharmaceutical product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the clinical study sponsor's control. Clinical studies are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing

procedures, subject selection and exclusion criteria, how the results will be analyzed and presented and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical studies must be conducted in accordance with GCP. Further, each clinical study must be reviewed and approved by an independent institutional review board ("IRB") at, or servicing, each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The pharmaceutical product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients, with a goal of characterizing the safety profile of the drug and establishing a maximum tolerable dose ("MTD"). Our pharmaceutical products fall into this latter category because its products are intended to treat cancer and contain cytotoxic agents. Hence, our Phase 1 studies are conducted in late-stage cancer patients whose disease has progressed after treatment with other agents.

- Phase 2: With the maximum tolerable dose established in a Phase 1 trial, the pharmaceutical product is evaluated in a limited patient population at the MTD to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, to determine dosage tolerance, optimal dosage and dosing schedule and to identify patient populations with specific characteristics where the pharmaceutical product may be more effective.

- Phase 3: Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. The studies must be well controlled and usually include a control arm for comparison. One or two Phase 3 studies are usually required by the FDA for an NDA approval, depending on the disease severity and other available treatment options. In some instances, an NDA approval may be obtained based on Phase 2 clinical data with the understanding that the approved drug can be sold subject to a confirmatory trial to be conducted post-approval.

Post-approval studies, or Phase 4 clinical studies, may be conducted after initial marketing approval. These studies are often used to gain additional experience from the treatment of patients in the intended therapeutic indication. The FDA also may require Phase 4 studies, Risk Evaluation and Mitigation Strategies ("REMS") and post-marketing surveillance, among other things, to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, companies may complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the pharmaceutical product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the pharmaceutical product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final pharmaceutical product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the pharmaceutical product candidate does not undergo unacceptable deterioration over its shelf life.

The results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the pharmaceutical product, proposed labeling and other

relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees. A waiver of such fees may be obtained under certain limited circumstances.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA has 10 months after the 60-day filing date in which to complete its initial review of a standard review NDA and respond to the applicant, and six months after the 60-day filing date for a priority review NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs.

After the NDA submission is accepted for filing, the FDA reviews the NDA application to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel pharmaceutical products or pharmaceutical products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the pharmaceutical product approval process, the FDA also will determine whether a risk evaluation and mitigation strategy ("REMS") is necessary to assure the safe use of the pharmaceutical product. If the FDA concludes that a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites as well as the site where the pharmaceutical product is manufactured to assure compliance with GCP and cGMP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. In addition, the FDA will require the review and approval of product labeling.

The NDA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical studies designed to further assess pharmaceutical product safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new pharmaceutical products that meet certain criteria. Specifically, new pharmaceutical products are eligible for Fast Track designation if they are intended to treat a serious condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, if the FDA determines that the schedule is acceptable and if the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for market, including a Fast Track program, may also be eligible for other FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it is intended to treat a serious condition and it offers a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new pharmaceutical product designated for priority review in an effort to facilitate the review. Additionally, accelerated approval may be available for a product intended to treat a serious condition that provides meaningful therapeutic benefit over existing treatments, which means the product may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint. As a condition of accelerated approval, the FDA may require the sponsor to perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires pre-approval of promotional materials for products receiving accelerated approval, which could impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

Any pharmaceutical products for which the Company receives FDA approvals are subject to continuing regulation by the FDA, including, among other things, cGMP compliance, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, prohibitions on promoting pharmaceutical products for uses or in patient populations that are not described in the pharmaceutical product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, actions by the U.S. Department of Justice and/or U.S. Department of Health and Human Services' Office of Inspector General, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available pharmaceutical products for off-label uses, manufacturers may not directly or indirectly market or promote such off-label uses.

We rely and expect to continue to rely on third parties for the production of clinical and commercial quantities of our products. Manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Pharmaceutical product manufacturers and other entities involved in the manufacture and distribution of approved pharmaceutical products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our pharmaceutical product candidates, some of our products covered by U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process for a product the approval of which is the first permitted commercial marketing of the active pharmaceutical ingredient. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved pharmaceutical product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent unless an extension is obtained. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and renders a decision on the application for any patent term extension or restoration. In the future, we may be able to apply for extension of patent term for one or more of our currently licensed patents or any future owned patents to add patent life beyond its current expiration date, depending upon the expected length of the clinical studies and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the U.S. Food, Drug, and Cosmetic Act can also delay the submission or the approval of certain applications of other companies seeking to reference another company's NDA or seeking approval for a similar product. Pediatric exclusivity adds six months to existing exclusivity periods and patent terms and may be granted based on the completion of a pediatric clinical study that "fairly responds" to an FDA-issued "Written Request" for such a clinical study.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical product candidates for which we may obtain regulatory approval. In the United States and in markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part upon the availability of reimbursement from third-party payers. Third-party payers include government payers such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. The process for determining whether a payer will provide coverage for a pharmaceutical product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the pharmaceutical product. Third-party payers may limit coverage to specific pharmaceutical products on an approved list, or formulary, which might not, and frequently does not, include all of the FDA-approved pharmaceutical products for a particular indication. Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. A payer's decision to provide coverage for a pharmaceutical product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In addition, in the United States there is a growing emphasis on comparative effectiveness research, both by private payers and by government agencies. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our pharmaceutical product candidates may not be considered medically necessary or cost-effective. To the extent other drugs or therapies are found to be more effective than our products, payers may elect to cover such therapies in lieu of our products and/or reimburse our products at a lower rate.

Orphan Drug exclusivity prevents for seven years the approval of another product with the same active moiety for the same rare disease. If a product is a new chemical entity (i.e., generally that the moiety has not previously been approved), it may receive five years of exclusivity, during which period FDA may not accept for review certain NDAs for another product with the same moiety. If approval of a product required new clinical data, it may convey three years of exclusivity against approval of certain NDAs for similar products.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical studies that compare the cost-effectiveness of a particular pharmaceutical product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any pharmaceutical product candidates for which we may receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect this will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we may receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

International Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our future drugs. Whether or not we obtain FDA approval for a drug, we must obtain approval of a drug by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country, and the time may be longer or

shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our future drugs

Subsequent Events

On March 22, 2018, we entered into a Lease Agreement (the "Lease") with IPX Memorial Drive Investors, LLC (the "Landlord") for the lease of 2,333 rentable square feet "RSF", which we will use for corporate office space and meetings. The term of the Lease is estimated to begin in May 2018, depending on construction, and continue for an initial term of 66 months, which may be renewed for an additional 5 years. We are required to remit base monthly rent of approximately $4,300 which will increase at an average approximate rate of 3% each year. We are also required to pay additional rent in the form of our pro-rata share of certain specified operating expenses of the Landlord. The newly leased space is located in Houston, Texas.

On February 16, 2018, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors (the "Investors") for the sale of 4,290,000 shares of our common stock, at a purchase price of $2.10 per share. Concurrently with the sale of the shares, pursuant to the Purchase Agreement, we also sold warrants to purchase 2,145,000 shares of common stock (the "Warrants"). We sold the shares and Warrants for aggregate gross proceeds of approximately $9.0 million. Subject to certain beneficial ownership limitations, the Warrants will be initially exercisable on the six-month anniversary of the issuance date at an exercise price equal to $2.80 per share, subject to adjustments as provided under the terms of the Warrants. The Warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the Purchase Agreement occurred on February 21, 2018.

In connection with the offering, we entered into a placement agent agreement (the "Placement Agency Agreement") with Roth Capital Partners, LLC ("Roth"), pursuant to which Roth agreed to serve as exclusive placement agent for the issuance and sale of the shares and Warrants. We paid Roth an aggregate fee equal to 6.5% of the gross proceeds received from the sale of the securities in the transactions. Pursuant to the Placement Agency Agreement, we also agreed to grant to Roth or its designees warrants to purchase up to 3% of the aggregate number of shares sold in the transactions (the "Roth Warrants"). The Roth Warrants have substantially the same terms as the Warrants, except that the Roth Warrants will expire on February 15, 2023. We also reimbursed Roth for its expenses of $75,000.

We agreed to give Roth a nine-month right of first refusal to act as our lead underwriter or exclusive placement agent for any further capital raising transactions. With certain exceptions, we also granted Roth a six-month tail fee equal to the cash and warrant compensation in the offering, if any investor with which Roth had substantive discussions with respect to the offering, provides us with further capital during such six-month period following termination of our engagement of Roth.

Employees

As of December 31, 2017, we had four full-time employees and four part-time employees, and accordingly, a high percentage of the work performed for our development projects is outsourced to qualified independent contractors. In early 2018, an additional four employees, three full time and one part-time, joined the Company.

Legal Proceedings

We are not subject to any litigation.

ITEM 1A. RISK FACTORS

The following risks and uncertainties should be carefully considered. If any of the following occurs, our business, financial condition or operating results could be materially harmed. An investment in our securities is speculative in nature, involves a high degree of risk and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment.

Risks Relating to Our Business

We are developing our drugs to treat patients who are extremely or terminally ill, and patient deaths that occur in our clinical trials could negatively impact our business even if such deaths are not shown to be related to our drugs.

It is our intention to further develop Annamycin and WP1066 with clinical trials in the near future for the treatment of AML and glioblastoma, respectively. Patients suffering from these diseases are extremely sick and have a high likelihood of experiencing adverse outcomes, including death, as a result of their disease or due to other significant risks including relapse of their underlying malignancies. Many patients have already received high-dose chemotherapy and/or radiation therapy, which are associated with their own inherent risks, prior to treatment with our drugs.

As a result, it is likely that we will observe severe adverse outcomes during our clinical trials for our drugs, including patient death. If a significant number of study subject deaths were to occur, regardless of whether such deaths are attributable to one of our drugs, our ability to obtain regulatory approval and/or achieve commercial acceptance for the related drug may be adversely impacted and our business could be materially harmed.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We intend to use the proceeds from our previous offerings, as well as the proceeds from any possible future offerings, to, among other uses, advance Annamycin through clinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital in order to complete clinical development and commercialize Annamycin. If the FDA requires that we perform additional nonclinical studies or clinical trials, or if we determine, as we did in October 2016, that additional clinical trials are required for Annamycin, our expenses would further increase beyond what we currently expect and the anticipated timing of any potential approval of Annamycin would likely be delayed. Further, there can be no assurance that the costs we will need to incur to obtain regulatory approval of Annamycin will not increase.

We will continue to require substantial additional capital to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual amount of funding we will require to complete research and development and commercialize our products under development.

The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- whether our updated plan for clinical trials will be completed on a timely basis and, if completed, whether we will be able to publicly announce results from our phase I/II clinical trials in accordance with our announced milestones;
- whether we are successful in obtaining the benefits of FDA's expedited development and review programs related to Annamycin or our other drug candidates;
- the progress, costs, results of and timing of our clinical trials;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of our product candidates;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;

- our ability to maintain, expand and enforce the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

- our need and ability to hire additional management and scientific and medical personnel;

- the effect of competing drug candidates and new product approvals;

- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and

- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Some of these factors are outside of our control. Based upon our currently expected level of operating expenditures, we believe that we will be able to fund our operational plan into 2019, assuming not a significant amount of the warrants in our recent public offering are exercised for cash. This period could be shortened if there are any significant increases in planned spending on development programs or more rapid progress of development programs than anticipated. We do not believe that our existing capital resources are sufficient to enable us to complete the development and commercialization of Annamycin, if approved, or to initiate any clinical trials or additional development work needed for any other drug candidates. Accordingly, we expect that we will need to raise additional funds in the future.

We may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

We have recently commenced clinical trials, have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on an annual basis, which may make it difficult to predict our future performance.

We are a clinical stage pharmaceutical company with a limited operating history. Our operations to date have been limited to acquiring our technology portfolio and preparing several drugs for authorization to conduct clinical trials. We have only recently commenced clinical trials with Annamycin and have yet to commence clinical trials for any other drug candidates in our pipeline and have yet to receive regulatory approvals for any of our drug candidates. With regard to Annamycin, the FDA has taken a more risk adverse view than European regulatory authorities, placing greater restrictions on our ability to increase dosing for AML patients, which could cause development in the US to lag behind development in Europe. Additionally, we have a limited amount of drug supply and the amount of drug required may depend upon patient response and the need for additional, unplanned treatments, making it difficult to predict the total amount of drug required.

Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our operating results are expected to significantly fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- any delays in regulatory review and approval of our product candidates in clinical development, including our ability to receive approval from the FDA or the Polish authorities for Annamycin;

- delays in the commencement, enrollment and timing of clinical trials;

- difficulties in identifying patients suffering from our target indications;

- the success of our clinical trials through all phases of clinical development;

- potential side effects of our product candidate that could delay or prevent approval or cause an approved drug to be taken off the market;

- our ability to obtain additional funding to develop drug candidates;

- our ability to identify and develop additional drug candidates beyond Annamycin and our WP1066 and WP1122 Portfolios;

- competition from existing products or new products that continue to emerge;

- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;

- our ability to adhere to clinical trial requirements directly or with third parties such as contract research organizations (CROs);

- our dependency on third-party manufacturers to manufacture our products and key ingredients;

- our ability to establish or maintain collaborations, licensing or other arrangements, particularly with MD Anderson;

- our ability to defend against any challenges to our intellectual property including, claims of patent infringement;

- our ability to enforce our intellectual property rights against potential competitors;

- our ability to secure additional intellectual property protection for our developing drug candidates and associated technologies;

- our ability to attract and retain key personnel to manage our business effectively; and

- potential product liability claims.

Accordingly, the results of any historical quarterly or annual periods should not be relied upon as indications of future operating performance.

Risks associated with conducting research and clinical trials abroad could materially adversely affect our business.

We have submitted a request for Clinical Trial Authorization in Poland which, if allowed, will enable a clinical trial to study Annamycin for the treatment of relapsed or refractory AML in Poland. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;

- unexpected changes in price and exchange controls and other regulatory requirements;

- increased difficulties in managing the logistics and transportation of collecting and shipping patient material;
- import and export requirements and restrictions;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses, and other obligations incident to doing business in another country;

- difficulties staffing and managing foreign operations;

- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;

- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We have in the past completed related party transactions that were not conducted on an arm's length basis.

We acquired the rights to the license agreement with MD Anderson covering our WP1122 Portfolio held by IntertechBio Corporation, a company affiliated with certain members of our management and board of directors. We acquired the rights to all data related to the development of Annamycin held by AnnaMed, Inc., a company affiliated with certain members of our management and board of directors. Prior to our IPO, Moleculin, LLC merged with and into our company. Moleculin, LLC was affiliated with certain members of our management and board of directors. Prior to our IPO, we, on Moleculin, LLC's behalf, entered into an agreement with HPI whereby HPI agreed to terminate its option to sublicense certain rights to the WP1066 Portfolio and entered into a co-development agreement with us. Our largest shareholder and a member of our management are shareholders of HPI. None of the foregoing transactions were conducted on an arm's length basis. As such, it is possible that the terms were less favorable to us than in an arm's length transaction.

Our ability to retain the development rights to the WP1066 Portfolio will require us to make up to a total of $1.75 million in payments to HPI, in addition to payments of shares of our common stock and cash made in connection with our IPO, pursuant to the development agreement we entered into with HPI.

Our acquisition of Moleculin, LLC prior to our IPO provided us with the rights to the license agreement Moleculin, LLC had with MD Anderson covering the WP1066 Portfolio. However, Moleculin, LLC previously granted HPI an option to obtain an exclusive sub-license to develop the WP1066 Portfolio in all non-dermatological fields. Prior to our IPO, we, on Moleculin, LLC's behalf, entered into two agreements with HPI. The first agreement terminated HPI's option to obtain the aforementioned exclusive sublicense in exchange for a payment of $100,000 and the issuance of 629,000 shares of our common stock. The second agreement, the HPI Out-Licensing Agreement is a technology rights and development license agreement that provided HPI with a non-exclusive sublicense to develop the WP1066 Portfolio. Pursuant to this HPI Out-Licensing Agreement, we agreed to make payments to HPI of $750,000 over a three-year period commencing after our IPO in exchange for HPI allowing us to access any data, information or know-how resulting from the research and development conducted by HPI, which payments will be expensed when incurred. Notwithstanding our obligation to make the foregoing payments, the HPI Out-Licensing Agreement does not obligate HPI to conduct any specific research or to meet any milestones. Pursuant to the HPI Out-Licensing Agreement, we have the right within three years of the date we entered into the agreement, which occurred in May 2016, to buy-out from HPI all rights granted to HPI under the agreement for a payment of $1.0 million. If we do not exercise the foregoing buy-out right within three years, the license granted to HPI shall convert into an exclusive license even as to our company. As such, if we do not exercise the buy-out right for any reason, we will no longer have access to the non-dermatology uses of the WP1066 Portfolio and all amounts paid to HPI prior to such date will have value only to the extent that the data, information and know-how may be applicable to dermatology applications of the WP1066 Portfolio. We do not expect to maintain a reserve of $1.0 million to exercise the buy-out payment and, as such, we will need to raise additional funds to make the buy-out payment. We cannot assure you that such additional funding, if required, will be available on satisfactory terms, or at all.

We have never been profitable, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.

We have never been profitable and do not expect to be profitable in the foreseeable future. We have not yet submitted any drug candidates for approval by regulatory authorities in the United States or elsewhere. For the year ended December 31, 2017, we incurred a net loss of $9.8 million. We had an accumulated deficit of $14.5 million as of December 31, 2017.

To date, we have devoted most of our financial resources to research and development, including our drug discovery research, preclinical development activities and clinical trial preparation, as well as corporate overhead. We have not generated

any revenues from product sales. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for Annamycin and our other drug candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our continuing product development efforts. We anticipate that any such losses could be significant for the next several years. If Annamycin or any of our other drug candidates fail in clinical trials or do not gain regulatory approval, or if our drug candidates do not achieve market acceptance, we may never become profitable. As a result of the foregoing, we expect to continue to experience net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our drug candidates. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

Our financial condition would be adversely impacted if our intangible assets become impaired.

As a result of the accounting for our acquisition of Moleculin, LLC and the agreement we, on Moleculin, LLC's behalf, entered into with Houston Pharmaceuticals, Inc., we have carried on our balance sheet within intangible assets in-process research and development ("IPR&D") of $11.1 million as of December 31, 2017. Intangibles are evaluated quarterly and are tested for impairment at least annually or when events or changes in circumstances indicate the carrying value of each segment, and collectively our company taken as a whole, might exceed its fair value.

Intangible assets related to IPR&D are considered indefinite-lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets will be written-off and the Company will record a noncash impairment loss on its statement of operations. For those compounds that reach commercialization, if any, the IPR&D assets will be amortized over their estimated useful lives.

If we determine that the value of our intangible assets is less than the amounts reflected on our balance sheet, we will be required to reflect an impairment of our intangible assets in the period in which such determination is made. An impairment of our intangible assets would result in our recognizing an expense in the amount of the impairment in the relevant period, which would also result in the reduction of our intangible assets and a corresponding reduction in our stockholders' equity in the relevant period. As the transactions discussed above were related party transactions and were not conducted on an arm's length basis, it is possible that the terms were less favorable to us than what we would have received in an arm's length transaction.

There are limited suppliers for active pharmaceutical ingredients ("API") used in Annamycin.
Problems with the third parties that manufacture the API used in Annamycin may delay our clinical trials or subject us to liability.

We do not currently own or operate manufacturing facilities for clinical or commercial production of the API used in Annamycin or any of our product candidates. We have no experience in API manufacturing, and we lack the resources and the capability to manufacture any of the APIs used in Annamycin and our product candidates, on either a clinical or commercial scale. As a result, we rely on third parties to supply the API used in Annamycin and each of our product candidates. We expect to continue to depend on third parties to supply the API for Annamycin and our current and future product candidates and to supply the API for Annamycin in commercial quantities. We are ultimately responsible for confirming that the APIs used in Annamycin and our product candidates are manufactured in accordance with applicable regulations.

