



Groundbreaking Cancer Therapies

2018
Annual Report



Moleculin is a clinical stage pharmaceutical company focused on the treatment of highly resistant cancers.

These resistant cancers range from deadly glioblastoma brain tumors to acute myeloid leukemia, pancreatic cancer, among others.

Our diverse pipeline of technologies was built around the recognition that treatment resistant tumors tend to have a common set of traits, including specific multidrug resistant mechanisms, an evasion of the natural immune system, a marked upregulation of certain key oncogenic transcription factors and an increased dependence on glycolysis for energy production. Each of these elements is addressed by the unique and innovative mechanisms introduced by one or more of our three core technologies.

We believe this approach not only provides the opportunity to help the many patients in need of new, more effective therapies, but also to work in combination with numerous existing drugs that often inevitably fail as tumors present immediate or acquired resistance. By focusing on targeting such significant unmet needs in highly resistant cancers, we believe we not only provide new hope to cancer patients, but also present our shareholders with an important strategic advantage. Showing even modest improvements in highly resistant cancers can lead to accelerated approval pathways, reducing the time and capital required to ultimately realize success.

To Our Shareholders

On the strength of our successful clinical preparation in 2018, we enter 2019 with a great deal of momentum with our clinical trials. 2018 was very exciting as we gained regulatory consent to commence our initial trials for our lead drug candidate Annamycin and our STAT3 inhibiting Immune/Transcription Modulator, WP1066. We believe that 2019 will be the “year of data,” as we report the initial cohort data on some of those clinical trials.

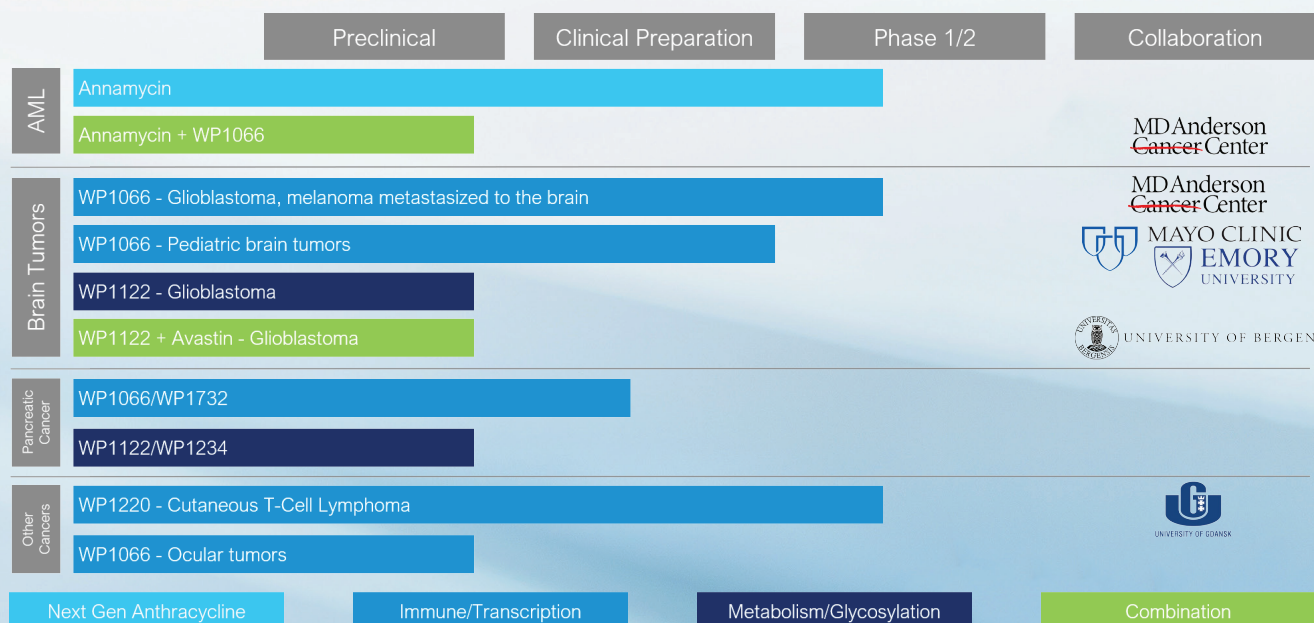
Our Annamycin trials for the treatment of acute myeloid leukemia are proceeding very well as we conclude the first cohort in the U.S. In our U.S. study, four patients have completed treatment at what we consider to be a low initial dose – 100 mg/m² – in the first cohort with no significant adverse events related to Annamycin, and the study will now proceed to the next higher dose of 120 mg/m² in the second cohort. In our Annamycin trial in Poland, the first patient treated in that trial received a single course of Annamycin and his bone marrow blasts reduced from 60% to 11%. Our principal investigator considered this response sufficient for the patient to proceed to consolidation therapy, with the goal of receiving a potentially curative bone marrow transplant.

This outcome is the first step in achieving one of our primary objectives at Moleculin – developing therapies that can extend and improve the lives of those afflicted with rare and difficult cancers, and that have exhausted virtually all current therapies.

The recent initiation of our WP1220 skin cancer clinical trial in Poland achieves an important milestone – Moleculin now has three unique drug candidates in four ongoing clinical trials. Given those ongoing clinical trials we believe 2019 will be a “year of data” for us – concretely establishing our transition to a clinical stage company developing oncology drug candidates that could be “game-changers” in treating rare and difficult cancers. All the years of painstaking research and visionary drive are beginning to produce tangible data. This is a testament to the dedication and focus of the entire Moleculin team to boldly advance our vision for “multiple shots on goal” in the treatment of certain rare and highly resistant cancers.

With our three core technologies and six oncology drug candidates, we are increasingly better positioned to develop treatments for highly resistant cancers in the coming years. We are pleased that the FDA recently

Development Pipeline



"This is why we do what we do; develop drugs, and combinations of those drugs, that can provide hope for a longer and better quality of life to those that have exhausted all current therapies."

granted Orphan Drug Designation for our drug candidate WP1066 for the treatment of glioblastoma, one of the most aggressive forms of brain tumors. This adds to the Orphan Drug Designation we already have for Annamycin. The FDA grants Orphan Drug Designation to drugs and biologics that are intended for the treatment of rare diseases. In addition to glioblastoma, WP1066 could be effective in the treatment of a range of highly resistant tumors including acute myeloid leukemia ("AML") and pancreatic cancer.

We have seen strong anti-tumor activity with WP1066, our flagship STAT3 Immune/Transcription Modulator (an inhibitor of the activated form of STAT3, among other important properties) in a wide range of animal models. We are extremely excited with the results of our preclinical research, as the data is showing positive results of combining our drug candidate WP1066 with checkpoint inhibitors, suggesting that WP1066 may have the ability to improve the outcome of immune checkpoint therapy in tumors that have been resistant to these therapies. We believe this represents an important new approach to treating many types of rare and highly resistant cancers.

These important research developments along with the regulatory approvals are a complement to our vision of developing numerous drugs that support our "multiple shots on goal" strategy.

On a macro level, we are encouraged by animal models showing the significant accumulation of WP1122 in the brain and the pancreas to potentially starve brain and pancreatic tumors; and the water solubility of our STAT3 Immune/Transcription Modulator, WP1732, greatly enhancing the potential for IV delivery of this unique class of compounds. We believe there is a significant opportunity for the synergistic combination of our drug candidates to develop additional treatments for the cancers we are targeting. We are excited with the opportunities ahead.

We finished the year with cash of approximately \$7.1 million, no long-term debt, and access to capital in our \$20 million equity line. The equity line provides us with the flexibility of accessing additional working capital to help fund our ongoing research programs. With four drug candidates in clinical trials, we will continue to carefully focus on being capital efficient through this important developmental process. With that in mind,

we recently completed a public offering generating proceeds of approximately \$5.25 million. In addition to our current cash on hand, we believe this will permit us to continue development of our clinical programs without interruption.

I would like to call your attention to the new Moleculin website that has gone live in recent weeks. It provides a very comprehensive overview of our technologies, the potential they represent in attacking rare and difficult cancers and an up-to-date overview of news and all corporate developments. We hope you find the new website to be a useful resource in helping you stay current on our development efforts.

2018 was a great year. We initiated important clinical trials that will set the stage for our future success. As we move into the new year, we are excited with the progress achieved in the very early months of 2019. Our first Annamycin cohort in the U.S. is complete and we are progressing to the second cohort with a higher dosage level that corresponds with the dosage level in our Polish trial that appears to have shown some level of activity. In our Annamycin clinical trial in Poland, the first patient responded well enough to be eligible for a potential lifesaving bone marrow transplant. This is why we do what we do; develop drugs, and combinations of those drugs, that can provide hope for a longer and better quality of life to those that have exhausted all current therapies. We are also very optimistic with the progress being achieved in the physician-sponsored IND for the Phase I trial of our WP1066 drug candidate for brain tumors as it has moved into its third cohort. The progress in this trial has also now led to an agreement with Emory University to begin a pediatric brain tumor trial expected to begin this year.

We could not do this without the support of our loyal shareholders. We appreciate your confidence in Moleculin, and we are dedicated to developing the "multiple shots on goal" that we believe will enhance the value of your investment in this Company for many years to come.

Best regards,



Walter Klemp, Chairman and CEO

Key Developments

Subsequent to the end of 2018 we have had a number of developments take place, including:

- The announcement of the enrollment of the first two patients in our WP1220 clinical trial in Europe for the topical treatment of cutaneous T-cell lymphoma ("CTCL"). This marks the Company's fourth clinical trial with enrolled patients. In this case, we are targeting CTCL with a topical p-STAT3 inhibitor in light of the significant role that STAT3 appears to play in CTCL skin lesions. Our intent is to take an early read on the first five patients in this trial to assess whether we think topical delivery is viable. We expect preliminary data to be available during 2019.
- We announced that Dr. Martin Tallman, Chief of Leukemia for Memorial Sloan Kettering Cancer Center has joined the Company's Science Advisory Board. Dr. Tallman is a board-certified hematologist and oncologist with clinical expertise in treating patients with acute myeloid leukemia and acute lymphoblastic leukemia. We are honored to have a leukemia expert the caliber of Dr. Tallman joining our Science Advisory Board.
- We announced that the first patients, in Poland, have been treated in the Company's second clinical trial to study Annamycin for the treatment of relapsed and refractory adults with acute myeloid leukemia. We indicated that the initial treatment of the first patient with a single course of Annamycin appeared to reduce the patient's bone marrow blasts from 60% to 11%, a reduction the Principal Investigator believes is sufficient to warrant progressing this patient to a consolidation phase (additional dose of Annamycin) in preparation for a potentially curative bone marrow transplant. This European trial features a higher starting dosage as compared to the U.S. trial and may provide us a clearer view of the potential of Annamycin.
- With the traction achieved in our clinical trials we submitted a request for Fast Track Designation with the FDA for Annamycin. A drug that receives Fast Track designation is eligible for certain FDA facilitations that could ultimately lead to Accelerated Approval and Priority Review. Given our progress, we believe it is appropriate to request Fast Track designation for Annamycin.
- We announced the FDA granted Orphan Drug Designation for our drug candidate WP1066 for the treatment of glioblastoma, the most aggressive form of brain tumor.
- We announced Dr. James L. Abbruzzese, Chief of Oncology at Duke University has joined Moleculin's Science Advisory Board. Dr. Abbruzzese is recognized as one of the world's leading experts in the clinical study and treatment of pancreatic cancer. The addition of his expertise will be invaluable to our efforts on developing a potential treatment for pancreatic cancer. We are honored to have Dr. Abbruzzese, a distinguished medical oncologist, join our Science Advisory Board.

Anticipated Milestones

NEXT GENERATION ANTHRACYCLINE - ANNAMYCIN	POTENTIAL TIMEFRAME
Initial IRB (Institutional Review Board) approvals and site initiations of various clinical sites participating in our Phase I/II clinical trial of Annamycin	Accomplished and ongoing
Complete cohort of 150 mg/m ² - prior trial recommended Phase II dose (RP2D)	2019
Start treating patients in Annamycin Phase I/II clinical trial in Poland	Accomplished and ongoing
Announcement of initial clinical data for Annamycin trial	Accomplished and ongoing
Poland clinical trial (MB-105) begins Phase II	2020
Approach FDA on U.S. trial (MB-104) regarding dose expansion using Poland trial data	2020

IMMUNE/TRANSCRIPTION MODULATOR - WP1066 PORTFOLIO	POTENTIAL TIMEFRAME
Announced FDA grants Orphan Drug Designation to WP1066 for treatment of glioblastoma	Accomplished
Announcement of preliminary clinical data from WP1066 clinician sponsored trial	2019
Phase I surgical cohort begins in MD Anderson clinical trial of WP1066 for brain tumors	Second Half of 2019
Transfer MD Anderson-sponsored WP1066 IND to Moleculin	Second Half of 2019
Emory physician led pediatric medulloblastoma trial begins	Second Half of 2019
Announcement of further benefits of our sponsored research agreement with MD Anderson	Accomplished and ongoing into 2019
Announced approval of Clinical Trial Authorization for WP1220 for the treatment of cutaneous T-cell lymphoma (CTCL) in Poland	Accomplished
Assess preliminary patient data in WP1220 clinical trial	Q4-2019
IND for WP1732 submitted	2019
Dose first patient in Phase I trial for WP1732	2020
Announce further preclinical research results on WP1066 portfolio	2019

METABOLISM/GLYCOSYLATION INHIBITORS - WP1122 PORTFOLIO	POTENTIAL TIMEFRAME
Begin preclinical work on WP1122	Accomplished
File IND for WP1122	2020

GENERAL CLINICAL	POTENTIAL TIMEFRAME
Announce a fourth approved clinical trial	Accomplished
Announce a fifth approved clinical trial	2019

We are developing breakthrough discoveries into therapies for cancers that are unresponsive to currently available treatments.



Three Core Technologies

1

Next Generation Anthracycline

Reinventing a Cornerstone of Cancer Treatment with the Intent to Provide Safer and More Effective Chemotherapy.

Chemotherapy continues to be a cornerstone of cancer therapy. Annamycin is an anthracycline designed to be an improved chemotherapeutic agent that may be safer and more effective. Anthracyclines are a class of chemotherapy drugs considered to be among the most effective available, and with a broader spectrum of anticancer activity than most other classes of chemotherapeutic agents.

Acute leukemia (including both AML and ALL) is among a number of cancer types that usually are treated with anthracyclines. In the case of acute leukemia, anthracyclines are typically used in “induction therapy,” where the goal is to induce sufficient remission of patients’ tumor cells to allow for a curative bone marrow transplant.

Two key factors limit the safety and effectiveness of currently approved anthracyclines: cardiotoxicity (potential to damage the heart) and multidrug resistance. Annamycin shows promise to possibly overcome these two factors; if preliminary data are borne out, Annamycin may ultimately provide clinically meaningful benefits over currently approved anthracyclines in treating certain cancers. Preliminary data from very early-stage clinical trials suggest acute leukemia as a potentially opportune indication in which to further study Annamycin.

In the animal model recommended 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 would be especially valuable in the case of pediatric acute leukemia (both AML and ALL) because of the potential impact of cardiotoxicity on long-term survival. In our current Phase I/II trial for Annamycin, we are collecting 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.

In addition, the effectiveness of currently approved anthracyclines is limited by their propensity for succumbing to “multidrug resistance.” In many instances, the likelihood of cardiotoxicity (and other serious side effects) prevents increasing the dosing of current therapies in order to overcome multidrug resistance. As a result, most patients cannot receive current anthracyclines in doses that are adequate to produce lasting remission and thereby qualify for a bone marrow transplant. A laboratory study has suggested that Annamycin may resist being expelled by P-glycoprotein pumps and similar 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.

2

Immune/Transcription Modulators

Enabling Immune Response and Inhibiting p-STAT3 and other Oncogenic Transcription Factors.

We believe our WP1066 portfolio (including lead drugs WP1066, WP1220 and WP1732) represents a novel class of agents capable of hitting multiple targets, including the activated form of a key oncogenic transcription factor, STAT3. A substantial body of published research has identified STAT3 as a master regulator of a wide range of tumors and has linked the activated form, p-STAT3, with the survival and progression of these tumors. For this reason, it is widely believed that targeted inhibition of p-STAT3 may be an effective way to reduce or eliminate the progression of these diseases.

The high level of anticancer activity demonstrated in multiple tumors in animal models by WP1066 and WP1732 is potentially related to their ability to also inhibit such important key oncogenic transcription factors like c-Myc and HIF-1 α . In addition to direct anticancer effects not related to the function of the immune system, our lead drug WP1066 has also been shown to boost immune response in animals, in part by inhibiting activity of Regulatory T cells (Tregs), which are coopted by tumors to evade the immune system. We believe the dual effect of (1) directly inhibiting tumor growth and

Immune/Transcription Modulators continued

inducing tumor cell death and (2) separately boosting and directing the natural immune response to tumors is therapeutically highly promising. If additional preclinical and clinical data validate the two avenues of apparent activity, this class of drugs may be well-suited to treat a wide range of tumors, both as single agents and as critical elements of successful combination therapies targeting even some of the most difficult to treat cancers.