Our third-party suppliers may not carry out their contractual obligations or meet our deadlines. In addition, the API they supply to us may not meet our specifications and quality policies and procedures or they may not be able to supply the API in commercial quantities. If we need to find alternative suppliers of the API used in Annamycin or any of our product candidates, we may not be able to contract for such supplies on acceptable terms, if at all. Any such failure to supply or delay caused by such contract manufacturers would have an adverse effect on our ability to continue clinical development of our product candidates or commercialize Annamycin.

If our third-party drug suppliers fail to achieve and maintain high manufacturing standards in compliance with cGMP regulations, we could be subject to certain product liability claims in the event such failure to comply resulted in defective products that caused injury or harm.

We cannot be certain that Annamycin will receive regulatory approval, and without regulatory approval we will not be able to market Annamycin.

Our business currently depends largely on the successful development and commercialization of Annamycin. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of Annamycin for the treatment of relapsed or refractory acute myeloid leukemia, or AML.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States until we receive approval of a NDA from the FDA. We have not submitted any marketing applications for any of our product candidates.

NDAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of a NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete and approval is never guaranteed. If we submit a NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators in other jurisdictions have their own procedures for approval of product candidates. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates with which we must comply with prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

If we are unable to obtain approval from the FDA, or other regulatory agencies, for Annamycin and our other product candidates, or if, subsequent to approval, we are unable to successfully commercialize Annamycin or our other product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

Any statements in this report indicating that Annamycin has demonstrated preliminary evidence of efficacy are our own and are not based on the FDA's or any other comparable governmental agency's assessment of Annamycin and do not indicate that Annamycin will achieve favorable efficacy results in any later stage trials or that the FDA or any comparable agency will ultimately determine that Annamycin is effective for purposes of granting marketing approval.

Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for Annamycin and our other product candidates.

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. We do not know whether any future trials or studies of our other product candidates will begin on time or will be completed on schedule, if at all. The start or end of a clinical study is often delayed or halted due to changing regulatory requirements, manufacturing challenges, including delays or shortages in available drug product, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparative drug or required prior therapy, clinical outcomes or financial constraints. For instance, delays or difficulties in patient enrollment or difficulties in retaining trial participants can result in increased costs, longer development times or termination of a clinical trial. Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease the product candidate is intended to treat and who meet other eligibility criteria. Rates of patient enrollment are affected by many factors, including the size of the patient population, the eligibility criteria for the clinical trial, that include the age and condition of the patients and the stage and severity of disease, the nature of the protocol, the proximity of patients to clinical sites and the availability of effective treatments and/or availability of investigational treatment options for the relevant disease.

A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including, but not limited to, a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects, or other adverse initial experiences or findings. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- inability to obtain sufficient funds required for a clinical trial;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- serious and unexpected drug-related side effects experienced by subjects in our clinical trials or by individuals using drugs similar to our product candidates;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling research subjects in clinical trials;
- high drop-out rates and high fail rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness of our product candidates during clinical trials; or
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or vendor.

We have only recently commenced clinical trials and have never submitted an NDA, and any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and our collaborators or we may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. The commencement and completion of future clinical studies could be substantially delayed or prevented by several factors, including, but not limited to:

- a limited number of, and competition for, suitable patients with particular types of cancer for enrollment in our clinical studies;
- delays or failures in reaching acceptable clinical study agreement terms;
- failure of patients to complete the clinical study; and
- unforeseen safety issues.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts.

If Annamycin is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be harmed.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we or any of our potential future collaborators may conduct will demonstrate the consistent or adequate efficacy and safety that would be required to obtain regulatory approval and market any products. If we are unable to bring Annamycin to market, or to acquire other products that are on the market or can be developed, our ability to create long-term stockholder value will be limited.

Our product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if any product candidates are approved, after the approved product has been marketed. For example, in the most recent Phase I/II dose-ranging clinical trial of Annamycin, conducted by a prior developer, two patients succumbed to tumor lysis syndrome ("TLS") resulting from the debris created by Annamycin killing the targeted leukemic blasts more rapidly than their body's ability to cope. Now that this potential has been identified, prophylactic measures intended to protect patients from TLS will be deployed in future clinical trials, but there can be no assurance that such measures will be effective or that other adverse events may not emerge related to our drug. As another example, we intend to attempt to increase the maximum tolerable dose ("MTD") for Annamycin by conducting another Phase I dose-ranging trial, however, unforeseen side effects could prevent us from increasing the MTD from the one established in the prior Phase I/II trial. Additional or unforeseen side effects from Annamycin or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed.

The range and potential severity of possible side effects from therapies such as Annamycin are significant. If Annamycin causes undesirable or unacceptable side effects in the future, this could interrupt, delay or halt clinical trials and result in the failure to obtain or suspension or termination of marketing approval from the FDA and other regulatory authorities or result in marketing approval from the FDA and other regulatory authorities only with restrictive label warnings or other limitations.

If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

If the FDA does not find the manufacturing facilities of our future contract manufacturers acceptable for commercial production, we may not be able to commercialize any of our product candidates.

We do not intend to manufacture the pharmaceutical products that we plan to sell. We are currently utilizing contract manufacturers for the production of the active pharmaceutical ingredients and the formulation of drug product for our trials of Annamycin that we will need to conduct prior to seeking regulatory approval. However, we do not have agreements for supplies of Annamycin or any of our other product candidates and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to commercialize Annamycin if it is approved. Additionally, the facilities used by any contract manufacturer to manufacture Annamycin or any of our other product candidates must be the subject of a satisfactory inspection before the FDA approves the product candidate manufactured at that facility. We are completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and the FDA's current good manufacturing practice standards, or cGMP, and other requirements of any governmental agency whose jurisdiction to which we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls or other negative actions. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidates, including:

- the possibility that we are unable to enter into a manufacturing agreement with a third party to manufacture our product candidates;

- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and

- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer.

Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the government agencies that regulate our products.

We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.

We have no sales, marketing or distribution experience. To develop sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that Annamycin or any of our other product candidates will be approved by the FDA. For product candidates where we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including that we or our third-party sales collaborators may not be able to build and maintain an effective marketing or sales force. If we use third parties to market and sell our products, we may have limited or no control over their sales, marketing and distribution activities on which our future revenues may depend.

We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we may seek to enter into collaborations with companies that have more experience. Additionally, if any of our product candidates receives marketing approval, we may enter into sales and marketing arrangements with third parties with respect to our unlicensed territories. If we are unable to enter into arrangements on acceptable terms, if at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and

time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our product candidates.

When we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. For example, we have formed a collaboration with a Polish drug development company called Dermin, where we have provided them with sub-license rights to our technologies for use in limited territories in exchange for their use of Polish government grant funding to pay for development costs we would otherwise have to fund ourselves. With the exception of Annamycin, Dermin's territories are primarily Poland and lesser surrounding countries, but not including any of the major European markets (UK, Germany, France, Spain and Italy). In the case of Annamycin, Dermin's territories also include Germany, but we retain the right to repurchase that territory for $500,000 at any time in the future.

One or more of our collaboration partners may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may contain provisions that are not favorable to us. In addition, any collaboration that we enter into may be unsuccessful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a product candidate or research program under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development. If we are unable to reach agreements with suitable collaborators for our product candidates, we would face increased costs, we may be forced to limit the number of our product candidates we can commercially develop or the territories in which we commercialize them. As a result, we might fail to commercialize products or programs for which a suitable collaborator cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition could be materially and adversely affected.

Our success depends greatly on the success of Annamycin's development for the treatment of relapsed or refractory AML, and our pipeline of product candidates beyond this lead indication is extremely early stage and limited.

Other than Annamycin, our other two drug candidates, our WP1066 Portfolio and our WP1122 Portfolio, are each in the early stages of development. In addition, our current plan is to use a significant portion of our available funds to support our clinical plan for Annamycin, although this cash utilization may change in the future. As such, we are dependent on the success of Annamycin in the near term. We cannot provide you any assurance that we will be able to successfully advance any of these indications through the development process.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in the United States, Europe and other jurisdictions, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing drugs for the diseases that we are targeting before we do or may develop drugs that are deemed to be more effective or gain greater market acceptance than ours. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. In addition, many universities and private and public research institutes may become active in our target disease areas. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than any of our product candidates that we are currently developing or that we may develop, which could render our products obsolete or noncompetitive.

A number of attempts have been made or are under way to provide an improved treatment for AML. Drugs attempting to target a subset of AML patients who present with particular anomalies involving a gene referred to as FLT3 are currently in clinical trials. Other approaches to improve the effectiveness of induction therapy are in early stage clinical trials and, although

they do not appear to address the underlying problems with anthracyclines, we can provide no assurance that such improvements, if achieved, would not adversely impact the need for improved anthracyclines. A modified version of doxorubicin designed to reduce cardiotoxicity is in clinical trials for the treatment of sarcoma and, although this drug does not appear to address multidrug resistance and is not currently intended for the treatment of acute leukemia, we can provide no assurance that it will not become a competitive alternative to Annamycin. Although we are not aware of any other single agent therapies in clinical trials that would directly compete against Annamycin in the treatment of relapsed and refractory AML, we can provide no assurance that such therapies are not in development, will not receive regulatory approval and will reach market before our drug candidate Annamycin. In addition, any such competing therapy may be more effective and / or cost-effective than ours.

If our competitors market products that are more effective, safer or less expensive or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, because of our limited resources, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We may not receive Orphan Drug exclusivity for Annamycin, and if we do, it may not effectively prevent approval of a competing product.

On March 21, 2017, we received notice that the FDA granted Orphan Drug designation for Annamycin for the treatment of AML. Although we would anticipate Orphan Drug exclusivity being awarded with the approval of Annamycin for that use, we cannot be sure that will occur. Moreover, even if Orphan Drug exclusivity is granted, we cannot know that it will prevent approval of another product containing Annamycin and intended to treat AML, because any such subsequent product could be demonstrated to be clinically superior to Annamycin.

The composition of matter patent for Annamycin has expired, and other patents have not yet issued, and may not issue.

We intend to pursue patents with claims directed to Annamycin drug product formulations and the methods of use of Annamycin to treat relapsed or refractory AML and other conditions, and methods for its synthesis, as the composition of matter patent protection for Annamycin has expired. As a result, competitors may be able to offer and sell products so long as these competitors do not infringe any other patents that third parties or we hold, including formulation, synthesis and method of use patents. However, particularly with regard to products approved for more than one indication, method of use patents may not provide significant protection, because a competitor could obtain approval for only a non-protected use and thus come to market, where the product may legally be prescribed for the protected use, thus undermining the protection provided by the patent. Although off-label prescriptions may infringe our method of use patents, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. Off-label sales would limit our ability to generate revenue from the sale of Annamycin, if approved for commercial sale

The intellectual property rights we have licensed from MD Anderson are subject to the rights of the U.S. government.

We have obtained a royalty-bearing, worldwide, exclusive license to intellectual property rights, including patent rights related to our WP1066 Portfolio and WP1122 Portfolio drug product candidates from MD Anderson. Some of our licensed intellectual property rights from MD Anderson have been developed in the course of research funded by the U.S. government. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980. Government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us, or an assignee or exclusive licensee to such inventions, to grant licenses to any of these inventions to a third party if they determine that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; (iii) government action is necessary to meet requirements for public use under federal regulations; or (iv) the right to use or sell such inventions is exclusively licensed to an entity within the U.S. and substantially manufactured outside the U.S. without the U.S. government's prior approval. Additionally, we may be restricted from granting exclusive licenses for the right to use or sell our inventions created pursuant to such agreements unless the licensee agrees to additional restrictions (e.g., manufacturing substantially all of the invention in the U.S.). The U.S. government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title in any country in which a patent application is not filed within specified time limits. Additionally, certain inventions are subject to transfer restrictions during the term of these agreements and for a period thereafter, including sales of products or components, transfers to foreign subsidiaries for the purpose of the relevant agreements, and transfers to certain foreign third parties. If any of our intellectual property becomes subject to any of

the rights or remedies available to the U.S. government or third parties pursuant to the Bayh-Dole Act of 1980, this could impair the value of our intellectual property and could adversely affect our business.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

We may from time to time seek to enforce our intellectual property rights against infringers when we determine that a successful outcome is probable and may lead to an increase in the value of the intellectual property. If we choose to enforce our patent rights against a party, then that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced. Additionally, the validity of our patents and the patents we have licensed may be challenged if a petition for post grant proceedings such as inter-partes review and post grant review is filed within the statutorily applicable time with the U.S. Patent and Trademark Office ("USPTO"). These lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our intellectual property rights. In addition, in recent years the U.S. Supreme Court modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of a challenge of any patents we obtain or license.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

As of December 31, 2017, we had four full-time and four part-time employees. As we advance our product candidates through preclinical studies and clinical trials, we will need to increase our product development, scientific and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we may need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We are highly dependent on the development, regulatory, commercialization and business development expertise of our management team, key employees and consultants. If we lose one or more of our executive officers or key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time. Replacing executive officers, key employees and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

In addition, we have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Our chief executive officer is currently working for another company.

Walter Klemp, our chairman and chief executive officer is also the chief executive officer of Soliton, Inc., a medical device development company whose business operations we do not believe conflict with those of our company. As we progress, if more of his time as CEO is required and the current officer cannot provide that level of commitment, we will need to identify a suitable CEO who can dedicate such time to our company. We can provide no assurance that we will be able to successfully identify and retain a qualified candidate for this position.

We do not expect that our insurance policies will cover all of our business exposures thus leaving us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Although we intend to obtain product insurance before we commence any clinical trials, there can be no assurance that we will secure adequate insurance coverage or that any such insurance coverage will be sufficient to protect our operations to significant potential liability in the future. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Additionally, we use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time-consuming or costly. We do not carry specific hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination.

We may incur penalties if we fail to comply with healthcare regulations.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. In addition to FDA restrictions on the marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical device industries in recent years, as well as consulting or other service agreements with physicians or other potential referral sources. These laws include anti-kickback statutes and false claims statutes that prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or, in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally-financed healthcare programs, and knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services, reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and any practices we adopt may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs, criminal fines and imprisonment. Any challenge to our business practices under these laws could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to recover from any catastrophic event affecting our suppliers.

Our suppliers may not have adequate measures in place to minimize and recover from catastrophic events that may substantially destroy their capability to meet customer needs, and any measures they may in place may not be adequate to recover production processes quickly enough to support critical timelines or market demands. These catastrophic events may include weather events such as tornadoes, earthquakes, floods or fires. In addition, these catastrophic events may render some or all of the products at the affected facilities unusable.

We may be materially adversely affected in the event of cyber-based attacks, network security breaches, service interruptions, or data corruption.

We rely on information technology to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities. We use technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. Although we have developed systems and processes that are designed to protect proprietary or confidential information and prevent data loss and other security breaches, such measures cannot provide absolute security. If our systems are breached or suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may significantly suffer and we may be subject to litigation, government enforcement actions or potential liability. Security breaches could also cause us to incur significant remediation costs, result in product development delays, disrupt key business operations, including development of our product candidates, and divert attention of management and key information technology resources.

Risks Relating to Our Common Stock

Our stock price has been and may continue to be volatile, which could result in substantial losses for investors.

Since our IPO in June 2016, our stock price has ranged from a high of $9.58 to a low of $0.71, and the market price of our common stock is likely to continue to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control. In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also significantly affect the market price of our common stock.

Your ownership may be diluted if additional capital stock is issued to raise capital, to finance acquisitions or in connection with strategic transactions.

We intend to seek to raise additional funds, finance acquisitions or develop strategic relationships by issuing equity or convertible debt securities, which would reduce the percentage ownership of our existing stockholders. Our board of directors has the authority, without action or vote of the stockholders, to issue all or any part of our authorized but unissued shares of common or preferred stock. Our certificate of incorporation authorizes us to issue up to 75,000,000 shares of common stock and 5,000,000 shares of preferred stock. Future issuances of common or preferred stock would reduce your influence over matters on which stockholders vote and would be dilutive to earnings per share. In addition, any newly issued preferred stock could have rights, preferences and privileges senior to those of the common stock. Those rights, preferences and privileges could include, among other things, the establishment of dividends that must be paid prior to declaring or paying dividends or other distributions to holders of our common stock or providing for preferential liquidation rights. These rights, preferences and privileges could negatively affect the rights of holders of our common stock, and the right to convert such preferred stock into shares of our common stock at a rate or price that would have a dilutive effect on the outstanding shares of our common stock.

Shares issuable upon the conversion of warrants or the exercise of outstanding options may substantially increase the number of shares available for sale in the public market and depress the price of our common stock.

We issued the underwriters in our IPO warrants to purchase 107,802 shares of common stock exercisable at a price of $7.50 per share and these warrants remain outstanding as of March 1, 2018. From the February 2017 Offering, we had as of March 1, 2018, outstanding warrants exercisable for an aggregate of 419,772 shares of our common stock at a weighted average exercise price of approximately $1.41 per share. On July 29, 2017, the Company entered into a consulting agreement for its investor relations operations and in exchange for the consulting services, we agreed to issue two warrants (to purchase 100,000 and 50,000 shares of common stock at exercise prices of $2.41 and $3.00 per share). These warrants were outstanding

as of March 1, 2018. Additionally from the February 2018 Offering, we had as of March 1, 2018, outstanding warrants exercisable for an aggregate of 2,145,000 shares of common stock, at an exercisable price of $2.80 per share. As of December 31, 2017, we had 1,345,000 options to purchase shares of common stock at a weighted average price of $3.50 per share. To the extent any of these warrants or options are exercised and any additional options are granted and exercised, there will be further dilution to stockholders and investors. Until the options and warrants expire, these holders will have an opportunity to profit from any increase in the market price of our common stock without assuming the risks of ownership. Holders of options and warrants may convert or exercise these securities at a time when we could obtain additional capital on terms more favorable than those provided by the options or warrants. The exercise of the options and warrants will dilute the voting interest of the owners of presently outstanding shares by adding a substantial number of additional shares of our common stock.

The concentration of our common stock ownership by our current management will limit your ability to influence corporate matters.

Our founders, directors and executive officers beneficially own and are able to vote in the aggregate 34% of our outstanding common stock. As such, our founders, directors and executive officers, as stockholders, will continue to have the ability to exert significant influence over all corporate activities, including the election or removal of directors and the outcome of tender offers, mergers, proxy contests or other purchases of common stock that could give our stockholders the opportunity to realize a premium over the then-prevailing market price for their shares of common stock. This concentrated control will limit your ability to influence corporate matters and, as a result, we may take actions that our stockholders do not view as beneficial. In addition, such concentrated control could discourage others from initiating changes of control. In such cases, the perception of our prospects in the market may be adversely affected and the market price of our common stock may decline.

Certain provisions in our organizational documents could enable our board of directors to prevent or delay a change of control.

Our organizational documents contain provisions that may have the effect of discouraging, delaying or preventing a change of control of, or unsolicited acquisition proposals, that a stockholder might consider favorable. These include provisions:

- prohibiting the stockholders from acting by written consent;
- requiring advance notice of director nominations and of business to be brought before a meeting of stockholders;
- requiring a majority vote of the outstanding shares of common stock to amend the bylaws; and
- limiting the persons who may call special stockholders' meetings.

Furthermore, our board of directors has the authority to issue shares of preferred stock in one or more series and to fix the rights and preferences of these shares without stockholder approval. Any series of preferred stock is likely to be senior to our common stock with respect to dividends, liquidation rights and, possibly, voting rights. The ability of our board of directors to issue preferred stock also could have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

In addition, Delaware law makes it difficult for stockholders that recently have acquired a large interest in a corporation to cause the merger or acquisition of the corporation against the directors' wishes. Under Section 203 of the Delaware General Corporation Law, a Delaware corporation may not engage in any merger or other business combination with an interested stockholder for a period of three years following the date that the stockholder became an interested stockholder except in limited circumstances, including by approval of the corporation's board of directors.