The recent oncology drug landscape has been dominated by immunotherapy, specifically including checkpoint inhibitors. To summarize checkpoint blockade therapy, the T-Cells within an individual's own immune systems should be capable of identifying tumor cells and destroying them before they destroy the individual. Unfortunately, tumors develop the ability to prevent this natural immune response by regulating the expression of certain receptors referred to as "immune checkpoints" that then bind to T-Cells and prevent them from attacking

the tumor. Immune checkpoint inhibitors are antibodies that block these receptor mechanisms and allow the T-Cells to act normally and attack the tumor.

As a result, companies are now focusing heavily on combination therapies, combining immune checkpoint inhibitors with chemotherapy, as well as other agents. There appears to be tremendous demand and we believe there is a clear need for new chemotherapeutic agents that, by their specific mechanism of action, would produce potent combination effects with immune checkpoint inhibitors, and that additionally can boost immune system response on their own. In this regard, there is early nonclinical evidence that WP1066, as a single agent, has the ability to reverse immune tolerance in brain tumor patients (Cancer Res, 67(20), 9630, 2007), and preliminary data in animal models that suggests WP1066 may have a potential for combination use with checkpoint inhibitors.

3

Metabolism/Glycosylation Inhibitors

*Using the Warburg Effect to Starve Tumor Cells to Death.
Targeting Cancer's Sweet Tooth.*

Science has recognized that many types of cancer cells have a unique metabolism, distinct from that of normal cells. Cancer cells' dependence on glycolysis (a specific way of converting glucose into energy) to proliferate and metastasize has been described as the "sweet tooth of cancer" and is a classic example of how the metabolism of cancer cells and normal cells differ. Glycolysis is a glucose-intensive means of producing energy that is used by normal cells only if oxygen levels are low. However, many types of tumor cells are essentially addicted to glycolysis even in the presence of abundant oxygen. This is known as the "Warburg Effect" after its discoverer, Dr. Otto Warburg, and such tumors are said to be highly "glycolytic."

It is the Warburg Effect that enables imaging of actively growing tumors by positron emission tomography ("PET scans"). The success of PET scanning points to the potential therapeutic benefit of the tumor-specific inhibition of glycolysis that would block energy (adenosine triphosphate ("ATP")) production and could potentially "starve tumor cells to death" and/or make them sensitive to other existing therapies, including radiotherapy.


We have designed and are studying a novel and patented prodrug of "2-deoxy-D-glucose" (2-DG) (WP1122). We believe WP1122 has the potential for developing into a technology platform for enabling increased cellular uptake, increased drug half-life and, importantly, enabling greater uptake and retention in organs where the most

resistant and glycolytic tumors are localized, including the brain and pancreas.

Altering Glycosylation to Enhance Immune Checkpoint Therapy

A recently published study (Am J Cancer Res, 8(9), 1837-1846, 2018) focused on the analysis of tumor resistance to immune checkpoint therapy. The study found that a process known as glycosylation plays an important role in the ability of checkpoint receptors to suppress immune activity and thereby protect tumors from attack. The researchers discovered that an alteration of the glycosylation of these receptor mechanisms could effectively prevent this evasion of the immune system. Although the data are preliminary, the findings suggest that 2-DG could act as an effective anticancer agent in combination with checkpoint inhibitors and potentially with other anticancer therapies.

2-DG's short circulation time and lack of other drug-like properties mean the drug does not stay in the system long enough or concentrate sufficiently in targeted organs, which severely limits its effectiveness. This suggests a possible role for our patented drug candidate, WP1122. WP1122 is a prodrug of 2-DG, meaning it is a molecule that may be able to be converted into pharmacologically active 2-DG within the body of the patient. The design of WP1122 is intended to allow for a longer circulation time and improved organ distribution, which should provide it a greater opportunity to become an effective drug.



We are dedicated to developing therapies that can extend and improve the lives of those affected with rare and difficult cancers.

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, 2018

Commission File Number: 001-37758



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

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

47-4671997
(I.R.S. Employer
Identification Number)

5300 Memorial Drive, Suite 950
Houston, Texas 77007
(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 every Interactive Data File required to be submitted 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 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 ☐

Non-accelerated filer ☒

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 \$38,692,158. 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 February 1, 2019 was 28,528,663.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of this registrant's definitive proxy statement for its 2019 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.

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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 effects of future government shutdowns on our ability to raise financing;
- 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 product candidates;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- the ability of our sublicense partners to successfully develop our product candidates in accordance with our sublicense agreements;
- 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

Moleculin Biotech, Inc., a Delaware corporation, is a clinical stage pharmaceutical company focused on the treatment of highly resistant cancers. We have three core technologies, all of which are based on discoveries made at M.D. Anderson Cancer Center (“MD Anderson”). We have three drugs in four clinical trials in the US and Poland. Our clinical stage drugs are Annamycin, believed by management to be a “Next Generation” Anthracycline, being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML, and WP1066, an Immune/Transcription Modulator targeting brain tumors, pancreatic cancer and AML. Additionally, a third drug, WP1220 (a molecule similar to WP1066), was approved for a clinical trial in January 2019 in Poland for the topical treatment of cutaneous T-cell lymphoma. We are also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as Metabolism/Glycosylation Inhibitors.

We believe that our Next Generation Anthracycline, Annamycin, is unlike any currently approved anthracyclines, as it is designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity – hence the use of the term “Next Generation.” Annamycin has preliminary clinical data suggesting its potential to become the first successful therapy suitable for the majority of relapsed or refractory AML patients and is currently in two Phase I/II clinical trials.

WP1066 is one of several Immune/Transcription Modulators designed to stimulate the immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs) while also inhibiting key oncogenic transcription factors, including p-STAT3, c-Myc and HIF-1 α . These transcription factors are widely sought targets that may also play a role in the inability of immune checkpoint inhibitors to affect more resistant tumors.

We are also developing new compounds designed to exploit the potential uses of inhibitors of glycolysis such as 2-deoxy-D-glucose (“2-DG”), which we believe may provide an opportunity to cut off the fuel supply of tumors by taking advantage of their high level of dependence on glucose in comparison to healthy cells. A key drawback to 2-DG is its lack of drug-like properties, including a short circulation time and poor tissue/organ distribution characteristics. Our lead Metabolism/Glycosylation Inhibitor, WP1122, is a prodrug of 2-DG that appears to improve the drug-like properties of 2-DG by increasing its circulation time and improving tissue/organ distribution. New research also points to the potential for 2-DG to be capable of enhancing the usefulness of checkpoint inhibitors. Considering that 2-DG lacks sufficient drug-like properties to be practical in a clinical setting, we believe WP1122 may also become an important drug to potentiate checkpoint inhibitors.

Mission and Strategy

Moleculin is focused on developing treatments for highly resistant cancers. These include AML, glioblastoma, cutaneous t-cell lymphoma, pancreatic cancer, and others. Our diverse pipeline of technologies was built around the recognition that many highly resistant tumors tend to have a common set of traits, including an increase in multidrug resistant mechanisms, an evasion of the natural immune system, a marked upregulation of certain key oncogenic transcription factors and an increased dependence on glycolysis for energy production. We believe each of these elements may be addressed by the unique and innovative mechanisms introduced by one or more of our three core technologies.

We believe this approach not only provides the opportunity to help the many patients in need of alternative therapies, but also to work in combination with numerous existing technologies that often fail as tumors present immediate or acquired resistance. We believe showing even modest improvements in highly resistant cancers may lead to accelerated approval pathways, potentially reducing the time and capital required to ultimately realize success.

Corporate Overview

We were founded in 2015 in order to combine and consolidate the development efforts involving several oncology technologies, based on license agreements with MD Anderson. 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, on behalf of Moleculin, LLC, we entered into a co-development agreement with Houston Pharmaceuticals, Inc., or HPI, which culminated with the merger of Moleculin, LLC into MBI coincident with our initial public offering allowing us to gain control of the WP1066 Portfolio.

Moleculin, LLC was formed in 2006 and was working to develop the WP1066 Portfolio it licensed from MD Anderson. On May 2, 2016, Moleculin, LLC was merged with and into MBI. As a result of the merger, we issued the holders of Moleculin, LLC equity interests and convertible notes representing in the aggregate approximately 999,931 shares of our common stock. Since Moleculin, LLC commenced operations in 2006, substantially all of its efforts had been focused on research, development and the advancement of the WP1066 Portfolio. Moleculin, LLC did not generate any revenue from product sales and, as a result, incurred significant losses.