As a biotechnology company, we are at increased risk of securities class action litigation.

Biotechnology companies have experienced greater than average stock price volatility in recent years, and our common stock price has been particularly volatile ranging from a high of $9.58 to a low of $0.71. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of management would be diverted from the operation of our business.

We have no intention of declaring dividends in the foreseeable future.

The decision to pay cash dividends on our common stock rests with our board of directors and will depend on our earnings, unencumbered cash, capital requirements and financial condition. We do not anticipate declaring any dividends in the foreseeable future, as we intend to use any excess cash to fund our operations. Investors in our common stock should not expect to receive dividend income on their investment, and investors will be dependent on the appreciation of our common stock to earn a return on their investment.

Failure to maintain effective internal control over our financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could cause our financial reports to be inaccurate.

We are required pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, to maintain internal control over financial reporting and to assess and report on the effectiveness of those controls. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our management concluded that our internal controls over financial reporting were, and continue to be ineffective, and as of the year ended December 31, 2017, identified a material weakness in our internal controls due to the lack of segregation of duties. While management is working to remediate the material weakness, there is no assurance that such changes, when economically feasible and sustainable, will remediate the identified material weaknesses or that the controls will prevent or detect future material weaknesses. If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business.

Failure to continue improving our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, and the related rules and regulations of the SEC. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

Management performed an annual assessment as of December 31, 2017 of the effectiveness of our internal control over financial reporting for its annual report. Our management concluded that our internal control over financial reporting was, and continues to be, ineffective and as of the year ended December 31, 2017, due to a material weakness in our internal controls due to the lack of segregation of duties. For as long as we remain an "emerging growth company" as defined in the JOBS Act, we have and intend to consider to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may continue to take advantage of these reporting exemptions until we are no longer an "emerging growth company." During 2016, we were required to restate certain financial periods due to an error in the accounting for our business combination of Moleculin, LLC. To remediate this material weakness, we engaged an outside firm to assist management with such accounting and will continue to use outside firms as a resource to deal with other non-recurring or unusual transactions. However, notwithstanding our remediation efforts, there is no assurance we will not encounter future accounting errors in the future. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information.

As an "emerging growth company" under the Jumpstart Our Business Startups Act, or JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements.

As an "emerging growth company" under the JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements. We are an emerging growth company until the earliest of:

- the last day of the fiscal year during which we have total annual gross revenues of $1 billion or more;
- the last day of the fiscal year following the fifth anniversary of our IPO, or December 31, 2021;
- the date on which we have, during the previous 3-year period, issued more than $1 billion in non-convertible debt; or
- the date on which we are deemed a "large accelerated issuer" as defined under the federal securities laws.

For so long as we remain an emerging growth company, we will not be required to:

- have an auditor report on our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;

- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis);

- submit certain executive compensation matters to shareholders advisory votes pursuant to the "say on frequency" and "say on pay" provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010;

- include detailed compensation discussion and analysis in our filings under the Securities Exchange Act of 1934, as amended, and instead may provide a reduced level of disclosure concerning executive compensation; and

- may present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A.

We intend to take advantage of all of these reduced reporting requirements and exemptions. Certain of these reduced reporting requirements and exemptions were already available to us due to the fact that we also qualify as a "smaller reporting company" under SEC rules. For instance, smaller reporting companies are not required to obtain an auditor attestation and report regarding management's assessment of internal control over financial reporting; are not required to provide a compensation discussion and analysis; are not required to provide a pay-for-performance graph or CEO pay ratio disclosure; and may present only two years of audited financial statements and related MD&A disclosure.

Under the JOBS Act, we may take advantage of the above-described reduced reporting requirements and exemptions until December 31, 2021, or such earlier time that we no longer meet the definition of an emerging growth company. In this regard, the JOBS Act provides that we would cease to be an "emerging growth company" if we have more than $1.0 billion in annual revenues, have more than $700 million in market value of our common stock held by non-affiliates, or issue more than $1.0 billion in principal amount of non-convertible debt over a three-year period. Further, under current SEC rules, we will continue to qualify as a "smaller reporting company" for so long as we have a public float (i.e., the market value of common equity held by non-affiliates) of less than $75 million as of the last business day of our most recently completed second fiscal quarter.

We cannot predict if investors will find our securities less attractive due to our reliance on these exemptions. If investors were to find our common stock less attractive as a result of our election, we may have difficulty raising capital.

If we are unable to maintain compliance with the listing requirements of The Nasdaq Capital Market, our common stock may be delisted from The Nasdaq Capital Market which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares.

Our common stock is listed on The Nasdaq Capital Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly-held shares, market value of listed shares, minimum bid price per share, and minimum stockholder's equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from The Nasdaq Capital Market.

In May 2017, we received a notice that we were not in compliance with the $1.00 minimum closing bid price requirement set forth in NASDAQ Listing Rule 5550(a)(2). On July 6, 2017, we received a letter from NASDAQ notifying us that we had regained compliance with the rule as a result of the closing bid price of our common stock being at $1.00 per share or greater for the 10 consecutive business days from June 21, 2017 through July 5, 2017.

In the future, we may again fail to comply with the continued listing requirements of the Nasdaq Capital Market, which would subject our common stock to being delisted. Delisting from The Nasdaq Capital Market would adversely affect

our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate, executive offices and laboratory are in located in a leased facility in Houston, Texas. The current lease is month-to-month. On March 22, 2018, we entered into a Lease Agreement (the "Lease") with IPX Memorial Drive Investors, LLC (the "Landlord") for the lease of 2,333 rentable square feet "RSF", which we will use for corporate office space and meetings. The term of the Lease is estimated to begin in May 2018, depending on construction, and continue for an initial term of 66 months, which may be renewed for an additional 5 years. We are required to remit base monthly rent of approximately $4,300 which will increase at an average approximate rate of 3% each year. We are also required to pay additional rent in the form of our pro-rata share of certain specified operating expenses of the Landlord. The newly leased space is located in Houston, Texas. We believe our facilities, as expanded, will be sufficient to meet our current needs and that suitable space will be available as and when needed. We do not own any real property.

ITEM 3. LEGAL PROCEEDINGS

From time to time in the ordinary course of our business, we may be involved in legal proceedings, the outcomes of which may not be determinable. The results of litigation are inherently unpredictable. Any claims against us, whether meritorious or not, could be time consuming, result in costly litigation, require significant amounts of management time and result in diversion of significant resources. We are not able to estimate an aggregate amount or range of reasonably possible losses for those legal matters for which losses are not probable and estimable, primarily for the following reasons: (i) many of the relevant legal proceedings are in preliminary stages, and until such proceedings develop further, there is often uncertainty regarding the relevant facts and circumstances at issue and potential liability; and (ii) many of these proceedings involve matters of which the outcomes are inherently difficult to predict. We have insurance policies covering potential losses where such coverage is cost effective.

We are not at this time involved in any legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

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

Market Information

Our common stock has been listed on the NASDAQ Capital Market since June 1, 2016, the date of our initial public offering, under the symbol "MBRX". On March 18, 2018, the closing price reported on the NASDAQ Capital Market for our common stock was $2.05. The following tables set forth, for the calendar quarter indicated, the quarterly high and low sales price of our common stock, respectively, as reported on the NASDAQ Capital Market.

	Price Range	
Year-Ended December 31, 2016	**High**	**Low**
First Quarter	n/a	n/a
Second Quarter (commencing June 1, 2016)	$ 9.58	$ 6.24
Third Quarter	$ 7.02	$ 5.50
Fourth Quarter	$ 5.90	$ 1.46
Year-Ended December 31, 2017		
First Quarter	$ 2.69	$ 1.02
Second Quarter	$ 3.28	$ 0.73
Third Quarter	$ 2.99	$ 1.54
Fourth Quarter	$ 2.54	$ 1.52

Holders

As of March 16, 2018, there were approximately 170 holders of record of our common stock. In addition, we believe that a significant number of beneficial owners of our common stock hold their shares in nominee or in "street name" accounts through brokers.

Dividends

We have never paid any dividends on our common stock. The payment of dividends in the future will be contingent upon our revenues and earnings, if any, capital requirements and general financial condition. It is the present intention of our Board of Directors to retain all earnings, if any, for use in our business operations and, accordingly, our Board of Directors does not anticipate declaring any dividends in the foreseeable future.

Shares Forgone to Satisfy Minimum Statutory Withholdings

Under the terms of our stock plans, at the election of each employee, we can authorize a net settlement of distributable shares to employees after satisfaction of an individual employees' tax withholding obligations. For the years ended December 31, 2017 and 2016, respectively, we received no shares from employees for tax withholding obligations.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information regarding our equity compensation plans at December 31, 2017:

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 (by class) remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	1,345,000	$ 3.50	1,155,000
Equity compensation plans not approved by security holders (2)	107,802	$ 7.50	—
Equity compensation plans not approved by security holders (3)	150,000	$ 2.61	—
Total	1,602,802		1,155,000

(1)Represents shares of common stock issuable upon exercise of outstanding stock options under our 2015 Stock Plan, as amended. Our 2015 Stock Plan has been approved by our stockholders.
(2)Consists of a five-year warrant issued to the underwriters in our initial public offering.
(3)Consists of warrants issued to a consultant for services.

Recent Sales of Unregistered Securities

On February 16, 2018, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors for the sale by us of 4,290,000 shares of our common stock, at a purchase price of $2.10 per share. Concurrently with the sale of the common shares, pursuant to the Purchase Agreement, we also sold to the investors warrants to purchase 2,145,000 shares of common stock. We sold the common shares and warrants for aggregate gross proceeds of approximately $9.0 million. Subject to certain beneficial ownership limitations, the warrants will be initially exercisable on the six-month anniversary of the issuance date at an exercise price equal to $2.80 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the Purchase Agreement closed on February 21, 2018.

The net proceeds from the transactions was approximately $8.27 million after deducting certain fees due to the placement agent and transaction expenses. The net proceeds will be used for planned clinical trials, preclinical programs, for other research and development activities and for general corporate purposes.

The common shares were offered and sold by us pursuant to an effective shelf registration statement on Form S-3, which was filed with the Securities and Exchange Commission on July 24, 2017 and subsequently declared effective on August 21, 2017 (File No. 333-219434), and the base prospectus contained therein. We filed a prospectus supplement with the SEC on February 16, 2018 in connection with the sale of the common shares.

The warrants and the shares issuable upon exercise of the warrants were sold without registration under the Securities Act in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering to accredited investors, and in reliance on similar exemptions under applicable state laws.

We also entered into a placement agent agreement (the "Placement Agency Agreement") with Roth Capital Partners, LLC ("Roth"), pursuant to which Roth agreed to serve as exclusive placement agent for the issuance and sale of the common shares and warrants. We paid Roth an aggregate fee equal to 6.5% of the gross proceeds received by us from the sale of the securities in the transactions. Pursuant to the Placement Agency Agreement, we also agreed to grant to Roth or its designees warrants to purchase up to 3% of the aggregate number of shares of common stock sold in the transactions (the "Roth Warrants"). The Roth Warrants have substantially the same terms as the warrants, except that the Roth Warrants will expire on February 15, 2023. The Roth Warrants and the shares issuable upon exercise of the Roth Warrants will be issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and in reliance on similar exemptions under applicable state laws. We also reimbursed Roth for its expenses of $75,000.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the years ended December 31, 2017.

ITEM 6. SELECTED FINANCIAL DATA

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

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

The following discussion should be read in conjunction with the Financial Statements and Notes thereto included in this Form 10-K. The forward-looking statements included in this discussion and elsewhere in this Form 10-K involve risks and uncertainties, including those set forth under "Cautionary Statement About Forward-Looking Statements." Actual results and experience could differ materially from the anticipated results and other expectations expressed in our forward-looking statements as a result of a number of factors, including but not limited to those discussed in this Item and in Item 1A - "Risk Factors."

Overview

MBI is a clinical-stage pharmaceutical company organized as a Delaware corporation in July 2015 to focus on the development of oncology drug candidates, all of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center, which we refer to as "MD Anderson". MBI has three core drug technologies: a uniquely designed anthracycline (Annamycin), a portfolio of STAT3 inhibitors (WP1066 Portfolio) and a collection of inhibitors of glycolysis (WP1122 Portfolio). Our clinical stage drugs are Annamycin, an anthracycline designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML, and WP1066, an immuno-stimulating STAT3 inhibitor targeting brain tumors, pancreatic cancer and AML. We are also engaged in preclinical development of additional drug candidates, including additional STAT3 inhibitors and compounds targeting the metabolism of tumors through the inhibition of glycolysis.

Our lead drug candidate is liposomal Annamycin, which we refer to as Annamycin, an anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML. Annamycin has been in clinical trials pursuant to an IND, that had been filed with the FDA. Due to a lack of development activity by a prior drug developer, this IND was terminated. To permit the renewed investigation of Annamycin, we submitted a new IND for a Phase I/II trial for the treatment of relapsed or refractory AML in August 2017, which was subsequently allowed by the FDA in September 2017. We have two other drug development projects: (i) one involving a library of small molecules, which we refer to as the WP1066 Portfolio, a collection of STAT3 inhibitors, some of which also have immuno-stimulating capability, targeting brain tumors, pancreatic cancer and AML, and (ii) the WP1122 Portfolio, a library of small molecules targeting the metabolic processes involved in cancer in general and glioblastoma (the most aggressive and most common form of brain tumor) and pancreatic cancer in particular through the inhibition of glycolysis. A physician-sponsored IND for a Phase I trial of WP1066 in patients with recurrent malignant glioma and brain metastasis from melanoma was allowed by the FDA in December 2017. We also continue to sponsor ongoing research at MD Anderson in order to improve and expand our drug development pipeline.

We have been granted royalty-bearing, worldwide, exclusive licenses for the patent and technology rights related to all of our drug technologies, as these patent rights are owned by MD Anderson. The Annamycin drug substance is no longer covered by any existing patent protection, however, we intend to submit patent applications for formulation, synthetic process and reconstitution related to our Annamycin drug product candidate, although there is no assurance that we will be successful in obtaining such patent protection. Independently from potential patent protection, we have received Orphan Drug designation from the FDA for Annamycin for the treatment of AML, which would entitle us to market exclusivity of 7 years from the date of approval of a New Drug Application ("NDA") in the United States. We may then benefit from Orphan Drug exclusivity, during which period FDA generally could not approve another Annamycin product for the same use. We also intend to apply for similar status in the European Union ("EU") where market exclusivity extends to 10 years from the date of Marketing Authorization Application ("MAA"). Separately, the FDA may also grant market exclusivity of 5 years for newly approved new chemical entities (of which Annamycin would be one), but there can be no assurance that such exclusivity will be granted.

With regard to additional potential clinical activity, we submitted in October 2017 a request for Clinical Trial Authorization ("CTA") in Poland which, if allowed, will enable a Phase I/II clinical trial to study Annamycin for the treatment of relapsed or refractory AML in Poland. This will be in addition to the previously announced allowance of our IND in the United States. In December 2017, the Ethics Committee in Poland approved our Phase I/II clinical trial of Annamycin. The CTA remains subject to final approval by the Polish National Office. Furthermore, in September 2017 we engaged a contract research organization ("CRO") to prepare for a proof-of-concept clinical trial in Poland to study our drug candidate WP1220, a part of the WP1066 portfolio, for the treatment of cutaneous T-cell lymphoma ("CTCL").

Our Drug Candidates

Annamycin

Our lead product candidate is Annamycin, for which FDA has allowed an IND for a Phase I/II trial for the treatment of relapsed or refractory AML and granted Orphan Drug designation for the treatment of AML. We intend to conduct Phase I/II clinical trials for Annamycin as a monotherapy for the treatment of relapsed or refractory AML in the United States and in Poland.

Planned Clinical Trials for Annamycin

In October 2016, we adjusted our clinical strategy for Annamycin by adding in a Phase I arm to our trial, which will add expense to our development effort. We believe this change in strategy will add several months to the eventual final approval of the drug, if the drug is approved.

Because the prior developer of Annamycin allowed their IND to lapse, we were required to submit a new IND for continued clinical trials with Annamycin. We filed our IND application for Annamycin, with the clinical strategy of increasing the MTD mentioned above, on February 10, 2017. In subsequent discussions with us, FDA requested certain revisions to the protocol, additional information, and additional data related to Chemistry, Manufacturing and Controls ("CMC"). We made the requested revisions to the protocol and included the CMC data in our re-submission of the IND in August 2017 and the FDA allowed this IND in September 2017.

In August 2017, we met with the European Medicines Agency ("EMA") to discuss a CTA in Europe for the study of Annamycin for the treatment of AML. As a result of that meeting, we decided to proceed with an application in October 2017 for a CTA for Annamycin in Poland. Unlike in the United States, the process for beginning a clinical trial in Poland requires a hospital contract before a request for CTA can be made. We obtained the required hospital contract, which allowed the formal request for Polish approval. In December 2017, the Ethics Committee in Poland approved our Phase I/II trial of Annamycin for the treatment of relapsed or refractory AML. A final approval is required by the Polish National Office. In March we received requests for and provided additional information to the Polish National Office. We expect a response from the Polish National Office in the first half of 2018 and at the earliest mid-April 2018. The start of clinical trials in Poland remains subject to confirmation and approval of the CTA by the Polish National Office. We can provide no assurance that we will receive such confirmation on a timely basis, if at all.

We have appointed a CRO in both the United States and Poland. In addition, we continue to recruit and contract clinics both in the United States and Poland. In the US, we have one site - University Hospitals Cleveland Medical Center ("UHCMC") - recruiting patients and active with drug ready to provide treatments. A patient has been enrolled with anticipated treatment to occur in the near term. We can provide no assurance treatment will occur on a timely basis, if at all.

One of the key dose-limiting toxicities associated with currently available anthracyclines is their propensity to induce life-threatening heart damage. In our current Phase I/II trial for Annamycin, we will collect data to further validate the design intent of Annamycin to have little or no cardiotoxicity. Unless otherwise noted, all of our references to Annamycin refer to the liposomal form (L-Annamycin).

On March 21, 2017, we received notice that FDA had granted Orphan Drug designation for Annamycin for the treatment of AML, effective March 20, 2017.

The WP1066 Portfolio

We have a license agreement with MD Anderson pursuant to which we have been granted a royalty-bearing, worldwide, exclusive license for the patent and technology rights related to our WP1066 Portfolio and its close analogs, molecules targeting the modulation of key oncogenic transcription factors.

Planned Clinical Testing of WP1066 Portfolio

In vitro testing has shown a high level of activity for WP1066 against a wide range of solid tumors, and *in vivo* testing has shown significant activity against head and neck, pancreatic, stomach, and renal cancers, as well as metastatic melanoma and glioblastoma, among others. *In vivo* testing in mouse tumor models has shown that WP1066 inhibits tumor growth, blocks angiogenesis (a process that leads to the formation of blood vasculature needed for tumor growth) and increases survival.

With respect to our WP1066 Portfolio, we collaborated with a clinician at MD Anderson who submitted an IND for WP1066 treatment of brain tumors to the FDA. In December 2017, the FDA allowed this application for a Phase I trial of WP1066 in patients with recurrent malignant glioma and brain metastasis from melanoma.

This Phase I trial with WP1066 drug will receive $2 million in private grant funding at MD Anderson which is in addition to two Specialized Programs of Research Excellence (SPORE) peer reviewed grants awarded by the National Cancer Institute. We believe the rigorous peer-review process applied to SPORE grant applications represents an important additional measure of independent assessment and validation of the research connected with our approach to using WP1066/STAT3 for the treatment of cancer. The grants described here do not flow through Moleculin's financial statements, but instead are applied to the cost of preclinical and clinical activities at and conducted by MD Anderson.

We estimate that this physician-sponsored Phase I trial will begin treating patients in the first half of 2018. However, as this is a physician-sponsored clinical trial, we have limited influence on the process in beginning clinical trials and, as such, any disruptions to this process may delay the treatment of patients with WP1066, which may delay the commencement of this trial beyond the first half of 2018.