In June 2018, we formed Moleculin Australia Pty. Ltd., a wholly-owned subsidiary to oversee pre-clinical development in Australia. The Australian government provides an aggressive incentive for research and development carried out in their country. We believe having an Australian subsidiary could provide a great opportunity to speed up pre-clinical development and reduce the overall cost of our continued drug development efforts.

We do not have manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, we do not have a sales organization.

Technology Overview

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, but 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 (“ODD”) from the FDA for Annamycin for the treatment of AML and, subsequent to December 31, 2018, we received ODD for WP1066 for the treatment of glioblastoma. If we receive approval for either product for the orphan use, we may obtain market exclusivity of 7 years from the date of approval of a New Drug Application (“NDA”) in the United States. During that period FDA generally could not approve another product with the same active moiety 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.

Next Generation Anthracycline

Chemotherapy continues to be a cornerstone of cancer therapy. Despite the progress made with immunotherapy and precision medicine, the first-line treatment for many cancers continues to include chemotherapy. And, in part because of the emphasis placed on alternatives to chemotherapy, we believe that not enough has been done to improve chemotherapeutic agents to make them safer and more effective. Anthracyclines are a class of chemotherapy drugs designed to destroy the DNA of targeted cancer cells. Acute leukemia is one of a number of cancers that are usually treated with anthracyclines. In the case of acute leukemia, anthracyclines are typically used in “induction therapy,” where the goal is to induce sufficient remission of patients’ blood-born tumor cells to allow for a curative bone marrow transplant.

Two key factors limit the safety and effectiveness of anthracyclines: cardiotoxicity (potential to damage the heart) and multidrug resistance. We believe Annamycin may overcome these two factors; if preliminary data are borne out, Annamycin may ultimately provide clinically meaningful benefits over currently approved anthracyclines in treating certain cancers. Preliminary data from very early-stage clinical trials suggest acute leukemia as a potentially opportune indication in which to further study Annamycin.

One of the key dose-limiting toxicities associated with currently available anthracyclines (including the anthracycline in the recently approved drug, Vyxeos) is the propensity to induce life-threatening heart damage (also known as cardiotoxicity). This is a particularly significant risk for pediatric leukemia patients, whose life spans can be severely shortened by the induction therapy intended to cure them of acute leukemia. In the animal model recommended 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. If this characteristic is shown to be the same in humans, it may allow L-Annamycin to be used more aggressively to help patients achieve remission. This would be especially valuable in the case of pediatric acute leukemia (both AML and ALL) because of the potential impact of cardiotoxicity on long-term survival. In our current Phase I/II trial for Annamycin, we are collecting 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).

In addition, the effectiveness of currently approved anthracyclines is limited by their propensity for succumbing to “multidrug resistance.” This can occur where, as a natural defense mechanism, transmembrane proteins acting as transporters (one type of which is referred to as a “P-glycoprotein pump” or “ABCB1 transporter”) develop on the outer surface of cells to expel perceived threats like anthracyclines. In many instances, the likelihood of cardiotoxicity (and other serious side effects) prevents increasing the dosing of current therapies in order to overcome multidrug resistance. As a result, most patients cannot receive current anthracyclines in doses that are adequate to produce lasting remission and thereby qualify for a bone marrow transplant. A laboratory study has suggested that Annamycin may resist being expelled by P-glycoprotein pumps and similar 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.

Immune/Transcription Modulators: Enabling Immune Response and Inhibiting p-STAT3 and other Oncogenic Transcription Factors –

We believe our WP1066 Portfolio (including lead drugs WP1066, WP1220 and WP1732) represents a novel class of agents capable of hitting multiple targets, including the activated form of a key oncogenic transcription factor, STAT3. A substantial body of published research has identified STAT3 as a master regulator of a wide range of tumors and has linked the activated form, p-STAT3, with the survival and progression of these tumors. For this reason, it is widely believed that targeted inhibition of p-STAT3 may be an effective way to reduce or eliminate the progression of these diseases.

The high level of anticancer activity demonstrated in multiple tumors in animal models by WP1066 and WP1732 is potentially related to their ability to also inhibit such important key oncogenic transcription factors like c-Myc and HIF-1 α . In addition to direct anticancer effects not related to the function of the immune system, our lead drug WP1066 has also been shown to boost immune response in animals, in part by inhibiting activity of Regulatory T cells (Tregs), which are coopted by tumors to evade the immune system. We believe the dual effect of (1) directly inhibiting tumor growth and inducing tumor cell death and (2) separately boosting and directing the natural immune response to tumors is therapeutically highly promising. If additional preclinical and clinical data validate the two avenues of apparent activity, this class of drugs may be well-suited to treat a wide range of tumors, both as single agents and as critical elements of successful combination therapies targeting even some of the most difficult-to-treat cancers.

The recent oncology drug landscape has been dominated by immunotherapy, specifically including checkpoint inhibitors. In just the last 5 years, checkpoint inhibitors (such as Opdivo and Keytruda) have reached over \$10 billion in annual revenues. To summarize checkpoint blockade therapy, the T-Cells within an individual’s own immune systems should be capable of identifying tumor cells and destroying them before they destroy the individual. Unfortunately, tumors develop the ability to prevent this natural immune response by regulating the expression of certain receptors referred to as “immune checkpoints” that then bind to T-Cells and prevent them from attacking the tumor. Immune checkpoint inhibitors are antibodies that block these receptor mechanisms and allow the T-Cells to act normally and attack the tumor.

In certain types of tumors, like melanoma, checkpoint inhibitors work well and the results can be impressive, creating durable suppression of tumors where no other therapy had succeeded. However, despite the outstanding results in select patients, checkpoint inhibitors benefit only a limited number of patients in certain cancers, and they are essentially not effective in what are called “non-responsive” tumors like glioblastoma and pancreatic cancer, among others. As a result, companies are now focusing heavily on combination therapies, combining immune checkpoint inhibitors with chemotherapy, as well as other agents. There appears to be tremendous demand and we believe there is a clear need for new chemotherapeutic agents that, by their specific mechanism of action, would produce potent combination effects with immune checkpoint inhibitors, and that additionally can boost immune system response on their own. In this regard, there is early nonclinical evidence that WP1066, as a single agent, has the ability to reverse immune tolerance in brain tumor patients (Cancer Res, 67(20), 9630, 2007), and preliminary data in animal models that suggests WP1066 may have a potential for combination use with checkpoint inhibitors.

Recently published research papers have presented several findings that may point to major new opportunities for Moleculin’s WP1066 class of drugs. One such article suggested that our STAT3 inhibitor WP1066 abrogated PD-L1/2 expression in cancer cells and may be a useful agent in addition to checkpoint inhibitor immunotherapy in cancer patients (J Clin Exp Hematop, 57(1), 21-25, 2017). Other published results show that CTLA4-induced immune suppression occurs primarily via an intrinsic STAT3 pathway, suggesting that, through its inhibition of activated STAT3, WP1066 might work well in combination with this checkpoint inhibitor (Cancer Res, 77(18), 5118–28, 2017).

A separate paper presents selected key transcription factors as being responsible for the upregulation of an often-targeted checkpoint actor in tumors known as PD-L1. Some of the most important transcription factors identified were HIF-1 α , c-Myc and STAT3, the very targets for which WP1066 was designed (Front Pharmacol, 2018 May 22, 9:536, doi: 10.3389/fphar.2018.00536, eCollection 2018). In summary, although much of the data is nonclinical and all of it is preliminary, we are

optimistic that administration of WP1066 could lead to improved treatment results in many patients receiving checkpoint inhibitor therapy.

Metabolism/Glycosylation Inhibitors: Using the Warburg Effect to Starve Tumor Cells to Death –

Science has recognized that many types of cancer cells have a unique metabolism, distinct from that of normal cells. Cancer cells' dependence on glycolysis (a specific way of converting glucose into energy) to proliferate and metastasize has been described as the "sweet tooth of cancer" and is a classic example of how the metabolism of cancer cells and normal cells differ. Glycolysis is a glucose-intensive means of producing energy that is used by normal cells only if oxygen levels are low. However, many types of tumor cells are essentially addicted to glycolysis even in the presence of abundant oxygen. This is known as the "Warburg Effect" after its discoverer, Dr. Otto Warburg, and such tumors are said to be highly "glycolytic."

This phenomenon of tumors relying preferentially on glycolysis and the resulting dramatic increase of glucose uptake to fulfill their metabolic demands has already been utilized very effectively in cancer diagnostics. It is the Warburg Effect that enables imaging of actively growing tumors by positron emission tomography ("PET scans"). This diagnostic test uses a fluorine-18 radiolabeled glucose decoy called F18DG that accumulates disproportionately in tumors, using the same process that increases glucose uptake and retention in cancer cells.

The success of PET scanning points to the potential therapeutic benefit of the tumor-specific inhibition of glycolysis that would block energy (adenosine triphosphate ("ATP")) production and could potentially "starve tumor cells to death" and/or make them sensitive to other existing therapies, including radiotherapy. Unsuccessful attempts to realize this therapeutic potential have been made in the past, using a glucose decoy known as "2-deoxy-D-glucose" (2-DG). Those attempts to target the metabolism of tumor cells have failed, we believe, because of 2-DG's lack of drug-like properties that include rapid metabolism, short half-life and limited tissue-organ distribution. Essentially, not enough 2-DG could be delivered to its intended target.

We have designed and are studying a novel and patented prodrug of 2-DG (WP1122). We believe WP1122 has the potential for developing into a technology platform for enabling increased cellular uptake, increased drug half-life and, importantly, enabling greater uptake and retention in organs where the most resistant and glycolytic tumors are localized, including the brain and pancreas.

Altering Glycosylation to Enhance Immune Checkpoint Therapy –

A recently published study (Am J Cancer Res, 8(9), 1837-1846, 2018) focused on the analysis of tumor resistance to immune checkpoint therapy. The study found that a process known as glycosylation plays an important role in the ability of checkpoint receptors to suppress immune activity and thereby protect tumors from attack. The researchers discovered that an alteration of the glycosylation of these receptor mechanisms could effectively prevent this evasion of the immune system. This study found that 2-deoxyglucose, or 2-DG, was capable of making this alteration. Although the data are preliminary, the findings suggest that 2-DG could act as an effective anticancer agent in combination with checkpoint inhibitors and potentially with other anticancer therapies.

Attempting to use 2-DG as a drug, however, faces the same problems discussed above. 2-DG's short circulation time and lack of other drug-like properties mean the drug does not stay in the system long enough or concentrate sufficiently in targeted organs, which severely limits its effectiveness. This suggests a possible role for our patented drug candidate, WP1122. WP1122 is a prodrug of 2-DG, meaning it is a molecule that may be able to be converted into pharmacologically active 2-DG within the body of the patient. The design of WP1122 is intended to allow for a longer circulation time and improved organ distribution, which should provide it a greater opportunity to become an effective drug.

We intend to study WP1122 for both its ability to directly inhibit tumor activity and to potentiate existing therapies via an inhibition of tumor metabolism and to improve the performance of checkpoint inhibitors by reducing the effect of glycosylation and have begun the necessary preclinical work required to file an IND.

Clinical Activity

Annamycin had previously been in clinical trials with a prior drug developer pursuant to an application for Investigational New Drug status ("IND") that had been filed with the FDA. Due to a lack of development activity by the 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. Patient treatment began in the US in March 2018. We are in the first cohort in our Phase I portion of the trial.

With regard to additional potential Annamycin clinical activity, we received Polish National Office approval in June 2018 for a Clinical Trial authorization (“CTA”) in Poland, which enables us to begin a Phase I/II clinical trial there to study Annamycin for the treatment of relapsed or refractory AML. In Poland, while the clinical trial and the first site were approved in June 2018, we were required to obtain final approval by two different authorities - one in Europe and one in Poland – to ship Annamycin drug product to Poland. Such approval is not necessary for use of Annamycin drug product in the US and we have Annamycin drug product ready and available in the US to treat potential patients. For Poland, we obtained the necessary approvals in November and December 2018 and shipped Annamycin drug product in late December 2018. In January 2019, we began screening patients in Poland.

We continue to recruit and contract with clinics both in the United States and Poland. We can provide no assurance of additional recruitment or that treatments will occur in the near term and on a timely basis, if at all.

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. In July 2018, this trial opened for recruitment in the US. This trial is now in its third cohort of the Phase I portion of the planned protocol. Because this trial is physician led, we are limited in our ability to manage the trial.

With regard to additional potential clinical activity on other drugs, in September 2017 we engaged a 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”). In 2018, we filed a CTA in Poland for this trial, which was approved in January 2019, giving us a third drug in clinic and our fourth clinical trial.

On May 1, 2018, we engaged another CRO to evaluate additional countries for the expansion of our AML clinical trial, specifically Australia and several Western European countries to provide additional clinical sites to improve access for patients to our Phase I/II trial.

We have begun planning and performing the necessary pre-clinical work required to submit an IND for WP1732 and WP1122. In June 2018, we entered into an agreement with The University of Iowa Pharmaceuticals for the development of a formulation for WP1732. This agreement marked the beginning of creating a preclinical package to submit to the FDA in order to request Investigational New Drug status. We have now completed formulation development, and our IND-enabling toxicology work will be progressing via our Australian subsidiary, Moleculin Australia, and we expect to submit an IND in the US in 2019.

We also continue to sponsor ongoing research at MD Anderson in order to improve and expand our drug development pipeline.

Our Drug Candidates

Annamycin

One of our lead product candidates 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 are conducting 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 $\leq 5\%$ blasts, granulocyte count of $\geq 1 \times 10^9/L$, and a platelet count of $\geq 100 \times 10^9/L$. 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 $\geq 100 \times 10^9/L$.” 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).

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 believe 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. 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.

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 begins with a therapy referred to as “7+3,” which consisted of combining seven injections of Cytarabine 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.

Clinical Trials for Annamycin

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, in February 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. Patient treatment began in the US in March 2018. We are in the first cohort in our Phase I portion of the trial.

With regard to additional potential Annamycin clinical activity, 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 which was received.

We received Polish National Office approval in June 2018 for a CTA in Poland, which enables us to begin a Phase I/II clinical trial there to study Annamycin for the treatment of relapsed or refractory AML. In Poland, while the clinical trial and the first site were approved in June 2018, we were required to obtain final approval by two different authorities - one in Europe and one in Poland – to ship Annamycin drug product to Poland. Such approval is not necessary for use of Annamycin drug product in the US and we have Annamycin drug product ready and available in the US to treat potential patients. We obtained the necessary approvals in November and December 2018 and shipped Annamycin drug product in December 2018. In early 2019 we began screening new patients in Poland.

We continue to recruit and contract with clinics both in the United States and Poland. We can provide no assurance of additional recruitment or that treatments will occur in the near term and on a timely basis, if at all.

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, which we refer to as 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 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.

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 perceived threats 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.

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. Subsequent to December 31, 2018, the FDA granted and Orphan Drug Designation (“ODD”) for WP1066 for the treatment of glioblastoma.

WP1066

WP1066 is our flagship Immune/Transcription Modulator. It has been the subject of over 50 peer-reviewed articles and its activity against p-STAT3 has now been validated in independent labs around the globe. This breakthrough discovery was inspired by a naturally occurring compound (caffeic acid) in propolis (from honey bees). Caffeic acid has shown a natural ability to inhibit p-STAT3, which is considered a master regulator of inflammatory processes that support tumor survival and proliferation.

WP1066 has exhibited an ability to inhibit other key oncogenic transcription factors, including c-Myc and HIF-1 α . A critical characteristic of WP1066 and its analogs is the ability to inhibit p-STAT3 independently of upstream cell signaling. We believe this overcomes the limitations of many other drugs designed to inhibit STAT3 activity by blocking upstream receptors.

Another important attribute of WP1066 (unlike some of our other Immune/Transcription Modulators) is its ability to cross the blood brain barrier, which we believe makes it a good candidate for potentially treating brain tumors and other malignancies of the central nervous system.

WP1066 has shown significant anti-tumor activity and increased survival in a wide range of tumor cell lines and animal models and this activity has been validated in multiple independent institutions worldwide.

As with other analogs in this portfolio, WP1066 also has a demonstrated ability to boost a natural immune response to tumor activity. In animal models, WP1066 has been shown to upregulate STAT1, a transcription factor associated with immune stimulation. At the same time, it has been shown to reduce levels of Regulatory T-Cells, or TRegs, which are coopted by tumors to protect themselves from attack by the patient's natural immune system. This forms a unique dual action (directly attacking the transcription factors that support tumor development and separately boosting the natural immune response to tumors) that may make WP1066 uniquely suited to treat a wide range of tumors and may also serve as an important element in combination therapies targeting some of the most difficult cancers.

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.