An analog of WP1066, referred to as WP1220, was previously the subject of an IND (WP1220 was referred to as "MOL4239" for purposes of this IND) related to use of the molecule in the topical treatment of psoriasis. Clinical trials were commenced on WP1220 in the US, but were terminated early due to limited efficacy in the topical treatment of psoriatic plaques. Notwithstanding its limitations in treating psoriasis, our pre-clinical research in multiple cutaneous T-cell lymphoma ("CTCL") cell lines has suggested that WP1220 may be effective in inhibiting CTCL. Based on this data, we are collaborating with a Polish drug development company, Dermin, which has received Polish government grant money to develop WP1220 in Poland for the topical treatment of early stage CTCL patients. CTCL is a potentially deadly form of skin cancer for which there are limited treatment options.

In September 2017, we engaged a CRO to prepare a proof-of-concept clinical trial in Poland to study WP1220 for the topical treatment of CTCL.

We also conducted a Phase II clinical trial for WP1066 for the topical treatment of psoriasis using a longer treatment period as compared with the WP1220 psoriasis trial, however this trial was terminated early as a significant number of patients experienced a non-permanent worsening of their psoriatic plaques after extended use of the drug, suggesting that its use as a topical agent for non-life-threatening diseases such as psoriasis will require further study to optimize dosing and scheduling regimens.

The WP1122 Portfolio

We have a license agreement with MD Anderson pursuant to which we have been granted a royalty-bearing, worldwide, exclusive license for the patent and technology rights related to our WP1122 Portfolio and similar molecules targeting the treatment of glioblastoma multiforme ("GBM") and related central nervous system malignancies.

We believe this technology has the potential to target a wide variety of solid tumors, which eventually become resistant to all treatments, and thereby provide a large and important opportunity for novel drugs. Notwithstanding this potential, we are focused on the treatment of central nervous system malignancies and especially GBM. Although less prevalent than some larger categories of solid tumors, cancers of the central nervous system are particularly aggressive and resistant to treatment. The prognosis for such patients can be particularly grim and the treatment options available to their physicians are among the most limited of any cancer.

We have preliminary preclinical data for WP1122, including *in vitro* activity against cancer cell lines, as well as data on survival of animals subjected to xenografts of human brain tumors, including data regarding biodistribution and pharmacokinetics. In non-optimal doses and treatment regimes, WP1122 performed equal to or better than the current market leader, temozolomide and provided for superior survival for animals treated in combination with temozolomide. Notwithstanding these early results, we recognize that substantial additional preclinical and clinical research remains to be done and may not support these initial findings or their translation into activity in humans.

We have begun planning and performing the necessary pre-clinical work required to submit an IND for WP1122.

Subsequent Events

$9 million Registered Direct Offering

On February 16, 2018, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors for the sale by us of 4,290,000 shares of our common stock, at a purchase price of $2.10 per share. Concurrently with the sale of the common shares, pursuant to the Purchase Agreement, we also sold warrants to purchase

2,145,000 shares of common stock. We sold the common shares and warrants for aggregate gross proceeds of approximately $9.0 million with net proceed approximating $8.3 million. Subject to certain beneficial ownership limitations, the warrants will be initially exercisable on the six-month anniversary of the issuance date at an exercise price equal to $2.80 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the Purchase Agreement closed on February 21, 2018.

Announcement of STAT3 Inhibitors and WP1732

In February 2018, we announced that, pursuant to our continued collaboration with MD Anderson we had developed and licensed what we believe, based on preclinical testing, is a potential breakthrough - WP1732, a new molecule in the WP1066 portfolio - in our effort to develop a new cancer treatment that selectively kills highly resistant tumors. We believe this new discovery could improve our ability to treat a broader range of the most difficult cancers, and especially pancreatic cancer. Specifically, we have preclinical evidence to suggest this new molecule is capable of controlling a process known as 'ubiquitination' to block the activated form of STAT3, an important oncogenic transcription factor.

We have begun planning and performing the necessary pre-clinical work required to submit an IND for WP1732

Lease Agreement

On March 22, 2018, we entered into a Lease Agreement (the "Lease") with IPX Memorial Drive Investors, LLC (the "Landlord") for the lease of 2,333 rentable square feet "RSF", which we will use for corporate office space and meetings. The term of the Lease is estimated to begin in May 2018, depending on construction, and continue for an initial term of 66 months, which may be renewed for an additional 5 years. We are required to remit base monthly rent of approximately $4,300 which will increase at an average approximate rate of 3% each year. We are also required to pay additional rent in the form of our pro-rata share of certain specified operating expenses of the Landlord. The newly leased space is located in Houston, Texas.

Moleculin Biotech, Inc. Results of Operations for the Year Ended December 31, 2017 Compared to the Year Ended December 31, 2016

The following table is data derived from the Statement of Operations (in thousands):

	Year ended December 31,	
	2017	**2016**
Revenue	$ —	$ —
Operating expenses:		
Research and development	$ 4,545	$ 1,496
General and administrative	4,090	2,381
Depreciation	18	6
Total operating expense	8,653	3,883
Loss from operations	(8,653)	(3,883)
Other income (expense):		
Loss from change in fair value of warrant liability	(2,548)	—
Gain from settlement of liability	149	—
Gain from expiration of warrants	1,238	—
Other income	9	—
Interest expense, net	—	(43)
Total other income (expense)	(1,152)	(43)
Net loss	$ (9,805)	$ (3,926)

Research and Development Expense. Research and development ("R&D") expense was $4.5 million and $1.5 million for the years ended December 31, 2017 and 2016, respectively. The increase in R&D of approximately $3.0 million mainly represents an increase of approximately: $2.0 million associated with developing and testing drug product as we prepared for clinical trials; $0.4 million related to an increase in R&D headcount and associated payroll costs; $0.3 million for

sponsored research and related expenses; and $0.3 million associated with license fees. The increase in R&D headcount mainly represents the associated costs of increasing the commitments of our part-time employees and the addition of a second Chief Medical Officer - New Molecules. These all are a reflection of the increased clinical and pre-clinical activity for our drug portfolio as compared to 2016.

General and Administrative Expense. General and administrative ("G&A") expense was $4.1 million and $2.4 million for the years ended December 31, 2017 and 2016, respectively. The increase in G&A of approximately $1.7 million was mainly attributable to: (a) the increase in headcount and associated payroll costs including additional stock-based compensation expense of $1.0 million; (b) approximately $0.4 million in legal, accounting, consulting, and other professional expenses; (c) $0.2 million in insurance expense; and (d) approximately $0.1 million in occupancy, office and other costs. These increases reflect the increase in support of our clinical activity described above as compared to 2016.

We utilize outside consultants, both in R&D and G&A, to a large extent to leverage the work of our employees. Total wages paid to our employees, including our CEO, CFO, COO, CMOs plus three other employees, were approximately $1.5 million.

Change in fair value of warrant liability. Loss from change in fair value of warrant liability was $2.5 million for the twelve months ended December 31, 2017. The non-cash loss in 2017 was associated with an increased fair value calculation. We record the change (income or expense) in fair value on revaluation of our warrant liability associated with the warrants we issued in conjunction with our stock offering in February 2017 (the "February 2017 Offering"). We are required to revalue certain of our 2017 warrants at the time of each warrant exercise and at the end of each reporting period and reflect in the statement of operations a gain or loss from the change in fair value of the warrant in the period in which the change occurred. We calculate the fair value of the warrants outstanding using the Black-Scholes and Monte Carlo Simulation models. A gain results principally from a decline in our share price during the period and a loss results principally from an increase in our share price.

Gain from settlement of liability. During the period, we settled a previously incurred expense utilizing shares of our common stock with an attributed value of $3.00 per share. The gain of roughly $0.1 million reflects the difference in our share price in the open market as of the settlement date and the $3.00 per share; which was recorded in the first quarter of 2017.

Gain from expiration of warrants. Gain from expiration of warrants was $1.2 million for the twelve months ended December 31, 2017, due to the termination during the period of short-term warrants, issued as part of our February 2017 stock offering.

Interest Expense. Interest expense in 2016 included expense accrued on our convertible promissory notes issued in prior years bearing interest at the rate of 8% per annum. During the period and, lastly, on June 22, 2017, pursuant to the conversion feature of the notes, we issued common shares, which effectively converted all remaining outstanding convertible debt and accrued interests outstanding on the notes as of that date.

Net Loss. The net loss for the twelve months ended December 31, 2017 was $9.8 million which included non-cash expenses of approximately $0.7 million, which was comprised almost completely of stock-based compensation.

Liquidity and Capital Resources

As of December 31, 2017, we had $7.7 million in cash. During 2017, via the February 2017 Offering, our at-the- market issuance agreement ("ATM"), and the exercise of warrants associated with the February 2017 Offering, we issued 7.2 million shares of common stock and received $10.1 million in net proceeds.

As mentioned above, subsequent to year-end in February 2018 we entered into the Purchase Agreement with certain investors for the sale of 4,290,000 shares of our common stock, at a purchase price of $2.10 per share. Concurrently with the sale of the common shares, pursuant to the Purchase Agreement, we also sold warrants to purchase 2,145,000 shares of common stock, which have an exercise price of $2.80 per share. We sold the common shares and warrants for aggregate gross proceeds of approximately $9.0 million with net proceeds approximating $8.3 million (the "February 2018 Offering").

We believe that our existing cash and cash equivalents as of December 31, 2017 along with the cash generated by the February 2018 Offering, will be sufficient to fund our planned operations into the first quarter of 2019. Such plans are subject to change depending on clinical enrollment and regulatory progress and the use and supply of drug product.

We will not generate revenue from product sales unless and until we successfully complete development of, obtain regulatory approval for and begin to commercialize one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we will need to raise additional capital to fund our future operations. Until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings and debt financings and we may seek to raise additional capital through strategic collaborations. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations, which may cause dilution to our existing stockholders.

During the period from January 1, 2016 through May 2, 2016, we sold 234,296 of common stock for $702,894. On May 31, 2016, we completed our initial public offering, pursuant to which we sold 1,540,026 shares of our common stock at $6.00 per share for net proceeds of $8,464,183 after deducting underwriting discounts and commissions and direct offering expenses payable by us. In the February 2017 Offering, we completed a public offering of our common stock and warrants, pursuant to which we received approximately $4.4 million in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses.

The following table sets forth the primary sources and uses of cash for the years indicated (in thousands):

	For the Year Ended December 31,	
	2017	**2016**
Net cash used in operating activities	$ (7,324)	$ (3,765)
Net cash used in investing activities	(28)	(121)
Net cash provided by financing activities	10,059	8,865
Net increase in cash and cash equivalents	$ 2,707	$ 4,979

Cash used in operating activities

Net cash used in operating activities was $7.3 million for the year ended December 31, 2017 compared to $3.8 million for the year ended December 31, 2016. This increase in use of cash for operations was due to the increase in R&D associated with: 1) developing and testing drug product as we prepared for clinical trials; 2) an increase in R&D headcount and associated payroll costs; 3) an increase in sponsored research and related expenses; and 4) an increase in license fees. These all are a reflection of the increased clinical and pre-clinical activity, and the associated G&A support, for our drug portfolio as compared to 2016.

Cash used in investing activities

Net cash used in investing activities was $0.03 million for the twelve months ended December 31, 2017 compared to $0.1 million for the twelve months ended December 31, 2016. The decrease in cash used in investing is primarily related to the cash outflow of funds in 2016 related to the acquisition of Moleculin, LLC. The only cash used for investing purposes in 2017 was related to the purchase of fixed assets.

Cash provided by financing activities

Net cash provided by financing activities was $10.1 million for the year ended December 31, 2017 compared to the prior period of $8.9 million. Net cash provided by financing in 2017 consisted of $4.0 million net proceeds from exercise of warrants, and $6.1 million net proceeds from issuance of common stock in the February 2017 Offering, as well as the use of our at-the-market agreement. The prior period financing activities consisted of $8.5 million net proceeds from our IPO stock issuance, $0.7 million from issuance of common stock at $3.00 per share, and $0.2 million from issuance of convertible notes.

Off-Balance Sheet Transactions

We do not engage in off-balance sheet transactions.

JOBS Act and Recent Accounting Pronouncements

The recently enacted JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We have implemented all new accounting pronouncements that are in effect and may impact our financial statements and we do not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on our financial position or results of operations.

Critical Accounting Policies and Significant Judgments and Estimates

The financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following accounting policies are the most critical to aid in fully understanding and evaluating our reported financial results, and they require our most difficult, subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain**.**

Acquisition

We acquired Moleculin, LLC on May 2, 2016, and, going forward our financial statements will include the operations of Moleculin, LLC. We account for acquired businesses using the acquisition method of accounting, which requires, among other things, that most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date and that the fair value of acquired in-process research and development ("IPR&D") be recorded on the balance sheet. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the assigned values of the net assets acquired will be recorded as goodwill. We obtained input from third-parties regarding our tangible and intangible assets and other information necessary to measure the fair value of the assets acquired and liabilities assumed in connection with the acquisition of Moleculin, LLC.

Beneficial Conversion Feature

From time to time, we may issue convertible notes that have conversion prices that create an embedded beneficial conversion feature on the issuance date. A beneficial conversion feature exists on the date a convertible note is issued when the fair value of the underlying common stock to which the note is convertible into is in excess of the remaining unallocated proceeds of the note after first considering the allocation of a portion of the note proceeds to the fair value of any attached equity instruments, if any related equity instruments were granted with the debt. We estimate the fair value of our common stock using the most recent selling price available. The intrinsic value of the beneficial conversion feature is recorded as a debt discount with a corresponding amount to additional paid-in capital. The debt discount is amortized to interest expense over the life of the note using the effective interest method.

Research and Development Costs

We record accrued expenses for estimated costs of our research and development activities conducted by third-party service providers, which include the conduct of pre-clinical studies and preparation for clinical trials and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and we include these costs in accrued liabilities in the balance sheets and within research and development expense in the statement of operations. These costs are a significant component of our research and development expenses. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these third parties.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. To date, there have been no material differences from our accrued expenses to actual expenses.

Impairment of Long-Lived Assets

Management reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be realizable or at a minimum annually during the fourth quarter of the year. If an evaluation is required, the estimated future undiscounted cash flows associated with the asset are compared to the asset's carrying value to determine if an impairment of such asset is necessary. The effect of any impairment would be to expense the difference between the fair value of such asset and its carrying value.

Components of our Results of Operations and Financial Condition

Operating expenses

We classify our operating expenses into three categories: research and development, general and administrative and depreciation.

Research and development. Research and development expenses consist primarily of:

- costs incurred to conduct research, such as the discovery and development of our product candidates;
- costs related to production of clinical supplies, including fees paid to contract manufacturers;
- fees paid to clinical consultants, clinical trial sites and vendors, including clinical research organizations, in preparation for clinical trials and our IND and Orphan Drug applications with the FDA; and
- costs related to compliance with drug development regulatory requirements.

We recognize all research and development costs as they are incurred. Pre-clinical costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed.

We expect our research and development expenses to increase in the future as we advance our product candidates into and through clinical trials and pursue regulatory approval of our product candidates in the United States and Europe. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors including: the quality of our product candidates, early clinical data, investment in our clinical program, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent, if any, we will generate revenue from the commercialization and sale of our product candidates.

General and administrative

General and administrative expense consists of personnel related costs, which include salaries, as well as the costs of professional services, such as accounting and legal, facilities, information technology and other administrative expenses. We expect our general and administrative expense to increase due to the anticipated growth of our business and related infrastructure as well as accounting, insurance, investor relations and other costs associated with becoming a public company.

Depreciation. Depreciation expense consists of depreciation on our property and equipment. We depreciate our assets over their estimated useful life. We estimate leasehold improvements to have a 1-year life; computer equipment to have a 2-year life; machinery and equipment to have a 5-year life and furniture and office equipment to have a 7-year life. Property and

equipment assets acquired as a result of the acquisition of Moleculin, LLC were given a 2-year life given the assessment at acquisition of their age and condition and expected useful remaining life.

Other income (expense), net

Other income (expense), net consists of interest expense associated with our notes payable and interest income.

Accounting for warrants

We issued warrants to purchase shares of common stock related to equity transactions in 2016. We account for our warrants issued in accordance with Accounting Standards Codification (ASC) Topic 815, Derivatives and Hedging, guidance applicable to derivative instruments, which requires every derivative instrument within its scope to be recorded on the balance sheet as either an asset or liability measured at its fair value, with changes in fair value recognized in earnings for liability classified warrants. Based on this guidance, we determined that our warrants meet the criteria for classification as equity. Accordingly, the warrants were classified as equity and are not subject to remeasurement at each balance sheet date. The fair value was estimated using the Black-Scholes option pricing model, based on the market value of the underlying common stock at the measurement date, the contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

The warrants issued in the February 2017 Offering generated a warrant liability. Our financial instruments consist primarily of account payables, accrued expenses, and a warrant liability. The carrying amount of accounts payables and accrued expenses approximates their fair value because of the short-term maturity of such.

We have categorized our assets and liabilities that are valued at fair value on a recurring basis into three-level fair value hierarchy in accordance with GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3).

Assets and liabilities recorded in the balance sheets at fair value are categorized based on a hierarchy of inputs as follows:

Level 1 - Unadjusted quoted prices in active markets of identical assets or liabilities.
Level 2 - Quoted prices for similar assets or liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument.
Level 3 - Unobservable inputs for the asset or liability.

Our financial assets and liabilities recorded at fair value on a recurring basis include the fair value of our warrant liability discussed below. The fair value of this warrant liability is included in current liabilities on the accompanying financial statements as of December 31, 2017, as warrants are currently being exercised.

The basis of value is fair value, which is defined pursuant to Accounting Standards Codification ("ASC") 820 to be "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date". We estimated the fair value of the warrants issued in the February 2017 Offering under ASC 820 as of February 14, 2017 for financial reporting purposes. We used the Black-Scholes option pricing model ("BSM") to determine the fair value of the Series A and Series B Warrants and a Monte Carlo simulation ("MCM") with regard to the Series C Warrants in consideration of path dependent vesting terms of the contract. Both the BSM and MCM models are acceptable in accordance with GAAP. The BSM requires the use of a number of assumptions including volatility of the stock price, the weighted average risk-free interest rate, and the weighted average term of the Warrant. The MCM simulates our common stock price from the valuation date through the Series B Warrant and the unvested Series C Warrant expiration dates using Geometric Browman Motion on a risk-neutral basis - thereby impacting the likelihood that the Series B Warrants would have been exercised and, subsequently, the Series C Warrants would then vest. As disclosed, all Series B and unvested Series C warrants expired on May 15, 2017.

The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the term of the warrants and is calculated by using the average daily historical stock prices through the day preceding the grant date.

Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the expected life of the warrants. Where appropriate, we used the historical volatility of peer entities due to the lack of sufficient historical data of our stock price during 2016-2017.

Changes in the fair value during the accounting period are shown as other income or expense.

Stock-based compensation

Stock based compensation transactions are recognized as compensation expense in the statement of operations based on their fair values on the date of the grant, with the compensation expense recognized over the period in which a grantee is required to provide service in exchange for the award. We estimate the fair value of options granted using the Black-Scholes option valuation model. This estimate uses assumptions regarding a number of inputs that require us to make significant estimates and judgments. Because we are a relatively new publicly traded common stock the expected volatility assumption was based on industry peer information.

Income taxes

We account for income taxes using ASC 740 Income Taxes. ASC 740 Income Taxes is an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in our financial statements or tax returns. In estimating future tax consequences, ASC 740 generally considers all expected future events other than enactments of and changes in the tax law or rates. The measurement of deferred tax assets is reduced, if necessary, by the amount of any tax benefits that, based on available evidence, are not expected to be realized. Valuation allowances are provided if, considering available evidence, it is more likely than not that the deferred tax assets will not be realized. ASC 740 clarifies the criteria that must be met prior to recognition of the financial statement benefit of a position taken in a tax return. ASC 740 provides a benefit recognition model with a two-step approach consisting of “more-likely-than-not” recognition criteria, and a measurement attribute that measures a given tax position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. ASC 740 also requires the recognition of liabilities created by differences between tax positions taken in a tax return and amounts recognized in the financial statements.