More recently, our own sponsored research and published findings from independent researchers point to the possibility that administration of WP1066 could lead to improved treatment results in many patients receiving checkpoint inhibitor therapy.

Clinical Activity

WP1066 is currently being studied in a dose-escalation Phase I brain tumor clinical trial via an investigator-initiated IND with MD Anderson Cancer Center and we recently announced pharmacokinetic data from that trial. That data demonstrated sufficient bioavailability of our drug via oral administration to show the presence of WP1066 in blood plasma on a dose-dependent basis. Investigators at MD Anderson are now in the midst of the 3rd dose escalation cohort in this trial. At the most recent annual meeting of the Society for Neuro Oncology (SNO), Emory University researchers reported encouraging activity in animals with their in vitro pediatric brain tumor models using WP1066. Based on this data, they have indicated their intent to begin a trial for pediatric brain tumors in humans, although we can provide no assurance regarding the likelihood and timing of such trial.

This Phase I trial with WP1066 drug is being supported by \$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 Molculin's financial statements, but instead are applied to the cost of preclinical and clinical activities at and conducted by MD Anderson.

As with brain tumors, AML is often associated with a high upregulation of p-STAT3. Since WP1066 is a potent inhibitor of p-STAT3 and the MD Anderson brain tumor trial is now indicating the ability to get WP1066 into patients' bloodstreams, we could now have a new way to combat AML, in addition to our Next Generation Anthracycline, Annamycin. In collaboration with Dr. Jorge Cortes of MD Anderson Cancer Center, Professor Waldemar Priebe, our drug's inventor, has now been able to demonstrate activity of WP1066 against AML cell lines in vitro. We believe the data now supports a move to get WP1066 into clinical studies for the treatment of AML.

WP1220

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 for a proof-of-concept clinical trial in Poland to study WP1220 for the topical treatment of CTCL. We submitted the CTA request to Polish regulatory authorities in 2018 and announced their approval of the CTA in February 2019. With this announcement, we now have three drugs in clinical, with a total of four clinical trials, representing a major milestone for Moleculin.

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 discovery – WP1732, a new molecule in the WP1066 portfolio – in our effort to develop a new cancer treatment that effectively targets 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 the same level of immune stimulation and inhibition of oncogenic transcription factors (including p-STAT3) as WP1066.

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 we believe its significantly increased solubility makes it ideal for administration via standard intravenous (IV) injection. In addition, preclinical testing has also shown that, while WP1732 does not appear to cross the blood brain barrier, it appears to accumulate disproportionately in the pancreas, making it a potentially 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. In June 2018, we entered into an agreement with The University of Iowa Pharmaceuticals for the development of a formulation for WP1732. This agreement marked the beginning of creating a preclinical package to submit to the FDA in order to request Investigational New Drug status. We have now completed formulation development, and our IND-enabling toxicology work will be progressing via our Australian subsidiary, Moleculin Australia, and we expect to submit an IND in the US in 2019.

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 focused on inhibitors of glycolysis and glycosylation.

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 currently focused on the use of WP1122 and related analogs for the treatment of central nervous system malignancies and especially glioblastoma multiforme (“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 23,820 new cases of brain and other nervous system cancers will occur in the United States in 2019, resulting in 17,760 deaths. Despite the severity and poor prognosis of these tumors, there are few FDA-approved drugs on the market.

WP1122

Moleculin is engaged in developing new drugs to exploit the metabolic differences between tumor cells and normal cells. With our lead Metabolism/Glycosylation Inhibitor compound, WP1122, we have been primarily focused on metabolically active brain cancers, taking advantage of the differential utilization of glucose by cancerous tissue versus normal brain cells. Moleculin believes that targeting this difference in metabolism is a promising, yet relatively unexplored strategy and could make its product candidates applicable to many other cancers.

Science has recognized that many types of cancer cells have a unique metabolism, distinct from that of normal cells. Cancer cells’ dependence on glycolysis (a specific way of converting glucose into energy) to proliferate and metastasize has been described as the “sweet tooth of cancer” and is a classic example of how the metabolism of cancer cells and normal cells differ. Glycolysis is a glucose-intensive means of producing energy that is used by normal cells only if oxygen levels are low. However, many types of tumor cells are essentially addicted to glycolysis even in the presence of abundant oxygen. This is known as the “Warburg Effect” after its discoverer, Dr. Otto Warburg, and such tumors are said to be highly “glycolytic.”

This phenomenon of tumors relying preferentially on glycolysis and the resulting dramatic increase of glucose uptake to fulfill their metabolic demands has already been utilized very effectively in cancer diagnostics. It is the Warburg Effect that enables imaging of actively growing tumors by positron emission tomography (“PET scans”). This diagnostic test uses a

fluorine-18 radiolabeled glucose decoy called F18DG that accumulates disproportionately in tumors, using the same process that increases glucose uptake and retention in cancer cells.

The success of PET scanning points to the potential therapeutic benefit of the tumor-specific inhibition of glycolysis that would block energy (adenosine triphosphate (“ATP”)) production and could potentially “starve tumor cells to death” and/or make them sensitive to other existing therapies, including radiotherapy. Unsuccessful attempts to realize this therapeutic potential have been made in the past, using a glucose decoy known as “2-deoxy-D-glucose” (2-DG). Those attempts to target the metabolism of tumor cells have failed, we believe, because of 2-DG’s lack of drug-like properties that include rapid metabolism, short half-life and limited tissue-organ distribution. Essentially, not enough 2-DG could be delivered to its intended target.

We have designed and are studying a novel and patented prodrug of 2-DG (WP1122). We believe WP1122 has the potential for developing into a technology platform for enabling increased cellular uptake, increased drug half-life and, importantly, enabling greater uptake and retention in organs where the most resistant and glycolytic tumors are localized, including the brain and pancreas.

WP1122 is a prodrug of a well-known glucose decoy called 2-deoxyglucose, or 2-DG, which enables 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 fold 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.

We believe based on pre-clinical testing that, just like heroin, WP1122 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 of using 2-DG in the treatment of tumors is the relatively short half-life of 2-DG and its general lack of drug-like properties preventing adequate accumulation in targeted organs. The free form of 2-DG is rapidly metabolized and rendered ineffective within minutes of entering the body. In contrast, WP1122 has a half-life of approximately 6 hours, making it much more feasible to deliver quantities adequate for a therapeutic effect. Animal studies have now shown that the prodrug structure of WP1122 results in accumulation in certain targeted organs, including the pancreas, making it a potentially good candidate for targeting pancreatic cancer.

WP1122 and its analogs (molecules with similar structures) have shown activity against brain tumor cell lines in in vitro testing and in an orthotopic brain tumor (implanted in the brain) animal model. In such studies, one candidate was shown to outperform Merck’s Temodar®, the frontline FDA approved drug, which is considered the standard of care for the treatment of brain tumors. The market for Temodar® has reached nearly \$1 billion in annual revenue. We believe that WP1122 and similar compounds have the potential to address a significant unmet need in the treatment of brain tumors and may be applicable to other difficult-to-treat, glucose dependent tumors, such as pancreatic cancer.

Enhancing Immune Checkpoint Therapy

Immune checkpoint therapy has gained wide recognition as an important new approach to treating cancer, however many tumors appear to be resistant to immune checkpoint therapy and recent efforts to understand why have resulted in important new findings. A recently published study focused on this issue found that a process known as glycosylation plays an important role in the ability of checkpoint receptors to suppress immune activity and thereby protect tumors from attack. Beyond this, however, the researchers discovered that an alteration of the glycosylation of these receptor mechanisms could effectively prevent this evasion of the immune system. This study found that 2-DG was capable of making this alteration. These findings suggest that 2-DG could be beneficial as an anticancer agent in combination with checkpoint inhibitors and potentially with other anticancer therapies.

WP1234

In June 2017, we announced the discovery of a metabolic inhibitor with what may be increased 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 (energy production by cells required when sufficient oxygen is not available) 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 and providing other critical drug-like properties, which we believe 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, the American Cancer Society estimates that in 2019, nearly 1.7 million new cases will be diagnosed and over 600,000 Americans will die from cancer.

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 27,380 of the estimated 61,780 new cases expected in the United States in 2019.

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 and WP1066, both of which have 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 and License Agreements with MD Anderson

We license all of our technology from MD Anderson and we also sponsor research there as well. Under license agreements associated with Annamycin, the WP1122 Portfolio, and the WP1066 Portfolio, which includes WP1732, all described below, we are responsible for certain license, milestone and royalty payments over the course of the agreements. Annual license fees, prior to the first sale of a licensed product, can be as high as \$100,000 depending upon the anniversary. Milestone payments for the commencement of phase II and phase III clinical trials can cost as high as \$500,000. Other milestone payments for submission of an NDA to the FDA and receipt of first marketing approval for sale of a license product can be as high as \$600,000. Royalty payments can range in the single digits as a percent of net sales on drug products or flat fees as high as \$600,000, depending upon certain terms and conditions. Not all of these payments are applicable to every drug. Total expenses under these agreements were \$0.3 million and \$0.2 million for the year ended December 31, 2018 and 2017.