U.S. Tax Reform

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the “Tax Act”) was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a federal corporate tax rate decrease from 35% to 21% for tax years beginning after December 31, 2017, the transition of U.S international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of foreign earnings. We have estimated our provision for income taxes in accordance with the Tax Act and guidance available as of the date of this filing, and the company has maintained the full valuation allowance. As a result we have recorded no income tax expense in the fourth quarter of 2017, the period in which the legislation was enacted. The amount related to the remeasurement of deferred tax assets and liabilities, based on the rates at which they are expected to reverse in the future, was an expense of $1.56 million. Since the Company maintains a full valuation allowance against its deferred tax assets, there is not net impact to the Company's earnings on this revaluation of its gross deferred tax assets.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of US GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, we have determined that the deferred tax expense of $1.56 million recorded in connection with the remeasurement of deferred tax assets is a provisional amount and a reasonable estimate at December 31, 2017 based upon the best information currently available. As discussed above, this deferred tax expense is fully offset by a valuation allowance and, thus, there is not net impact on the Company's earnings from this remeasurement. The ultimate impact may differ from these provisional amounts, possibly materially, due to, among other things, additional analysis, changes in interpretations and assumptions we have made, additional regulatory guidance that may be issued, and actions we may take as a result of the Tax Act. Additional work is necessary for a more detailed analysis of our deferred tax assets and liabilities. Any subsequent adjustment to these amounts will be recorded to current tax expense in the quarter of 2018 when the analysis is complete. The accounting is expected to be complete when the 2017 U.S. corporate income tax return is filed in 2018.

Recent accounting pronouncements

In May 2014, the FASB issued Accounting Standard Update ("ASU") 2014-9, Revenue from Contracts with Customers (Topic 606), which will replace numerous requirements in U.S. GAAP, including industry-specific requirements, and provide companies with a single revenue recognition model for recognizing revenue from contracts with customers. The core principle of the new standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In

August 2015, the FASB approved a proposal to defer the effective date of the guidance until annual and interim reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact that this standard will have on its financial statements at the time the Company starts to generate revenue or enters into other contractual arrangements, which the Company does not expect in the near term.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Under the new guidance, management will be required to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The provisions of this ASU are effective for annual periods ending after December 15, 2016, and for annual and interim periods thereafter; early adoption is permitted. This disclosure is effective within these financial statements for the year ended December 31, 2017. See also policy note disclosure on Going Concern in Note 2 to the Financial Statements.

On November 20, 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-17, "Balance Sheet Classification of Deferred Taxes", requiring all deferred tax assets and liabilities, and any related valuation allowance, to be classified as non-current on the balance sheet. The classification change for all deferred taxes as non-current simplifies entities' processes as it eliminates the need to separately identify the net current and net non-current deferred tax asset or liability in each jurisdiction and allocate valuation allowances. The adoption of this standard in 2016, did not have a significant impact on the Company's financial statements.

In January 2016, the FASB issued ASU No. 2016-1, Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-1"). ASU 2016-1 affects the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements of financial instruments. ASU 2016-1 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company is currently evaluating the impact that this standard will have on its financial statements. The Company does not believe that the adoption of this pronouncement will have a material impact on the Company's financial statements.

In February 2016, the FASB issued ASU No. 2016-2, Leases (Topic 842) ("ASU 2016-2"). Under ASU 2016-2, an entity will be required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. ASU 2016-2 offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. For public companies, ASU 2016-2 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. The Company is currently evaluating the impact that this standard will have on its financial statements.

In March 2016, the FASB issued ASU 2016-9, Compensation-Stock Compensation (Topic 718): Improvements to Employee-Share-Based Accounting". The new guidance changes the accounting and simplifies various aspects of the accounting for share-based payments to employees. The guidance allows for a policy election to account for forfeitures as they occur or based on an estimated number of awards that are expected to vest. We assumed no forfeiture since we have limited history. ASU 2016-9 is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The adoption of this standard on January 1, 2017, did not have a significant impact on our financial statements.

In August 2016, the FASB issued ASU, Statement of Cash Flows (Topic 230). This ASU applies to all entities that are required to present a statement of cash flows under Topic 230. The amendments provide guidance on eight specific cash flow issues and includes clarification on how these items should be classified in the statement of cash flows and is designed to help eliminate diversity in practice as to where items are classified in the cash flow statement. Furthermore, in November 2016, the FASB issued additional guidance on this Topic that requires amounts generally described as restricted cash and restricted cash equivalents to be included with cash and cash equivalents when reconciling the statement of cash flows. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, with earlier application permitted for all entities. We plan to adopt the provisions of this ASU for our fiscal year beginning January 1, 2018 and are currently evaluating the impact the adoption of this new accounting standard will have on our financial statements.

In January 2017, the FASB issued ASU 2017-01 "Business Combinations (Topic 805)," which provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. If the screen is not met, the amendments in this update (1) require that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments in this update also narrow the

definition of the term "output" so that the term is consistent with how outputs are described in Topic 606. Public business entities are required to apply the amendments in this update to annual periods beginning after December 15, 2017, including interim periods within those periods. Early application is permitted. The Company will evaluate the effect of the update at the time of any future acquisition or disposal.

In May 2017, the FASB issued ASU 2017-09 "Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting." This update clarifies the existing definition of the term "modification," which is currently defined as "a change in any of the terms or conditions of a share-based payment award." The update requires entities to account for modifications of share-based payment awards unless the (1) fair value, (2) vesting conditions and (3) classification as an equity instrument or a liability instrument of the modified award are the same as of the original award before modification. Public business entities are required to adopt the amendments in this update for fiscal years and interim periods beginning after December 15, 2017, with early adoption permitted. The Company will adopt the update when it becomes effective. The Company is in the process of determining the impact, if any, this adoption will have on its financial statements. The Company does not believe that the adoption of this pronouncement will have a material impact on the Company's financial statements.

The Company does not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth beginning in Item 15 of this report and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

There have been no disagreements with our independent registered public accountants on accounting or financial disclosure matters during our two most recent fiscal years.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

Our management, including our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Form 10-K. Based on this evaluation, our Chief Executive Officer (“CEO”) and our Chief Financial Officer (“CFO”), concluded that as a result of the material weakness in our internal controls over financial reporting discussed below, our disclosure controls and procedures were not effective at ensuring that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding disclosure.

Attestation Report of the Registered Public Accounting Firm

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal controls over financial reporting for as long as we are an “emerging growth company” pursuant to the provisions of the Jumpstart Our Business Startups Act.

Management's Report on Internal Control Over Financial Reporting

Our principal executive officer and our principal accounting and financial officer, are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31,

2017. In making this assessment, management used the criteria described in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Our management concluded that our internal controls over financial reporting were, and continue to be ineffective, as of December 31, 2017 due to a material weakness in our internal controls due to the lack of segregation of duties.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable and not absolute assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of certain events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

In light of the material weakness described below, we performed additional analysis and other post-closing procedures to ensure our financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, we believe that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

During the last quarter of fiscal 2016, and as our operational activities increased, management determined and continues to determine that it does not have sufficient segregation of duties within its accounting functions, which is a basic internal control. Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals. Management evaluated the impact of our failure to maintain effective segregation of duties on our assessment of our internal control over financial reporting and has concluded that the control deficiency represents a material weakness. Management added a full-time controller during the quarter ended September 30, 2017 and a Senior Accountant - Reporting in early 2018. Management intends to further increase its accounting staff and enhance its system of financial accounting and reporting, as soon as economically feasible and sustainable, to remediate this material weakness.

There has been no change in our internal control over financial reporting during our most recent calendar quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

On March 22, 2018, we entered into a Lease Agreement (the “Lease”) with IPX Memorial Drive Investors, LLC (the “Landlord”) for the lease of 2,333 rentable square feet “RSF”, which we will use for corporate office space and meetings. The term of the Lease is estimated to begin in May 2018, depending on construction, and continue for an initial term of 66 months, which may be renewed for an additional 5 years. We are required to remit base monthly rent of approximately $4,300 which will increase at an average approximate rate of 3% each year. We are also required to pay additional rent in the form of our pro-rata share of certain specified operating expenses of the Landlord. The newly leased space is located in Houston, Texas.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

Our Board of Directors has adopted a written Code of Business Conduct and Ethics applicable to all officers, directors and employees, which is available on our website (www.moleculin.com) under "Governance Documents" within the "Corporate Governance" section. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of this Code and by posting such information on the website address and location specified above.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

PART IV

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for the 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2017.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

(a)Documents filed as part of this Report

1. Financial Statements

The financial statements and notes thereto which are attached hereto beginning on page F-1 have been included by reference into Item 8 of this part of the annual report on Form 10-K. See the Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules are omitted because they are inapplicable or not required or the required information is shown in the financial statements or notes thereto.

3. Exhibits

The information required by this Item is set forth in the Exhibit Index that follows the signature page of this Annual Report.

Moleculin Biotech, Inc.
Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Moleculin Biotech, Inc.

Opinion on the financial statements

We have audited the accompanying balance sheets of Moleculin Biotech, Inc. (a Delaware corporation) (the "Company") as of December 31, 2017 and 2016 and the related statements of operations, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred an accumulated deficit of $14.5 million since inception and has not generated any revenue from operations. These conditions, along with other matters as set forth in Note 2, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

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

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

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

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2017.

Houston, Texas
March 28, 2018

Moleculin Biotech, Inc.
Balance Sheets
(in thousands, except for share and per share data)

	December 31, 2017	December 31, 2016
Assets		
Current Assets:		
Cash and cash equivalents	$ 7,714	$ 5,007
Prepaid expenses	588	215
Total current assets	8,302	5,222
Furniture and equipment, net of accumulated depreciation of $21 and $6, respectively	33	23
Intangible assets	11,148	11,148
Total Assets	$ 19,483	$ 16,393
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 810	$ 399
Accrued expenses and current liabilities	902	650
Warrant liability	503	—
Convertible notes payable	—	296
Total current liabilities	2,215	1,345
Long-term deferred compensation – related party	150	88
Total Liabilities	2,365	1,433
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 authorized, no shares issued and outstanding	—	—
Common stock, $0.001 par value; 75,000,000 authorized, 21,469,109 issued and outstanding at December 31, 2017 and 12,164,852 shares issued and outstanding at December 31, 2016	21	12
Additional paid-in capital	31,577	19,623
Accumulated deficit	(14,480)	(4,675)
Total Stockholders' Equity	17,118	14,960
Total Liabilities and Stockholders' Equity	$ 19,483	$ 16,393

See accompanying notes to the financial statements.

Moleculin Biotech, Inc.
Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31, 2017	Year Ended December 31, 2016
Revenue	$ —	$ —
Operating expenses:		
Research and development	4,545	1,496
General and administrative	4,090	2,381
Depreciation	18	6
Total Operating Expenses	8,653	3,883
Loss from operations	(8,653)	(3,883)
Other income (expense):		
Loss from change in fair value of warrant liability	(2,548)	—
Gain from settlement of liability	149	—
Gain from expiration of warrants	1,238	—
Other income	9	—
Interest expense, net	—	(43)
Net loss	$ (9,805)	$ (3,926)
Net loss per common share - basic and diluted	$ (0.53)	$ (0.40)
Weighted average common shares outstanding - basic and diluted	18,569,193	9,827,510

See accompanying notes to the financial statements.

Moleculin Biotech, Inc.
Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2017	Year Ended December 31, 2016
Cash Flows from Operating Activities:		
Net loss	$ (9,805)	$ (3,926)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	18	6
Stock-based compensation	707	324
Deferred compensation - related party	62	87
Change in fair value of warrant liability	2,548	—
Gain in settlement of liability	(149)	—
Gain from expiration of warrants	(1,238)	—
Other	(9)	—
Changes in operating assets and liabilities:		
Prepaid expenses	(364)	(215)
Accounts payable	411	(41)
Accrued expenses	495	—
Net Cash Used in Operating Activities	(7,324)	(3,765)
Cash Flows from Investing Activities:		
Purchase of fixed assets	(28)	(21)
Acquisition of Moleculin, LLC, net	—	(100)
Net Cash Used in Investing Activities	(28)	(121)
Cash Flows from Financing Activities:		
Proceeds from notes payable	—	165
Payments on notes payable	—	(470)
Proceeds from exercise of warrants	3,988	—
Proceeds from sale of common stock, net of cash stock issuance costs	6,071	9,170
Net Cash Provided by Financing Activities	10,059	8,865
Net change in cash and cash equivalents	2,707	4,979
Cash and cash equivalents, at beginning of period	5,007	28
Cash and cash equivalents, at end of period	$ 7,714	$ 5,007
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 3	$ 5
Cash paid for income taxes	$ —	$ —
Supplemental disclosure of non-cash investing and financing activities:		
Common stock issued for the Acquisition of Moleculin, LLC	$ —	$ 9,774
Common stock issued for conversion of debt	$ 302	$ 364
Warrants issued for services provided	$ 104	$ 375
Common stock issued for services provided	$ 89	$ 158

See accompanying notes to the financial statements.

Moleculin Biotech, Inc.
Statements of Stockholders' Equity
(in thousands except for shares and per unit)

	Common Stock					
	Number of Shares	Par Value Amount	Additional Paid-In-Capital	Subscriptions Receivable	Accumulated Loss	Stockholders' Equity (Deficit)
Balance at December 31, 2015	6,661,000	$ 7	$ —	$ (3)	$ (749)	$ (745)
Private issuance @ $3.00 / share	234,297		703			703
Issued for Moleculin acquisition	999,931	1	5,998			5,999
Issued for technology	629,000	1	3,773			3,774
Issued for cash - IPO, net of stock issuance costs of $1,150	1,540,026	1	8,088			8,089
Warrants issued for services			375			375
Stock granted for services	24,000		158			158
Stock-based compensation			166			166
Issued for convertible debt	2,076,598	2	362			364
Subscription agreement settled for cash				3		3
Net loss					(3,926)	(3,926)
Balance at December 31, 2016	12,164,852	12	19,623	—	(4,675)	14,960
Issued for cash - sale of units at $1.35 per unit, net of stock issuance costs of $550	3,710,000	4	313			317
Warrants exercised, net of issuance costs of $73	2,728,434	3	8,900			8,903
Issued for cash - sale of common stock in ATM offering, net of issuance costs of $166	776,016		1,645			1,645
Stock-based compensation			707			707
Issued for convertible debt	2,010,640	2	300			302
Issued for settlement of service	79,167		89			89
Net Loss					(9,805)	(9,805)
Balance at December 31, 2017	21,469,109	$ 21	$ 31,577	$ —	$ (14,480)	$ 17,118

See accompanying notes to the financial statements.

Moleculin Biotech, Inc.
Notes to the Financial Statements

1. Nature of Business and Liquidity

The terms “MBI” or “the Company”, “we”, “our” and “us” are used herein to refer to Moleculin Biotech, Inc. MBI is a clinical-stage pharmaceutical company organized as a Delaware corporation in July 2015 to focus on the development of oncology drug candidates, all of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center, which we refer to as MD Anderson. MBI has three drug technologies. Our clinical stage drugs are Annamycin, an anthracycline designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML, and WP1066, an immuno-stimulating STAT3 inhibitor targeting brain tumors, pancreatic cancer and AML. We are also engaged in preclinical development of additional drug candidates, including additional STAT3 inhibitors and compounds targeting the metabolism of tumors.

Our lead drug candidate is liposomal Annamycin, which we refer to as Annamycin, an anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML. Annamycin had been in clinical trials pursuant to an investigative new drug application or IND that had been filed with the U.S. Food and Drug Administration, or FDA. Due to a lack of development activity by a prior drug developer, this IND was terminated. To permit the renewed investigation of Annamycin, we submitted a new IND for a Phase I/II trial for the treatment of relapsed or refractory AML in August 2017, which was subsequently allowed by the FDA in September 2017.

We have two other drug development projects, one involving a collection of small molecules, which we refer to as the WP1066 Portfolio, a collection of STAT3 inhibitors, some of which also have immuno-stimulating capability, targeting brain tumors, pancreatic cancer and AML, and the WP1122 Portfolio, a suite of molecules targeting the metabolic processes involved in cancer in general and glioblastoma (the most common form of brain tumor) and pancreatic cancer in particular. A physician-sponsored IND for a Phase I trial of WP1066 in patients with recurrent malignant glioma and brain metastasis from melanoma was allowed by the FDA in December 2017. We also continue to sponsor ongoing research at MD Anderson in order to improve and expand our drug development pipeline.

We have been granted royalty-bearing, worldwide, exclusive licenses for the patent and technology rights related to all of our drug technologies, as these patent rights are owned by MD Anderson. The Annamycin drug substance is no longer covered by any existing patent protection, however, we intend to submit patent applications for formulation, synthetic process and reconstitution related to our Annamycin drug product candidate, although there is no assurance that we will be successful in obtaining such patent protection. Independently from potential patent protection, we have received Orphan Drug designation from the FDA for Annamycin for the treatment of AML, which would entitle us to market exclusivity of 7 years from the date of approval of a New Drug Application (NDA) in the United States. We may then benefit from Orphan Drug exclusivity, during which period FDA generally could not approve another Annamycin product for the same use. We also intend to apply for similar status in the European Union (EU) where market exclusivity extends to 10 years from the date of Marketing Authorization Application (MAA). Separately, the FDA may also grant market exclusivity of 5 years for newly approved new chemical entities (of which Annamycin would be one), but there can be no assurance that such exclusivity will be granted.

With regard to additional potential clinical activity, we submitted in October 2017 a request for Clinical Trial Authorization ("CTA") in Poland which, if allowed, will enable a Phase I/II clinical trial to study Annamycin for the treatment of relapsed or refractory AML in Poland. This will be in addition to the previously announced allowance of our IND in the United States. In December 2017, the Ethics Committee in Poland approved our Phase I/II clinical trial of Annamycin. In March we received requests for and provided additional information to the Polish National Office. We expect a response from the Polish National Office in the first half of 2018 and at the earliest mid-April 2018. The start of clinical trials in Poland remains subject to confirmation and approval of the CTA by the Polish National Office. We can provide no assurance that we will receive such confirmation on a timely basis, if at all.

In addition, we continue to recruit and contract clinics both in the United States and Poland. In the US, we have one site - University Hospitals Cleveland Medical Center (“UHCMC”) - recruiting patients and active with drug ready to provide treatments. A patient was enrolled in March 2018 with anticipated treatment to occur in the near term. We can provide no assurance treatment will occur on a timely basis, if at all.

Furthermore, in September 2017 we engaged a contract research organization ("CRO") to prepare for a proof-of-concept clinical trial in Poland to study our drug candidate WP1220, a part of the WP1066 portfolio, for the treatment of cutaneous T-cell lymphoma ("CTCL").

In accordance with FASB ASC Topic 280, Segment Reporting, we view our operations and manage our business as principally one segment. As a result, the financial information disclosed herein represents all of the material financial information related to our principal operating segment.

The Company filed a registration statement on Form S-1 (which was declared effective on May 2, 2016) with respect to the Company's initial public offering of shares of its common stock ("IPO") to fund the development of its technologies. Prior to the declaration of effectiveness of the registration statement on Form S-1, we acquired Moleculin, LLC which was merged with and into MBI. Moleculin, LLC was the holder of a license agreement with MD Anderson covering technology referred to as the WP1066 Portfolio, which is focused on the modulation of key oncogenic transcription factors.

2. Summary of Significant Accounting Policies

Basis of Presentation - The accompanying audited financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for financial information, and in accordance with the rules and regulations of the United States Securities and Exchange Commission (the "SEC").

Use of Estimates in Financial Statement Presentation - The preparation of these financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Acquisition – We acquired Moleculin, LLC ("Moleculin") on May 2, 2016, and, going forward our financial statements include the operations of Moleculin, LLC. We account for acquired businesses using the acquisition method of accounting, which requires, among other things, that assets acquired, and liabilities assumed be recognized at their estimated fair values as of the acquisition date and that the fair value of acquired in-process research and development ("IPR&D") be recorded on the balance sheet. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the assigned values of the net assets acquired will be recorded as goodwill. The Company obtained input from third-parties regarding its tangible and intangible assets and other information necessary to measure the fair value of the assets acquired and liabilities assumed in connection with the acquisition of Moleculin, LLC.

Going Concern - These financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The continuation of the Company as a going concern is dependent upon the ability of the Company to obtain necessary financing to continue operations and the attainment of profitable operations. As of December 31, 2017, the Company has incurred an accumulated deficit of $14.5 million since inception and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of December 31, 2017 plus the additional cash generated from its equity offering subsequent to year-end, discussed further within these notes to the financial statements, is sufficient to fund its planned operations into but not beyond the near term. These factors raise substantial doubt regarding the Company's ability to continue as a going concern. These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements and delay planned cash outlays or a combination thereof. Management cannot be certain that such events or a combination thereof can be achieved.

Cash and Cash Equivalents - The Company considers all highly liquid accounts with original maturities of three months or less at the date of acquisition to be cash equivalents. Periodically in the ordinary course of business, the Company may carry cash balances at financial institutions in excess of the insured limits of $250,000. The amount in excess of the applicable insurance coverage at December 31, 2017 was not material.

Property and equipment - Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line depreciation method as follows:

Leasehold improvement	Shorter of estimated useful lives or the term of the lease
Computer equipment	2 years*
Machinery and equipment	5 years*
Furniture and office equipment	7 years*

*Property and equipment assets acquired in the merger with Moleculin, LLC are being depreciated over a 2 years useful life due to their age and condition and expected remaining life assessed at merger date.

Intangible assets - Intangible assets with finite lives are amortized using the straight-line method over their estimated period of benefit. If an intangible asset is identified as an in-process research & development asset, then no amortization will occur until the development is complete. If the associated research and development effort is abandoned, the related assets will be written-off and the Company will record a noncash impairment loss on its statements of operations. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives.

We evaluate the recoverability of intangible assets periodically and take into account events or circumstances that warrant revised estimates of useful lives or that indicate that impairment exists. No material impairments of intangible assets have been identified during any of the periods presented. Intangible assets are tested for impairment on an annual basis, and between annual tests if indicators of potential impairment exist, using a fair-value-based approach.

Fair Value of Financial Instruments - Our financial instruments consist primarily of account payables, accrued expenses and a warrant liability. The carrying amount of accounts payables and accrued expenses approximates their fair value because of the short-term maturity of such.

We have categorized our assets and liabilities that are valued at fair value on a recurring basis into three-level fair value hierarchy in accordance with GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3).

Assets and liabilities recorded in the balance sheets at fair value are categorized based on a hierarchy of inputs as follows:

Level 1 – Unadjusted quoted prices in active markets of identical assets or liabilities.
Level 2 – Quoted prices for similar assets or liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument.
Level 3 – Unobservable inputs for the asset or liability.

The Company's financial assets and liabilities recorded at fair value on a recurring basis include the fair value of our warrant liability discussed in Note 6. The fair value of this warrant liability is included in current liabilities on the accompanying financial statements as of December 31, 2017, as warrants are currently being exercised.

The following table provides the financial assets and liabilities reported at fair value and measured on a recurring basis at December 31, 2017 (in thousands):

Description	Liabilities Measured at Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Fair value of warrant liability:				
2017	$ 503	$ —	$ —	$ 503

The following table provides a summary of changes in fair value associated with the Level 3 liabilities for the year ended December 31, 2017 (in thousands):

	Warrant Liability – Current	Warrant Liability – Long-Term	Warrant Liability – Total
Balance, beginning of period December 31, 2016	$ —	$ —	$ —
Issuances of warrants	2,453	1,690	4,143
Reclass of liability from long-term to current	1,846	(1,846)	—
Change in fair value - net	2,643	(95)	2,548
Transfers in and out (exercise of warrants)	(5,201)	251	(4,950)
Expiration of warrants	(1,238)	—	(1,238)
Balance, December 31, 2017	$ 503	$ —	$ 503

The above table of Level 3 liabilities begins with the initial valuation given the warrant issuances that occurred in the first quarter of 2017 and adjusts the balances for changes that occurred during the year. The ending balance of the Level 3 financial instrument presented above represent our best estimates and may not be substantiated by comparison to independent markets and, in many cases, could not be realized "through an" immediate settlement of the instruments.

Beneficial Conversion Feature - From time to time, the Company may issue convertible notes that have conversion prices that create an embedded beneficial conversion feature on the issuance date. A beneficial conversion feature exists on the date a convertible note is issued when the fair value of the underlying common stock to which the note is convertible into is in excess of the remaining unallocated proceeds of the note after first considering the allocation of a portion of the note proceeds to the fair value of any attached equity instruments, if any related equity instruments were granted with the debt. The Company estimated the fair value of its common stock on the dates issued. The intrinsic value of the beneficial conversion feature is recorded as a debt discount with a corresponding amount to additional paid-in capital, if any. The debt discount is amortized to interest expense over the life of the note using the effective interest method.

Income Taxes - The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of reported assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740-10 which prescribes a recognition threshold and measurement attribute for financial statement disclosure of tax positions taken, or expected to be taken, on its tax return. The Company evaluates and records any uncertain tax positions based on the amount that management deems is more likely than not to be sustained upon examination and ultimate settlement with the tax authorities in the tax jurisdictions in which it operates.

Stock-based Compensation - Stock-based compensation expense includes the estimated fair value of equity awards vested during the reporting period. The expense for equity awards vested during the reporting period is determined based upon the grant date fair value of the award and is recognized as expense over the applicable vesting period of the stock award using the straight-line method.

Loss Per Common Share - Basic net loss per common share are computed by dividing net loss available to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is determined using the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents. In periods when losses are reported, the weighted-average number of common shares outstanding excludes common stock equivalents, because their inclusion would be anti-dilutive. As of December 31, 2017, the Company’s potentially dilutive shares, which were not included in the calculation of net loss per share, included options to purchase 1,345,000 common shares and warrants to purchase 677,576 common shares. As of December 31, 2016, the Company's potentially dilutive shares, which were not included in the calculation of net loss per share, included notes convertible to 1,821,013 common shares, options to purchase 510,000 common shares and warrants to purchase 107,802 common shares.

Reclassifications - A reclassification was made to the December 31, 2016 financial statements to conform to the 2017 presentation. Such reclassification did not affect net loss as previously reported. Historically, "accrued expenses and current

liabilities" were included in the line item "accounts payable and accrued expenses". Management believes that these costs are best shown as a separate line item and, as such, a reclassification was made to the balance sheet for the year ended December 31, 2016 by reducing "Accounts payable" and creating a new line item "Accrued expenses and current liabilities."

Research and Development Costs - Research and development costs are expensed as incurred.

Subsequent Events - The Company's management reviewed all material events through the date these financial statements were issued for subsequent event disclosure consideration and has noted such events as described in Note 10.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standard Update ("ASU") 2014-9, Revenue from Contracts with Customers (Topic 606), which will replace numerous requirements in U.S. GAAP, including industry-specific requirements, and provide companies with a single revenue recognition model for recognizing revenue from contracts with customers. The core principle of the new standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In August 2015, the FASB approved a proposal to defer the effective date of the guidance until annual and interim reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact that this standard will have on its financial statements at the time the Company starts to generate revenue or enters into other contractual arrangements, which the Company does not expect in the near term.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Under the new guidance, management will be required to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The provisions of this ASU are effective for annual periods ending after December 15, 2016, and for annual and interim periods thereafter; early adoption is permitted. This disclosure is effective within these financial statements for the year ended December 31, 2017. See also policy note disclosure mentioned above on Going Concern.

On November 20, 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-17, "Balance Sheet Classification of Deferred Taxes", requiring all deferred tax assets and liabilities, and any related valuation allowance, to be classified as non-current on the balance sheet. The classification change for all deferred taxes as non-current simplifies entities' processes as it eliminates the need to separately identify the net current and net non-current deferred tax asset or liability in each jurisdiction and allocate valuation allowances. The adoption of this standard in 2016, did not have a significant impact on the Company's financial statements.

In January 2016, the FASB issued ASU No. 2016-1, Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-1"). ASU 2016-1 affects the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements of financial instruments. ASU 2016-1 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company is currently evaluating the impact that this standard will have on its financial statements. The Company does not believe that the adoption of this pronouncement will have a material impact on the Company's financial statements.

In February 2016, the FASB issued ASU No. 2016-2, Leases (Topic 842) ("ASU 2016-2"). Under ASU 2016-2, an entity will be required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. ASU 2016-2 offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. For public companies, ASU 2016-2 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. The Company is currently evaluating the impact that this standard will have on its financial statements.

In March 2016, the FASB issued ASU 2016-9, Compensation-Stock Compensation (Topic 718): Improvements to Employee-Share-Based Accounting". The new guidance changes the accounting and simplifies various aspects of the accounting for share-based payments to employees. The guidance allows for a policy election to account for forfeitures as they occur or based on an estimated number of awards that are expected to vest. MBI assumes no forfeiture since it has limited history. ASU 2016-9 is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The adoption of this standard on January 1, 2017, did not have a significant impact on the Company's financial statements.

In August 2016, the FASB issued ASU, Statement of Cash Flows (Topic 230). This ASU applies to all entities that are required to present a statement of cash flows under Topic 230. The amendments provide guidance on eight specific cash flow issues and includes clarification on how these items should be classified in the statement of cash flows and is designed to help eliminate diversity in practice as to where items are classified in the cash flow statement. Furthermore, in November 2016, the FASB issued additional guidance on this Topic that requires amounts generally described as restricted cash and restricted cash equivalents to be included with cash and cash equivalents when reconciling the statement of cash flows. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, with earlier application permitted for all entities. We plan to adopt the provisions of this ASU for our fiscal year beginning January 1, 2018 and are currently evaluating the impact the adoption of this new accounting standard will have on our financial statements.

In January 2017, the FASB issued ASU 2017-01 "Business Combinations (Topic 805)," which provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. If the screen is not met, the amendments in this update (1) require that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments in this update also narrow the definition of the term "output" so that the term is consistent with how outputs are described in Topic 606. Public business entities are required to apply the amendments in this update to annual periods beginning after December 15, 2017, including interim periods within those periods. Early application is permitted. The Company will evaluate the effect of the update at the time of any future acquisition or disposal.

In May 2017, the FASB issued ASU 2017-09 "Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting." This update clarifies the existing definition of the term "modification," which is currently defined as "a change in any of the terms or conditions of a share-based payment award." The update requires entities to account for modifications of share-based payment awards unless the (1) fair value, (2) vesting conditions and (3) classification as an equity instrument or a liability instrument of the modified award are the same as of the original award before modification. Public business entities are required to adopt the amendments in this update for fiscal years and interim periods beginning after December 15, 2017, with early adoption permitted. The Company will adopt the update when it becomes effective. The Company is in the process of determining the impact, if any, this adoption will have on its financial statements.

The Company does not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

3. Intangible Assets

The Acquisition of Moleculin, LLC

On May 2, 2016, Moleculin, LLC, a Texas limited liability company, was merged with and into the Company. As a result of the merger, the Company issued to the holders of Moleculin equity interests an aggregate of 999,931 shares of the Company’s common stock valued at $5,999,586, based on the estimated acquisition-date fair value of our common stock of $6.00 per share, equal to the IPO price announced in our prospectus filed on that date. Prior to the Company’s acquisition of Moleculin, the Company had loaned $57,822 to Moleculin which was treated as part of the consideration paid to acquire Moleculin.

As additional consideration payable to the Moleculin unit holders, we agreed pursuant to the merger agreement that if drugs for dermatology indications are successfully developed by us using any of the Existing IP Assets, then the Moleculin, LLC unit holders, in the aggregate, will be entitled to receive a 2.5% royalty on the net revenues generated by such drugs. Any such net revenues would include a deduction for license fees or royalty obligations payable to MD Anderson for such Existing IP Assets. The merger agreement defined “Existing IP Assets” to mean all intellectual property, licensed by us and Moleculin as of the time of the merger, including, without limitation, the intellectual property licensed from MD Anderson under the Patent and Technology License Agreement entered into by and between IntertechBio Corporation and MD Anderson dated April 2, 2012, as amended, and the Patent and Technology License Agreement dated June 21, 2010, as amended, between MD Anderson and Moleculin, LLC, but excluding any intellectual property relating to Annamycin. The right to receive the contingent royalty payments described herein is limited to drugs developed only for dermatology indications and does not include drugs developed for any other indications. We have no obligation of any nature to pursue the development of any drugs for dermatology indications.

Our acquisition of Moleculin, LLC, occurring prior to our IPO offering, provided us with the rights to the license agreement that Moleculin, LLC had with MD Anderson covering the WP1066 Portfolio. However, Moleculin, LLC had previously granted Houston Pharmaceuticals, Inc. (“HPI”), a related party, an option, which could be exercised at any time, to obtain an exclusive

sub-license to develop the WP1066 Portfolio in all non-dermatological fields. Moleculin, LLC had previously pursued development of the WP1066 Portfolio for treatment of psoriasis, however, psoriasis related clinical trials had been terminated. Because WP1066 has shown significant activity against a wide range of tumors, Moleculin, LLC's focus prior to the acquisition included the development of drugs for cancer treatment. However, the exclusive sub-license option held by HPI precluded Moleculin, LLC from pursuing drug development related to non-skin cancers, in addition to potentially creating significant intellectual property, clinical and commercialization risks associated with drug development for skin cancers. Re-acquisition of the HPI option was therefore essential for the values of both the WP1066 Portfolio and Moleculin, LLC.

Additionally, the merger agreement contained mutual representations and warranties between the parties. Pursuant to the merger agreement, we agreed for a period of six years to indemnify and hold harmless each present and former director and/or officer of Moleculin, LLC whom Moleculin, LLC would have had the power to indemnify under Delaware law that is made a party or threatened to be made a party to any threatened, pending or completed proceeding or claim by reason of the fact that he or she was a director or officer of the Moleculin, LLC prior to the effective time of the merger and arising out of actions or omissions of the indemnified party in any such capacity occurring at or prior to the effective time of the merger against any losses or damages reasonably incurred in connection with any claim. To our knowledge, no such proceeding or claim exists or has been threatened on the date hereof.

In connection with the acquisition of Moleculin, LLC, we also negotiated on behalf of Moleculin, LLC two agreements with HPI. Under the first agreement, HPI's option to obtain the aforementioned exclusive sublicense was terminated in exchange for a payment of $100,000 and the issuance of 629,000 shares of our common stock, valued at $6 per share. Under the second agreement (HPI Out-Licensing Agreement), HPI has received a non-exclusive technology rights and development sublicense under which it may continue its ongoing work to develop the WP1066 Portfolio related to treatment of non-skin cancer. Pursuant to this HPI Out-Licensing Agreement, we agreed to make payments to HPI totaling $750,000 over a three-year period, of which $300,000 was paid as of December 31, 2017. The Company expenses such costs as incurred as research and development expense, commencing after the IPO offering in exchange for HPI allowing us to access any data, information or know-how resulting from the research and development conducted by HPI. As of December 31, 2017, notwithstanding our obligation to make the foregoing payments, the HPI Out-Licensing Agreement does not obligate HPI to conduct any specific research or to meet any milestones. Pursuant to the HPI Out-Licensing Agreement, we have the right within three years of the effective date to buy-out from HPI all rights granted to HPI under the agreement for a payment of $1.0 million. Upon our exercise of the buy-out we will no longer be obligated to make any payments to HPI remaining from the $750,000 obligation discussed above. If we do not exercise the foregoing buy-out right within three years, the license granted to HPI shall convert into an exclusive license. As such, if we do not exercise the buy-out right for any reason, we will no longer have access to the non-skin cancer uses of the WP1066 Portfolio. As noted above, this will also potentially create risks for the development of skin cancer drugs. We do not intend to set aside and designate cash and cash equivalents in the amount of $1 million to make the buy-out payment. If we ultimately decide to exercise the buy-out right from HPI, we will need to raise additional funds to make the buy-out payment. We cannot assure that such additional funding will be available on satisfactory terms, or at all.

The agreements with HPI were executed on May 2, 2016, simultaneously with the closing of the Moleculin, LLC acquisition, and were non-cancelable but contingent on the Company's ability to complete the IPO by June 30, 2016. They became effective on May 31, 2016.

The termination of the HPI option was completed on behalf of Moleculin, LLC, which was required to enable the sale of Moleculin, LLC by materializing the value of its most significant asset and was non-cancelable by either party. Further, the HPI option termination price was determined simultaneously with the acquisition on May 2, 2016 as our IPO price was established at that time. Accordingly, we concluded that this transaction was primarily for the benefit of Moleculin, LLC and its former owners, resulting in control of the underlying intellectual property and thereby increasing the value of Moleculin, LLC intangible assets immediately prior to the closing of its acquisition by us.

The HPI option termination price amounted to $3,874,000, consisting of 629,000 shares of our common stock valued at the IPO price of $6.00 per share, and $100,000 paid in cash in July 2016, and was included in acquisition-date liabilities assumed.

Purchase Price Allocation

The acquisition price was allocated to the assets acquired and liabilities assumed based upon their estimated fair values and the information available to management. The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date (in thousands):

Cash	$	—
Property and equipment		8
Intangibles		11,148
Total assets acquired	$	11,156
Liability assumed (HPI)		(3,874)
Other liabilities assumed, including $470 of notes payable		(1,224)
Net assets acquired/total consideration transferred	$	6,057

The Company obtained input from third-parties regarding its tangible and intangible assets and other information necessary to measure the fair value of the assets acquired and liabilities assumed in connection with the acquisition of Moleculin, LLC. Management believes all or most of the intangible assets are IPR&D related to the WP1066 Portfolio, and, as such, no amortization has been recorded to date.

Intangible assets consisted of the following at December 31, 2017 and December 31, 2016 (in thousands):

	December 31, 2017	December 31, 2016
Intangibles acquired from Moleculin, LLC	$ 11,148	$ 11,148

Unaudited Pro Forma Results of Operations

The following comparative table presents the unaudited condensed pro forma results of operations that reflect the acquisition of Moleculin as if the acquisition had occurred as of the first day of each period presented, adjusted for items that are directly attributable to the acquisition. This information has been compiled from historical financial statements and is not necessarily indicative of the results that actually would have been achieved had the transaction already occurred or that may be achieved in the future (amounts in thousands except share data).

	Pro Forma For the Year Ended December 31, 2016
Total operating expenses	$ 3,979
Net loss	$ (3,963)
Net loss per common share – basic and diluted	$ 0.42
Weighted average outstanding common shares – basic and diluted	9,401,028

The year ended December 31, 2016 was adjusted on a pro forma basis to exclude $145,078 in net interest expense related to the amortization of deferred financing costs and debt discount amortization for Moleculin, LLC's convertible notes. The holders of the convertible notes were issued the Company's common shares upon the Company's acquisition of Moleculin, LLC.

4. Accrued Expenses and other accrued liabilities

Accrued expenses and other liabilities consist of the following components (in thousands):

	December 31,	
	2017	2016
Accrued payroll	$ 250	$ 84
Accrued clinical testing	320	238
Accrued license fees and SRA	260	157
Accrued legal and professional fees	50	66
Accrued board expenses	—	91
Accrued other	22	14
Total accrued expenses and other liabilities	$ 902	$ 650

5. Convertible Notes Payable

On various dates from August 31, 2015 through January 19, 2016, each as amended on March 10, 2016, the Company entered into seven unsecured promissory notes with three separate third-party investors. Each note bore interest at 8.0% per annum and was to mature on the earlier of June 30, 2016 or the completion of an IPO of the Company's securities.