With regard to the sponsored research agreements with MD Anderson, we amended our Sponsored Laboratory Study Agreement with MD Anderson on January 9, 2017 whereby we paid \$0.3 million in 2017, and the agreement was extended to October 31, 2018. On December 4, 2017, MBI we extended this agreement until October 31, 2019 for total payment amount of

\$0.35 million spread over that period of time. Of this amount, \$0.24 million was paid in the first quarter of 2018 and the final payment of \$0.11 million was paid in the third quarter of 2018. On September 25, 2018, we extended this agreement until October 31, 2020 for a total payment amount of \$0.4 million spread over that period of time. Of this amount, \$0.27 million was paid in the fourth quarter of 2018, and the final payment of \$0.13 million was paid in 2019. The expenses recognized under the MD Anderson agreement with regards to the Sponsored Laboratory Study were \$0.4 million and \$0.2 million for the year ended December 31, 2018 and 2017.

Annamycin

In 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 terms and payments of which are included in the summary above.

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 terms and payments of which are included in the summary above.

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. We have accrued the \$1.0 million payment and intend to make the payment, subject to available funding.

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. The terms and payments of which are included in the summary above.

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. The terms and payments of which are included in the summary above.

WPD Licensing Agreement

We entered into an agreement with WPD Pharmaceuticals (“WPD”), as described below. Such licensing agreements in Poland, we believe, may provide access to Polish grant money. We have previously entered into similar agreements with Dermin s.p. z.o.o. with some of our technologies in the same territories and Dermin has succeeded in obtaining grant funding in Poland benefiting our development objectives. We believe this is a potential non-dilutive source of capital. Furthermore, we believe that an added and extremely important benefit of this approach is that Moleculin does not have to invest its own resources in establishing an EU-based infrastructure that would be required to access such grant funding on our own. We believe this arrangement is consistent with our low overhead, capital efficient approach to development.

On February 19, 2019, we sublicensed certain intellectual property rights, including rights to Annamycin, our WP1122 portfolio, and our WP1066 portfolio to WPD Pharmaceuticals (“WPD”) (the “WPD Agreement”). WPD is affiliated with Dr. Waldemar Priebe, our founder and largest shareholder. Under the WPD Agreement, we granted WPD a royalty-bearing, exclusive license to research, develop, 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 Germany, Poland, Estonia, Latvia, Lithuania, Belarus, Ukraine, Moldova, Romania, Armenia, Azerbaijan, Georgia, Slovakia, Czech Republic, Hungary, Uzbekistan, Kazakhstan, Greece, Austria, Russia, Netherlands, Turkey, Belgium, Switzerland, Sweden, Portugal, Norway, Denmark, Ireland, Finland, Luxembourg, Iceland (“licensed territories”), provided that we have the right to buyback Germany from the licensed territories by making a cash payment \$500,000, or by issuing 235,850 shares of our common stock.

In consideration for entering into the WPD Agreement, WPD agreed that it must use Commercially Reasonable Development Efforts to develop and commercialize products in the licensed territories. For purposes of the WPD Agreement, the term “Commercially Reasonable Development Efforts” means the expenditure by or on behalf of WPD or any of its affiliates of at least: (i) \$2,000,000 during the first two years of the agreement on the research, development and commercialization of products in the licensed territories; and (ii) \$1,000,000 annually for the two years thereafter on the research and development of products in the licensed territories.

In addition, within sixty days we agreed to transfer to WPD certain development data, and, in exchange for such development data, WPD agreed to make a development reimbursement fee to us in the amount of \$300,000 (the “Development Reimbursement Fee”) within the first year of the agreement. Should WPD fail to make the Development Reimbursement Fee, then at our sole discretion: (i) Germany shall no longer be a part of the licensed territories; or (ii) the Commercially Reasonable Development Efforts during the first two years of the agreement shall increase from \$2,000,000 to \$2,500,000.

During the term of the WPD Agreement, to the extent we are required to make any payments to MD Anderson pursuant to our license agreements with MD Anderson, whether a milestone or royalty payment, as a result of the research and development or sale of a sublicensed product, WPD shall be required to advance or reimburse us such payments. In further consideration for the rights granted by us to WPD under the WPD Agreement, WPD agreed to pay us a royalty percentage at a rate equal to the royalty rate we owe MD Anderson under our license agreements with MD Anderson plus an additional royalty (the “override royalty percentage”) equal to 1.0% of net sales of any sublicensed products, provided, however, if WPD spends: (i) more than \$5,000,000 in Commercially Reasonable Development Efforts prior to the fifth anniversary of the date of the agreement and more than \$6,000,000 in Commercially Reasonable Development Efforts prior to the sixth anniversary of the date of the agreement, the override royalty percentage will decrease to 0.75% of net sales; or (ii) more than \$6,000,000 in Commercially Reasonable Development Efforts prior to the fifth anniversary of the date of the agreement and more than \$8,000,000 in Commercially Reasonable Development Efforts prior to the sixth anniversary of the date of the agreement, the override royalty percentage will decrease to 0.5% of net sales.

With certain exceptions, the WPD Agreement will remain in full force and effect until the expiration of the last patent within the sublicensed patents. Notwithstanding the foregoing, we have the right, in our sole discretion, to terminate the WPD Agreement in whole, or to materially amend the agreement by removing a portion of the sublicensed subject matter, in connection with certain fundamental transactions or in connection with the granting to an unaffiliated third party of a license or sublicense to all or to a material portion of the sublicensed subject matter within all or substantially all of the licensed territories (such event, the “buyback event”) by making a payment to WPD equal to a percentage of the consideration after transaction costs we receive in connection with the buyback event. The percentage payable will be the greater of: (i) 2% increasing to 5% upon the completion by WPD of its initial public offering, provided such offering provides WPD with net proceeds of not less

than \$2.0 million; or (ii) 10% multiplied by a fraction (A) the numerator of which is the total dollar amount of expenditures made by WPD that represent Commercially Reasonable Development Efforts under the WPD Agreement, up to a maximum of \$2.0 million; and (B) the denominator of which is \$2.0 million.

Prior to approval of the WPD Agreement, our board of directors received a fairness opinion from Roth Capital Partners, LLC stating their opinion that the consideration we will receive from WPD pursuant to the WPD Agreement is fair, from a financial point of view, to us.

Animal Life Sciences Licensing Agreement

On February 19, 2019, we sublicensed certain intellectual property rights, including rights to Annamycin, our WP1122 portfolio, and our WP1066 portfolio in the field of non-human animals to Animal Life Sciences, LLC (“ALI”) (the “ALI Agreement”). ALI is affiliated with Dr. Waldemar Priebe, our founder and largest shareholder. Under the ALI Agreement, we granted ALI a worldwide royalty-bearing, exclusive license to research, develop, manufacture, have manufactured, use, import, offer to sell and/or sell products in the field of non-human animals under the licensed intellectual property.

During the term of the ALI Agreement, to the extent we are required to make any payments to MD Anderson pursuant to our license agreements with MD Anderson, whether a milestone or royalty payment, as a result of the research and development or sale of a sublicensed product, ALI shall be required to advance or reimburse us such payments. In further consideration for the rights granted by us to ALI under the ALI Agreement, ALI agreed to pay us a royalty percentage at a rate equal to the royalty rate we owe MD Anderson under our license agreements with MD Anderson plus an additional royalty equal to 5.0% of net sales of any sublicensed products. As additional consideration, ALI issued us a 10% ownership interest in ALI.

With certain exceptions, the ALI Agreement will remain in full force and effect until the expiration of the last patent within the sublicensed patents.

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.

In June 2018, we formed Moleculin Australia Pty. Ltd., a wholly-owned subsidiary to oversee pre-clinical development in Australia. The Australian government provides an aggressive incentive for research and development carried out in their country. We believe having an Australian subsidiary could provide a great opportunity to speed up pre-clinical development and reduce the overall cost of our continued drug development efforts.

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 one of 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 candidate, 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 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.

Employees

As of December 31, 2018, we had nine 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.

Legal Proceedings

We are not subject to any litigation.