Since the completion of the IPO occurred prior to June 30, 2016, these notes were to be automatically converted according to their terms into shares of the Company's common stock at applicable conversion price upon the Company's IPO to the extent and provided that no holder of these notes was permitted to convert such notes to the extent that the holder or any of its affiliates would beneficially own in excess of 4.99% of our common stock after such conversion. Due to this 4.99% limitation, a portion of these notes was not converted at the time of the IPO and the remaining unconverted principal and accrued interest amounts of the effected notes remained outstanding and were converted into shares of our common stock at such time as the 4.99% limitation was met. Until such time as the notes were converted into shares of common stock, the maturity date of the notes was automatically extended, and we were not required to repay the notes or the accrued interest relating to the notes in cash.

The IPO was completed on May 31, 2016. On May 31, 2016, pursuant to the conversion feature of the foregoing notes and with restriction of the 4.99% beneficially owned condition limitation, discussed above, the Company issued 1,166,503 common shares in total, reducing the convertible debt principal by $183,356 and accrued interest by $17,699. Subsequent to these transactions and through December 31, 2016, an additional 910,095 common shares were issued due to the number of common shares outstanding allowing for conversion of additional shares under the 4.99% beneficially owned condition limitation. This reduced the convertible debt principal by $155,565 and accrued interest by $7,172.

The convertible notes were analyzed for a beneficial conversion feature on various issuance dates, at which time it was concluded that a beneficial conversion feature did not exist. On June 22, 2017, pursuant to the conversion feature of the foregoing notes and with restriction of the beneficially owned condition limitation discussed above, the Company issued common shares which effectively converted all remaining outstanding convertible debt and accrued interest outstanding as of that date.

The table below represents the shares that are convertible at December 31, 2017 relating to the principal amounts of these convertible notes payable and excludes any shares that are convertible relating to the associated accrued interest:

	(Amounts and shares in whole values)			
Issuance Date	December 31, 2017	December 31, 2016 (c)	Conversion Rate	Shares Convertible at December 31, 2016
August 31, 2015(a)	$ —	$ 38,299	$ 0.1299	294,832
September 3, 2015	—	125,000	0.1299	962,279
October 6, 2015(a)(b)	—	30,280	0.20	151,402
January 19, 2016	—	82,500	0.20	412,500
Total	$ —	$ 276,079		1,821,013

(a) Debt partially converted on May 31, 2016 and on August 19, 2016.
(b) Debt partially converted on September 1, 2016.
(c) Excluded from the $276,079 is $20,333 in accrued interest on the convertible notes payable which is included in the accompanying balance sheet.

The common shares relating to the above mentioned convertible notes payable contained the following trading restrictions: (a) beginning 90 days after the initial closing of our IPO and until the one-year anniversary of the initial closing of the IPO, the holder of the note will be able to sell 1% of the number of shares of common stock underlying the note on a monthly basis, subject to a maximum sale on any trading day of 4% of the daily volume; (b) if the common stock price is over $7.00 per share for five consecutive trading days then the holder of the note can sell up to 3% of the number of shares of common stock underlying the note on a monthly basis, subject to a maximum sale on any trading day of 4% of the daily volume; (c) if the common stock price is over $10.00 per share for five consecutive trading days then the holder of the note can sell up to an additional 5% of the number of shares of common stock underlying the note on a monthly basis, subject to a maximum sale on any trading day of 7% of the daily volume; and (d) if the common stock price is over $14.00 per share then the holder of the note is not restricted from making any sales until such time as the common stock price falls back below $14.00 per share; and (b) thereafter, until the two-year

anniversary of the initial closing of IPO, the holder of the note can sell on any trading day 10% of the daily volume; provided that if the common stock price is over $10.00 per share then the holder of the note is not restricted from making any sales until such time as the common stock falls back below $10.00 per share. The foregoing lock-up restrictions relate to public sales and do not restrict the transfer of the shares privately, if permitted by applicable law, provided the acquirer of the shares agrees to comply with the above restrictions with respect to any public sales.

6. Warrant Liability

On February 9, 2017, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Roth Capital Partners, LLC, as representative of the several underwriters identified therein (collectively, the "Underwriters"), pursuant to which we sold in a registered public offering (the "Offering"), 3,710,000 units, priced at a public offering price of $1.35 per unit (the closing price that day was $1.50), with each unit consisting of: (i) one share of common stock, (ii) a five-year Series A warrant to purchase 0.50 of a share of common stock, (iii) a 90-day Series B warrant to purchase one share of common stock, and (iv) a five-year Series C warrant to purchase 0.50 of a share of common stock. The Series C warrants in a unit could only be exercised to the extent and in proportion to a holder of the Series C warrants exercising its Series B warrants included in the unit. The Series A and Series C warrant have an exercise price of $1.50 per share of common stock. The Series B warrant had an exercise price of $1.35 per share of common stock.

Under the terms of the Underwriting Agreement, we granted the Underwriters a 45-day option to purchase an additional 556,500 shares of common stock and/or an additional 556,500 warrant combination (comprised of an aggregate of 278,250 Series A warrants, 556,500 Series B warrants and 278,250 Series C warrants), in any combinations thereof, from us to cover over-allotments at the public offering price per share of $1.349 and public offering price per warrant combination of $.001, respectively, less the underwriting discounts and commissions. Upon the closing of the Offering, the Underwriters exercised the over-allotment option with respect to $278,100 warrant combinations. We received approximately $4.5 million in net proceeds from the Offering, after deducting underwriting discounts and commissions and estimated offering expenses.

The basis of value is fair value, which is defined pursuant to Accounting Standards Codification ("ASC") 820 to be "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date". The Company estimated the fair value of the Warrants under ASC 820 as of February 14, 2017 for financial reporting purposes. We used the Black-Scholes option pricing model ("BSM") to determine the fair value of the Series A and Series B Warrants and a Monte Carlo simulation ("MCM") with regard to the Series C Warrants in consideration of path dependent vesting terms of the contract. Both the BSM and MCM models are acceptable in accordance with GAAP. The BSM requires the use of a number of assumptions including volatility of the stock price, the weighted average risk-free interest rate, and the weighted average term of the Warrant. The MCM simulates the Company's common stock price from the valuation date through the Series B Warrant and the unvested Series C Warrant expiration dates using Geometric Browman Motion on a risk-neutral basis - thereby impacting the likelihood that the Series B Warrants would have been exercised and, subsequently, the Series C Warrants would then vest. All Series B and unvested Series C warrants expired on May 15, 2017.

The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the term of the Warrants and is calculated by using the average daily historical stock prices through the day preceding the grant date.

Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the expected life of the Warrants. Where appropriate, we used the historical volatility of peer entities due to the lack of sufficient historical data of our stock price during 2016-2017.

The assumptions used in the BSM and MCM models for the Warrants are as follows:

	Year Ended December 31,	
	2017	**2016**
Risk-free interest rate	1.68%-1.86%	—%
Volatility	80.00%-160.11%	—%
Expected life (years)	0.5-5.0	—
Dividend yield	-%	—%

A summary of our Warrant activity and related information follows:

Description	Number of Shares Under Warrant	Range of Warrant Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Balance at January 1, 2017	—	—	—	—
Granted	8,235,923	$1.35-$1.50	$ 1.43	—
Exercised	(2,728,434)	—	$ 1.46	—
Expired	(5,087,717)	—	$ 1.40	—
Balance at December 31, 2017	419,772	—	$ 1.46	4.38
Vested and Exercisable at December 31, 2017	419,772	$1.35-$1.50	$ 1.46	4.38

Warrant Activity During 2017:

On February 14, 2017, 8,235,923 Warrants were granted, as discussed above. During the year, 1,833,984 Series A warrants were exercised, 596,300 Series B warrants were exercised - thereby vesting 298,150 Series C warrants - and all of the vested 298,150 Series C warrants were exercised. Of the remaining Series B and C warrants, 5,087,717 expired on May 15, 2017. Therefore, the associated warranty liability of $1.24 million was extinguished on that date.

7. Equity

On May 2, 2016, the Company amended and restated its certificate of incorporation to increase the number of shares authorized to 80,000,000 of which 5,000,000 shares of preferred stock are authorized and 75,000,000 shares of common stock are authorized.

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock. Our certificate of incorporation authorizes the board to issue these shares in one or more series, to determine the designations and the powers, preferences and relative, participating, optional or other special rights and the qualifications, limitations and restrictions thereof, including the dividend rights, conversion or exchange rights, voting rights (including the number of votes per share), redemption rights and terms, liquidation preferences, sinking fund provisions and the number of shares constituting the series. As of December 31, 2017, there was no issued preferred stock.

Common Stock

Settlement of a Liability

In January 2017, the Company issued 79,167 shares of common stock to a consultant in full settlement for prior services rendered to the Company. Settlement occurred February 21, 2017 with the issuance of the shares, resulting in a gain on settlement of $0.15 million recorded in gain in settlement of liability on the Statements of Operations. The obligation of $0.24 million had been recorded by the Company in accounts payable and accrued expenses as of December 31, 2016.

Follow-On Public Offering

In February 2017, the Company completed a public offering and sold 3,710,000 shares of the Company’s common stock. The offering price per unit was $1.35. The Company received net cash proceeds of $4.5 million after deducting underwriting discounts, commissions and direct offering expenses payable by us. See Note 6 above regarding Warrant issuances related to our February 2017 public offering.

At Market Issuance Sales Agreement (ATM)

On September 15, 2017, the Company entered into an At Market Issuance Sales Agreement (the “Agreement” or “ATM”) with Roth Capital Partners, LLC and National Securities Corporation (collectively, the “Agents”). Pursuant to the terms of the Agreement, the Company may sell from time to time through the Agents shares of the Company's common stock with an aggregate sales price of up to $13.0 million.

Any sales of Shares pursuant to the Agreement will be made under the Company's effective shelf registration statement on Form S-3 (File No. 333-219434) which became effective on August 21, 2017 and the related prospectus supplement and the accompanying prospectus, as filed with the Securities and Exchange Commission (the "SEC") on September 15, 2017. Under the Agreement, the Company may sell Shares through an Agent by any method that is deemed an at the market offering as defined in Rule 415 under the Securities Act of 1933, as amended (the "Securities Act").

Sales of the Shares may be made at market prices prevailing at the time of sale, subject to such other terms as may be agreed upon at the time of sale, including a minimum sales price that may be stipulated by the Company's Board of Directors or a duly authorized committee thereof. The Company or the Agents, under certain circumstances and upon notice to the other, may suspend the offering of the Shares under the Agreement. The offering of the Shares pursuant to the Agreement will terminate upon the sale of Shares in an aggregate offering amount equal to $13.0 million, or sooner if either the Company or the Agents terminate the Agreement pursuant to its terms.

The Company agreed to pay a commission to the Agents of 3.0% of the gross proceeds of the sale of the Shares sold under the Agreement and to reimburse the Agents for certain expenses. The Company has also provided the Agents with customary indemnification rights. The Company is not obligated to make any sales of Common Stock under the Agreement.

As of December 2017, the Company had sold 776,016 shares of common stock from $2.05 to $2.71 per share with gross proceeds of $1.6 million under this Agreement.

Initial Public Offering

On May 31, 2016, the Company completed its IPO and sold 1,540,026 shares of the Company's common stock. The IPO price per share was $6.00. The Company received net cash proceeds of $8,464,183 after deducting underwriting discounts, commissions and direct offering expenses payable by us. Pursuant to our agreement with our underwriters, as additional compensation, we issued the underwriters warrants to purchase 107,802 shares of common stock exercisable for a period of 5 years from date of issuance at an exercise price of $7.50 per share. The relative fair value of these warrants was $374,763 and is included in stock issuance costs calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.39% (2) expected life of 5 years, (3) expected volatility of 80.61%, and (4) zero expected dividends.

During the period from January 1, 2016 through May 2, 2016, the Company sold 234,297 common shares for $702,894.

On June 20, 2016, the Company agreed to issue 24,000 shares of common stock to PCG Advisory Group, the Company's investor relations firm, for services provided. The fair value of these shares was $157,680 based on the market price on the grant date.

GSK Consulting Agreement

On July 29, 2017, the Company entered into a consulting agreement with GSK Strategies, LLC ("GSK"), for its investor relations operations. The consulting agreement covers for a period of twelve months from the date of July 29, 2017. In exchange for the consulting services, the Company agreed to issue two warrants (collectively, the "Warrants") to purchase 100,000 and 50,000 shares of common stock at exercise prices of $2.41 and $3.00 per share, respectively, subject to approval by Nasdaq of a listing of additional shares application, which was received in August 2017. Each of the Warrants vests over a 12-month period in equal monthly installments starting July 29, 2017, provided that GSK is providing services to the Company pursuant to the consulting agreement on each vesting date. The Warrants became initially exercisable on August 8, 2017, and expire five years from the initial exercise date. The Company recorded stock compensation expense for the non-employee consulting agreement of $104,000 during the year ended December 31, 2017 based on the fair value of the warrants vested as of December 31, 2017.

Adoption of 2015 Stock Plan

On December 5, 2015, the Board of Directors of the Company approved the Company's 2015 Stock Plan, which was amended on April 22, 2016. The expiration date of the plan is December 5, 2025 and the total number of underlying shares of the Company's common stock available for grant to employees, directors and consultants under the plan is 2,500,000 shares. The awards under the 2015 Stock Plan can be in the form of stock options, stock awards or stock unit awards.

The following is a summary of option activities for the years ended December 31, 2016 and 2017:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2015	200,000	$ 0.14	$ 0.20		
Granted - 2016	460,000	3.75	5.83		
Cancelled - 2016	(150,000)	0.14	0.20		
Outstanding, December 31, 2016	510,000	$ 3.40	$ 5.28	9.29	$ 275,500
Granted - 2017	835,000	$ 1.59	$ 2.42		
Cancelled - 2017	—				
Outstanding, December 31, 2017	1,345,000	$ 1.93	$ 3.50	9.07	$ 83,000
Exercisable, December 31, 2017	50,000	$ 0.13	$ 0.20	2.42	$ 83,000

The fair value of the option grants has been estimated, with the following weighted-average assumptions:

	Year Ended December 31,	
	2017	**2016**
Risk-free interest rate	1.83% to 1.95%	1.3%
Volatility	80%	70.18% to 70.44%
Expected life (years)	5.0 to 6.25	6 to 6.25
Expected dividend yield	—%	—%

Stock-based compensation expense for the years ended December 31, 2017 and 2016, are as follows (in thousands):

	Year Ended December 31,	
	2017	**2016**
General and administrative	$ 684	$ 321
Research and development	23	3
Total	$ 707	$ 324

Options granted during 2017 have an aggregated fair value of $1.4 million that was calculated using the Black-Scholes option-pricing model. At December 31, 2017, total compensation cost not yet recognized was $2.5 million and the weighted average period over which this amount is expected to be recognized is 8.7 years. The aggregate fair value of options vesting in the years ended December 31, 2017 and 2016 was $3.1 million and $1.8 million, respectively. No options were exercised in 2017 or 2016. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the above paragraph and table. The expected term of the options was computed using the “plain vanilla” method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin 107 because we do not have sufficient data regarding employee exercise behavior to estimate the expected term. The volatility was determined by referring to the average historical volatility of a peer group of public companies because we do not have sufficient trading history to determine our historical volatility. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

The Company entered into a separation agreement with its former Chief Financial Officer in October 2016 and as part of the agreement, options to purchase 150,000 shares of common stock issued to the former Chief Financial Officer were cancelled and the vesting was accelerated on the remaining options to purchase 50,000 shares of common stock.

8. Income Taxes

The provision for income taxes consists of the following components (in thousands):

	December 31, 2017	December 31, 2016
Current Expense (Benefit):		
Federal	$ —	$ —
State	—	—
Current Income Tax Expense	$ —	$ —
Deferred Expense (Benefit):		
Federal	$ —	$ —
State	—	—
Deferred Income Tax Expense	$ —	$ —
Net Deferred Taxes	$ —	$ —

The following summarizes activity related to the Company's valuation allowance (in thousands):

	December 31, 2017	December 31, 2016
Valuation Allowance at Beginning of Period	$ 1,397	$ 155
Income Tax Benefit	1,164	1,242
Release of Valuation Allowance	—	—
Valuation Allowance at End of Period	$ 2,561	$ 1,397

A reconciliation of the income tax benefit computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows (in thousands):

	December 31, 2017		December 31, 2016	
(amounts in thousands)	Amount	Percent	Amount	Percent
Federal Tax Benefit at Statutory Rate	$ 3,334	34.00 %	$ 1,335	34.00 %
State Tax Benefit Net of Federal	(117)	(1.20)%	137	3.48 %
IPO Costs	(76)	(0.77)%	(227)	(5.78)%
Stock Warrant Costs	(395)	(4.03)%	—	— %
Other Permanent Differences	(9)	(0.09)%	(3)	(0.08)%
Change in Deferred Tax Rate due to Tax Reform	(1,562)	(15.93)%	—	— %
Other	(11)	(0.11)%	—	— %
Increase in Valuation Allowance	(1,164)	(11.87)%	(1,242)	(31.62)%
Total Tax (Expense) / Benefit	$ —	— %	$ —	— %

The Company's deferred tax assets and liabilities were remeasured to reflect the reduction in the U.S. corporate income tax rate from 35% to 21%, resulting in a deferred tax expense of $1.56 million for the year ended December 31, 2017 that is still fully valued against as of December 31, 2017. This expense is attributable to the Company being in a net deferred tax asset position at the time of remeasurement. As the company maintains fully valuation allowance, this amount can be seen on the rate reconciliation as an adjustment to deferred tax asset and corresponding valuation allowance.

The principal components of the Company's deferred tax assets and liabilities consist of the following at December 31, 2017 and 2016 (in thousands):

	December 31, 2017	December 31, 2016
Deferred Tax Assets:		
Start Up Costs	$ 1,105	$ 735
Federal Net Operating Loss Carryforwards	1,275	520
State Tax Loss Carryforwards	9	50
Deferred Compensation	176	96
Total Deferred Tax Assets	$ 2,565	$ 1,401
Less Valuation Allowance	(2,561)	(1,397)
Net Deferred Tax Assets	$ 4	$ 4
Deferred Tax Liabilities:		
Fixed Assets	(4)	(4)
Total Deferred Tax Liabilities	$ (4)	$ (4)
Net Deferred Taxes	$ —	$ —

The Company has incurred net operating losses since inception. As of December 31, 2017, the Company had total federal operating loss carry forwards of approximately $6.07 million which expire commencing in 2037. The value of these carryforwards depends on the Company's ability to generate taxable income. Additionally, because federal tax laws limit the time during which the net operating loss carryforwards may be applied against future taxes, if the Company fails to generate taxable income prior to the expiration dates of the carry forwards the Company may not be able to fully utilize the net operating loss carryforwards to reduce future income taxes. Finally, the Company has not undertaken a detailed analysis of the application of IRC Section 382 with respect to limitations on the utilization of net operating loss carryforwards and other deferred tax assets. However, the Company believes that this matter is not material to the overall tax position within the financial statements due to the full valuation allowance against the net operating losses and the lack of utilization of the net operating losses during tax years open under statute.

The Company conducts business in various locations and, as a result, files income tax returns in the United States Federal jurisdiction and in multiple state jurisdictions. As of December 31, 2017, the Company had state operating losses of approximately $5.81 million which expire commencing in 2037. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available.

Management has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. The Company has cumulative losses and there is no assurance of future taxable income, therefore, valuation allowances have been recorded to fully offset the deferred tax asset at December 31, 2017. Management has determined that it is more likely than not that the Company will not recognize the benefits of its federal and state deferred tax assets, and as a result, a valuation allowance of $2.56 million and $1.40 million has been established at December 31, 2017 and 2016, respectively. The change in the valuation allowance for the year ended December 31, 2017 was primary due to additional operating losses and capitalized research costs. The Company may be eligible to claim research and development tax credits in the future, but has not conducted a study to date.

There are no unrecognized tax benefits from any federal, state or foreign jurisdictions. The only tax years open under statute for the Company are December 31, 2017 and December 31, 2016.

The Company's policy is to recognize interest and penalties related to any unrecognized tax liabilities as additional tax expense. No interest or penalties have been accrued at December 31, 2017 and 2016, as the Company has not recorded any uncertain tax positions. The Company believes it has appropriate and adequate support for the income tax positions taken and to be taken on its tax returns and that its accruals for tax liabilities are adequate for all open years based on an assessment of many factors including past experience and interpretations of tax law applied to the facts of each matter.

Although the Company believes its recorded assets and liabilities are reasonable, tax regulations are subject to interpretation and tax litigation is inherently uncertain; therefore, the Company's assessments can involve both a series of complex judgments about future events and rely heavily on estimates and assumptions. Although the Company believes that the estimates and assumptions supporting its assessments are reasonable, the final determination of tax audit settlements and any related litigation

could be materially different from that which is reflected in historical income tax provisions and recorded assets and liabilities. If the Company were to settle an audit or a matter under litigation, it could have a material effect on the income tax provision, net income, or cash flows in the period or periods for which that determination is made. Any accruals for tax contingencies are provided for in accordance with U.S. GAAP.

The Company does not believe that its tax positions will significantly change due to any settlement and/or expiration of statutes of limitations prior to December 31, 2017.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a federal corporate tax rate decrease from 35% to 21% for tax years beginning after December 31, 2017, the transition of U.S international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of foreign earnings. We have estimated our provision for income taxes in accordance with the Tax Act and guidance available as of the date of this filing but have kept the full valuation allowance. As a result have recorded no income tax expense in the fourth quarter of 2017, the period in which the legislation was enacted.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of US GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. The deferred tax expense recorded in connection with the remeasurement of deferred tax assets is a provisional amount and a reasonable estimate at December 31, 2017 based upon the best information currently available. The ultimate impact may differ from these provisional amounts, possibly materially, due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the Tax Act. Any subsequent adjustment to these amounts will be recorded to current tax expense in the quarter of 2018 when the analysis is complete. The accounting is expected to be complete when the 2017 U.S. corporate income tax return is filed in 2018.

9. Commitments and Contingencies

Sponsored Research Agreements with MD Anderson

On January 9, 2017, we amended our Sponsored Laboratory Study Agreement with MD Anderson whereby we paid $302,500 in 2017, and the agreement was extended to October 31, 2018. On December 4, 2017, we extended this Agreement until October 31, 2019 for total payment amount of $346,687 spread over that period of time. Of this amount, $236,687 was paid in the first quarter of 2018. The final payment of $110,000 is due on July 31, 2018. The expenses recognized under the MD Anderson agreement with regards to the Sponsored Laboratory Study were $291,687 and $33,000, for the year ended December 31, 2017 and 2016, respectively.

Annamycin

As of August 2015, we obtained the rights and obligations of Annamed under a June 2012 Patent and Technology Development and License Agreement by and between Annamed and Dermin (the "Annamed Agreement"). Therefore, certain intellectual property rights, including rights, if any, covering the potential drug product, Annamycin have been licensed to Dermin and Dermin has been granted a royalty-bearing, exclusive license to manufacture, have manufactured, use, import, offer to sell and/or sell products in the field of human therapeutics under the licensed intellectual property in the countries of Poland, Ukraine, Czech Republic, Hungary, Romania, Slovakia, Belarus, Lithuania, Latvia, Estonia, Netherlands, Turkey, Belgium, Switzerland, Austria, Sweden, Greece, Portugal, Norway, Denmark, Ireland, Finland, Luxembourg, Iceland, Kazakhstan, Russian Federation, Uzbekistan, Georgia, Armenia, Azerbaijan and Germany ("Annamed licensed territories"). We are obligated to develop and provide a dossier containing data related to the licensed subject matter to Dermin. In consideration, Dermin will pay a royalty for the sale of any licensed product in the Annamed licensed territories and pay all out-of-pocket expenses incurred by us in filing, prosecuting and maintaining the licensed patents for which the license has been granted. Dermin also agrees to provide a percentage of certain consideration that Dermin receives pursuant to sublicense agreements. On June 29, 2017, the Company entered into an agreement with MD Anderson licensing certain technology related to the method of preparing Liposomal Annamycin. The agreement includes a one-time license documentation fee of $40,000, annual maintenance fees of $25,000 until the first sale of drug and has the following the milestone payments: (i) commencement of Phase III Study for first licensed drug/product - $125,000; (ii) submission of the first NDA within the United States - $175,000; and (iii) receipt of first marketing approval for sale of a license product in the United States - $225,000. The expenses recognized under this agreement were $52,500 and $0 for the year ended December 31, 2017 or 2016, respectively.

WP1066 Portfolio

The rights and obligations to a June 2010 Patent and Technology License Agreement entered into by and between Moleculin LLC and MD Anderson (the "Moleculin Agreement") have been assigned to us. Therefore, we have obtained a royalty-bearing, worldwide, exclusive license to intellectual property rights, including patent rights, related to our WP1066 drug product candidate. In consideration, we must make payments to MD Anderson including an up-front payment, milestone payments and minimum annual royalty payments for sales of products developed under the license agreement. Annual maintenance fee payments will no longer be due upon marketing approval in any country of a licensed product. One-time milestone payments are due upon commencement of the first Phase III study for a licensed product within the United States, Europe, China or Japan; upon submission of the first NDA for a licensed product in the United States; and upon receipt of the first marketing approval for sale of a licensed product in the United States. The rights we have obtained pursuant to the assignment of the Moleculin Agreement are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the U.S. government. The agreement, as amended, has the following the milestone payments: (i) commencement of Phase III Study for first licensed drug/product within the United States, Europe, China or Japan - $150,000; (ii) submission of the first NDA within the United States - $500,000; and (iii) receipt of first marketing approval for sale of a license product in the United States - $600,000. License fees expensed related to MD Anderson were $85,000 and $77,500, respectively, for the year ended December 31, 2017 and 2016.

We entered into an out-licensing agreement with Houston Pharmaceuticals, Inc. ("HPI"), pursuant to which we have granted certain intellectual property rights to HPI, including rights covering the potential drug candidate, WP1066 ("HPI Out-Licensing Agreement"). Under the HPI Out-Licensing Agreement we must make quarterly payments totaling $0.75 million for the first twelve quarters following the effective date of the HPI Out-Licensing Agreement, or May 2, 2016, in consideration for the right to development data related to the development of licensed products. Notwithstanding our obligation to make the foregoing payments, the HPI Out-Licensing Agreement does not obligate HPI to conduct any research or to meet any milestones. Upon payment in the amount of $1.0 million to HPI within three years of the effective date of the HPI Out-Licensing Agreement we will regain all rights to the licensed subject matter and rights to any and all development data and any regulatory submissions including any IND, NDA or ANDA related to the licensed subject matter and can end the license without any other obligation other than the aforementioned quarterly payments. In the event that we do not exercise our right to regain our rights to the licensed subject matter within three years of the effective date of the HPI Out-Licensing Agreement, the license granted to HPI shall convert to an exclusive license upon HPI's written notice and we shall be obligated to transfer all existing data relating to licensed subject matter including any development data and any IND to HPI. License fees expensed related to HPI were $225,000 and $75,000 respectively, for the year ended December 31, 2017 and 2016.

In February 2018, we entered into a license agreement covering a new group of molecules recently discovered in connection with research we have been sponsoring at MD Anderson Cancer Center called WP1732, a part of the WP1066 Portfolio. In consideration, we must make payments to MD Anderson including an up-front payment, license documentation fee, annual maintenance fee, milestone payments and minimum annual royalty payments for sales of products developed under the license agreement. Under the agreement, annual maintenance fees are $10,000 on the effective date of the agreement and increase by $5,000 per year up to a maximum of $50,000 per year. Under the agreement, we are required to make royalty payments ranging from 3% to 5% of Net Sales, depending on the intended use, each quarter upon the commencement of sales, with a minimum of $200,000 per year. Additional payments are due upon the commencement of a Phase II study $150,000, submission of a New Drug Application $500,000, and the receipt of marketing approval of a licensed product, $600,000.

WP1122 Portfolio

The rights and obligations to an April 2012 Patent and Technology License Agreement entered into by and between IntertechBio and MD Anderson (the "IntertechBio Agreement") have been assigned to us. Therefore, we have obtained a royalty-bearing, worldwide, exclusive license to intellectual property, including patent rights, related to our WP1122 Portfolio and to our drug product candidate, WP1122. In consideration, we must make payments to MD Anderson including an up-front payment, license documentation fee, annual maintenance fee, milestone payments and minimum annual royalty payments for sales of products developed under the license agreement. Under the agreement, annual maintenance fees are $10,000 on the first anniversary of the effective date of the agreement, $20,000 on the second anniversary of the effective date of the agreement, $40,000 on the third anniversary of the effective date of the agreement, $60,000 on the fourth anniversary of the effective date of the agreement, $80,000 on the fifth anniversary of the effective date of the agreement and $100,000 on the sixth anniversary of the effective date of the agreement, except that such payments will no longer be due upon the first sale of a licensed product. Under the assignment, we agreed to make a minimum annual royalty payment in the amount of $200,000 for the first anniversary following the first sale of a licensed product, $400,000 for the second anniversary following the first sale of a licensed product, and $600,000 for the third year following the first sale of a licensed product. License fees expensed related to MD Anderson were $95,000 and $75,000, respectively, for the year ended December 31, 2017 and 2016.

One-time milestone payments are due as follows: 1) Upon commencement of a Phase II study for a licensed product - $200,000; 2) Upon commencement of a Phase III study for a licensed product - $250,000; 3) Upon filing of a New Drug Application ("NDA") for a licensed product - $400,000; and 4) Upon receipt of market approval for sale of a licensed product - $500,000. The rights we have obtained pursuant to the assignment of the IntertechBio Agreement are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the U.S. government.

Employment Agreements

The Company has agreements with four employees to provide certain benefits in the event of termination where the base salary and certain other benefits would aggregate approximately $1.0 million using the rate of compensation in effect at December 31, 2017.

10. Subsequent Events

Appointment of Science Advisory Board Member

On January 11, 2018, the Company issued to a Science Advisory Board ("SAB") member 10,000 options with an exercise price of $1.89 with 3-year annual vesting.

$9 million Registered Direct Offering

On February 16, 2018, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors for the sale by us of 4,290,000 shares of our common stock, at a purchase price of $2.10 per share. Concurrently with the sale of the common shares, pursuant to the Purchase Agreement, we also sold warrants to purchase 2,145,000 shares of common stock. We sold the common shares and warrants for aggregate gross proceeds of approximately $9.0 million. Subject to certain beneficial ownership limitations, the warrants will be initially exercisable on the six-month anniversary of the issuance date at an exercise price equal to $2.80 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the Purchase Agreement occurred on February 21, 2018.

The net proceeds from the transactions was approximately $8.27 million after deducting certain fees due to the placement agent and transaction expenses. The net proceeds will be used for planned clinical trials, preclinical programs, for other research and development activities and for general corporate purposes.

The common shares were offered and sold by us pursuant to an effective shelf registration statement on Form S-3, which was filed with the SEC on July 24, 2017 and subsequently declared effective on August 21, 2017 (File No. 333-219434), and the base prospectus contained therein. We filed a prospectus supplement with the SEC on February 16, 2018 in connection with the sale of the common shares.

The warrants and the shares issuable upon exercise of the warrants were sold without registration under the Securities Act of 1933 in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors, and in reliance on similar exemptions under applicable state laws.

We also entered into a placement agent agreement (the "Placement Agency Agreement") with Roth Capital Partners, LLC ("Roth"), pursuant to which Roth agreed to serve as exclusive placement agent for the issuance and sale of the common shares and warrants. We have agreed to pay Roth an aggregate fee equal to 6.5% of the gross proceeds received by us from the sale of the securities in the transactions. Pursuant to the Placement Agency Agreement, we also agreed to grant to Roth or its designees warrants to purchase up to 3% of the aggregate number of shares of common stock sold in the transactions (the "Roth Warrants"). The Roth Warrants have substantially the same terms as the warrants, except that the Roth Warrants will expire on February 15, 2023. The Roth Warrants and the shares issuable upon exercise of the Roth Warrants will be issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and in reliance on similar exemptions under applicable state laws. We also reimbursed Roth for its expenses of $75,000.

Subject to the consummation of the offering, we agreed to give Roth a nine-month right of first refusal to act as our lead underwriter or exclusive placement agent for any further capital raising transactions undertaken by the us. With certain exceptions, the we also granted Roth a six-month tail fee equal to the cash and warrant compensation in the offering, if any

investor with which Roth had substantive discussions with respect to the offering, provides us with further capital during such six-month period following termination of our engagement of Roth.

Lease Agreement

On March 22, 2018, we entered into a Lease Agreement (the "Lease") with IPX Memorial Drive Investors, LLC (the "Landlord") for the lease of 2,333 rentable square feet "RSF", which we will use for corporate office space and meetings. The term of the Lease is estimated to begin in May 2018, depending on construction, and continue for an initial term of 66 months, which may be renewed for an additional 5 years. We are required to remit base monthly rent of approximately $4,300 which will increase at an average approximate rate of 3.00% each year. We are also required to pay additional rent in the form of our pro-rata share of certain specified operating expenses of the Landlord. The newly leased space is located in Houston, Texas.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Moleculin Biotech, Inc. (incorporated by reference to exhibit 3.1 of the Form S-1/A filed March 21, 2016)
3.2	Amended and Restated Bylaws of Moleculin Biotech, Inc. (incorporated by reference to exhibit 3.2 of the Form S-1/A filed March 21, 2016)
4.1	Form of Series A/B/C Warrant Agreement issued in February 2017 offering (incorporated by reference to Exhibit 4.1 of the Form 8-K filed February 9, 2017)
10.1 **	Moleculin Biotech, Inc. 2015 Incentive Plan (incorporated by reference to exhibit 10.1 of the Form S-1/A filed March 21, 2016)
10.2	Rights Transfer Agreement between Moleculin Biotech, Inc. and AnnaMed, Inc. (incorporated by reference to exhibit 10.2 of the Form S-1/A filed March 21, 2016)
10.3	Patent and Technology License Agreement dated June 21, 2010 by and between The Board of Regents of the University of Texas System and Moleculin, LLC (incorporated by reference to exhibit 10.3 of the Form S-1/A filed March 21, 2016)
10.4	Amendment No. 1 to the Patent and Technology License Agreement dated June 21, 2010 by and between The Board of Regents of the University of Texas System and Moleculin, LLC (incorporated by reference to exhibit 10.4 of the Form S-1/A filed March 21, 2016)
10.5	Patent and Technology License Agreement dated April 2, 2012 by and between The Board of Regents of the University of Texas System and IntertechBio Corporation (incorporated by reference to exhibit 10.5 of the Form S-1/A filed March 21, 2016)
10.6	Amendment No. 1 to the Patent and Technology License Agreement dated June 21, 2010 by and between The Board of Regents of the University of Texas System and IntertechBio Corporation (incorporated by reference to exhibit 10.6 of the Form S-1/A filed March 21, 2016)
10.7	Patent and Technology Development and License Agreement June 28, 2012 by and between Annamed, Inc. and Dermin Sp. z.o.o (incorporated by reference to exhibit 10.7 of the Form S-1/A filed April 15, 2016)
10.8	Patent and Technology Development and License Agreement dated April 15, 2011 by and between IntertechBio Corporation and Dermin Sp. z.o.o (incorporated by reference to exhibit 10.8 of the Form S-1/A filed March 21, 2016)
10.9	Patent and Technology Development and License Agreement dated October 27, 2010 by and between Moleculin, LLC and Dermin Sp. z.o.o (incorporated by reference to exhibit 10.9 of the Form S-1/A filed March 21, 2016)
10.10	Rights Transfer Agreement dated between Moleculin Biotech, Inc. and IntertechBio Corporation dated August 11, 2015 (incorporated by reference to exhibit 10.10 of the Form S-1/A filed March 21, 2016)
10.11	Agreement and Plan of Merger between Moleculin Biotech, Inc. and Moleculin, LLC (incorporated by reference to exhibit 10.11 of the Form S-1/A filed March 21, 2016)

10.12	Technology Rights and Development License Agreement to be entered into by Moleculin Biotech, Inc. and Houston Pharmaceuticals, Inc. (incorporated by reference to exhibit 10.13 of the Form S-1/A filed April 15, 2016)
10.13 **	Employment Agreement between Moleculin Biotech, Inc. and Jonathan P. Foster dated August 19, 2016 (incorporated by reference to Exhibit 10.1 of the Form 8-K filed August 25, 2016)
10.14 **	Executive Employment Agreement between Moleculin Biotech, Inc. and Walter Klemp dated October 13, 2016 (incorporated by reference to Exhibit 10.1 of the Form 8-K filed October 13, 2016)
10.15 **	General Release and Separation Agreement between Moleculin Biotech, Inc. and Louis Ploth dated October 7, 2016 (incorporated by reference to Exhibit 10.2 of the Form 8-K filed October 13, 2016)
10.16	Development Collaboration Agreement between Moleculin Biotech, Inc. and Dermin Sp. Z o. o. dated September 30, 2016 (incorporated by reference to Exhibit 10.4 of the Form 10-Q filed November 21, 2016)
21	Subsidiaries of the Registrant (incorporated by reference to exhibit 21 of the Form S-1/A filed April 15, 2016)
23.1*	Consent of Grant Thornton, LLP
31.1*	Certification of Principal Executive Officer Pursuant to Section 302 of Sarbanes- Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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.

** Denotes a management contract or compensatory plan or arrangement.

SIGNATURES

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

MOLECULIN BIOTECH, INC.

By: /s/ Walter V. Klemp
Walter V. Klemp,
Chief Executive Officer and Chairman

Date: March 28, 2018

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

Signature	Title	Date
/s/ Walter V. Klemp Walter Klemp	Chief Executive Officer and Chairman (Principal Executive Officer)	March 28, 2018
/s/ Jonathan P. Foster Jonathan P. Foster	Executive Vice President Officer and Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2018
/s/ Robert George Robert George	Director	March 28, 2018
/s/ Michael Cannon Michael Cannon	Director	March 28, 2018
/s/ John Climaco John Climaco	Director	March 28, 2018

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 28, 2018, with respect to the financial statements included in the Annual Report of Moleculin Biotech, Inc. on Form 10-K for the year ended December 31, 2017. We consent to the incorporation by reference of said reports in the Registration Statements of Moleculin Biotech, Inc. on Form S-1 (File No. 333-214898), Form S-3 (File No. 333-219434) and Form S-8 (File No. 333-212619).

/s/GRANT THORNTON LLP

Houston, Texas
March 28, 2018

Exhibit 31.1

OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Walter Klemp, certify that:

1. I have reviewed this Annual Report on Form 10-K of Moleculin Biotech, 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 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 this 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; and

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.

March 28, 2018

By: /s/ Walter Klemp
Walter Klemp
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jonathan Foster, certify that:

1. I have reviewed this Annual Report on Form 10-K of Moleculin Biotech, 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 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 this 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; and

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.

March 28, 2018

By: /s/ Jonathan Foster
Jonathan Foster
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K for the fiscal year ended December 31, 2017 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Walter Klemp, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C 78m or 78o(d)); and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2018

By: /s/ Walter Klemp
Walter Klemp
Chief Executive Officer
(Principal Executive Officer)

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

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K for the fiscal year ended December 31, 2017 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan Foster, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C 78m or 78o(d)); and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2018

By: /s/ Jonathan Foster
Jonathan Foster
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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