Access to Information

Our website is at www.moleculin.com. We make available, free of charge, on our corporate website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as soon as reasonably practicable after they are electronically filed with the Securities and Exchange Commission (“SEC”). The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. Information contained on our website does not, and shall not be deemed to, constitute part of this Annual Report on Form 10-K. Our reference to the URL for our website is intended to be an inactive textual reference only.

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 continue to develop our drug candidates focused on rare and deadly forms of cancer. 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 have used the proceeds from our previous equity offerings, and we intend to use the proceeds from any possible future offerings, to, among other uses, advance Annamycin and WP1066 through clinical development, advancing the remainder of the existing portfolio through preclinical studies and into IND's or their equivalent, and sponsoring research at MD Anderson and HPI. 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 and WP1066. If the FDA or its EU equivalent 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 and also of our preclinical studies;
- 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 the second half of 2019, assuming a significant amount of our outstanding warrants are not exercised for cash, and assuming we do not complete any additional equity raises or draw from our Lincoln Park facility. 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 and WP1066, 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.

If another shutdown of the federal government occurs, we will not be able to effectively utilize a Form S-1 registration statement to conduct a primary offering of our securities, which will limit this avenue to raise financing and may require us to raise financing on less favorable terms.

The U.S. federal government shutdown from December 22, 2018 until January 25, 2019, and may shutdown again in the near future. During the pendency of any shutdown and assuming (as recently occurred) SEC operations during such shutdown prevent the SEC staff from declaring registration statements effective, we will be unable to effectively utilize a Form S-1 registration statement for a primary offering of our securities. As such, any financing we conduct during a shutdown would be limited to offerings from our currently effective Form S-3 registration statement or equity offered via the Lincoln Park facility, which would be severely limited in size due to statutory restrictions on our use of such registration statement, or from private placements, which generally carry less favorable terms due to the trading restrictions on such securities. Our inability to raise financing or our inability to raise financing on favorable terms, could cause the trading price of our common stock to decline substantially.

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 some of our drug candidates 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, we believe 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 our drugs in clinical trials;
- 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.

We are conducting important clinical trials in Poland, preclinical work in Australia, and studies for additional countries in which to perform preclinical studies and clinical trials and the risks associated with conducting research and clinical trials abroad could materially adversely affect our business.

We have an approved Clinical Trial Authorizations in Poland for two clinical trials. Additionally, we are performing substantial preclinical studies via our Australian subsidiary. Furthermore, we are performing studies to determine if there are

additional countries in which we should hold clinical and preclinical studies. 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.

Prior to our IPO, we acquired (i) 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, and (ii) 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. In addition, 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, Dr. Waldemar Priebe, and a member of our management are shareholders of HPI. In addition, in February 2019, we entered into sublicense agreements with WPD Pharmaceuticals, Inc. and Animal Lifesciences, LLC. Dr. Priebe is affiliated with both WPD Pharmaceuticals, Inc. and Animal Lifesciences, LLC.

For the sublicense agreements with WPD Pharmaceuticals, Inc., since Dr. Priebe was affiliated with the entity, our board of directors received a fairness opinion from Roth Capital Partners, LLC as to the adequacy of the consideration we received in the sublicense agreement. We did not receive a fairness opinion on the transactions that occurred prior to our IPO or with Animal Lifesciences, LLC. 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 \$1.15 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

forementioned 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. Of this amount, only \$75,000 was paid in January 2019 and an additional payment is due on May 15, 2019. At that time the \$1.0 million payment to conclude this out-licensing agreement is due.

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 have accrued the \$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, 2018, we incurred a net loss of \$11.9 million. We had an accumulated deficit of \$26.4 million as of December 31, 2018.

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, WP1066 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 or its EU equivalent 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.

We conduct significant operations through our Australia wholly-owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations will suffer.

In June 2018, we formed a wholly-owned Australian subsidiary, Moleculin Australia Pty Ltd, or (MAPL), to begin preclinical development in Australia for WP1732, an analog of WP1066. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop and commercialize our drug products in Australia, including conducting preclinical studies and clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our drug candidates in Australia will be accepted by the FDA or foreign regulatory authorities for development and commercialization approvals.

In addition, current Australian tax regulations provide for a refundable research and development tax credit equal to 43.5% of qualified expenditures. If we are ineligible or unable to receive the research and development tax credit, or if we lose

our ability to operate MAPL in Australia, or the Australian government significantly reduces or eliminates the tax credit, our business and results of operations would be adversely affected.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On October 4, 2018, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to \$20,000,000 of our common stock. Upon the execution of the Purchase Agreement, we issued 243,013 Commitment Shares to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. The remaining shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall. During the fourth quarter the Company additionally issued to Lincoln Park 1,399,153 shares including 10,918 commitment shares for \$1.8 million.

We generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

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, 2018. 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 our drug candidates. Problems with the third parties that manufacture the API used in our drug candidates 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 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 our product candidates, on either a clinical or commercial scale. As a result, we rely on third parties to supply the API used in each of our product candidates. We expect to continue to depend on third parties to supply the API for our current and future product candidates and to supply the API in commercial quantities. We are ultimately responsible for confirming that the APIs used in 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 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 commercialization of our product candidates.

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 any of our drug candidates will receive regulatory approval, and without regulatory approval we will not be able to market such drugs.

Our business currently depends on the successful development and commercialization of our drug candidates. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of our drug candidates.

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 any of our product candidates, or if, subsequent to approval, we are unable to successfully commercialize our 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 any of our drug candidates have demonstrated preliminary evidence of efficacy are our own and are not based on the FDA's or any other comparable governmental agency's assessment and do not indicate that such drug candidate will achieve favorable efficacy results in any later stage trials or that the FDA or any comparable agency will ultimately determine that such drug candidate 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 any of our 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 any of our drug product candidates are 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 any of our drug candidates 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 oncology therapies such as our drug candidates are significant. If any of our drug candidates cause 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. One example is that 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 any of our 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.

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 received Orphan Drug designation for Annamycin and WP1066 but it may not effectively prevent approval of a competing product.

On March 21, 2017, we received notice that the FDA granted Orphan Drug designation ("ODD") for Annamycin for the treatment of AML. Subsequent to December 31, 2018, we received notice that the FDA granted ODD for WP1066 in February 2019 for the treatment of glioblastoma. Moreover, even though Orphan Drug exclusivity was granted, we cannot know that it will prevent approval of another product containing Annamycin and intended to treat AML or WP1066 and intended to treat glioblastoma, because any such subsequent product could be demonstrated to be clinically superior to Annamycin or WP1066.

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

We are pursuing additional 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, 2018 we had nine 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.

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

As of December 31, 2018, we had a material number of outstanding options and warrants to purchase shares of common stock. To the extent any of these options or warrants are exercised and any additional options or warrants 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 24% 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, 2018, 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, 2018 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, 2018, 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.” 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.

We may require additional financing to sustain our operations and without it we may not be able to continue operations.

We may direct Lincoln Park to purchase up to \$20,000,000 worth of shares of our common stock under our agreement over a 36-month period generally in amounts up to 100,000 shares of our common stock, which may be increased to up to 250,000 shares of our common stock depending on the market price of our common stock at the time of sale and subject to a maximum limit of \$1,000,000 per purchase, on any such business day. Assuming a purchase price of \$1.56 per share (the closing sale price of the common stock on October 4, 2018) and the purchase by Lincoln Park of the 6,730,526 purchase shares, proceeds to us would only be \$10.5 million. During the fourth quarter of 2018 the Company additionally issued to Lincoln Park 1,399,153 shares including 10,918 commitment shares for \$1.8 million. During February 2019, the Company sold 600,000 shares to Lincoln Park for an aggregate purchase price of \$0.9 million and 5,367 commitment shares.

The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all \$20,000,000 under the Purchase Agreement to Lincoln Park, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate, executive offices laboratory and other spaces are in located in leased facilities in Houston, Texas. Our laboratory 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 use for corporate office space and meetings. The term of the Lease began in August 2018, and will 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 is listed on the NASDAQ Capital Market under the symbol "MBRX". On February 1, 2019, the closing price reported on the NASDAQ Capital Market for our common stock was \$1.41.

Holders

As of February 1, 2019, there were approximately 153 active 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.

Recent Sales of Unregistered Securities

On October 4, 2018, we entered into a purchase agreement, dated as of October 4, 2018 (the "Purchase Agreement"), and a registration rights agreement, dated as of October 4, 2018 (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to \$20.0 million worth of our common stock. Under the terms and subject to the conditions of the Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$20.0 million worth of shares of our common stock. Such sales of common stock will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on the date that a registration statement covering the resale of shares of common stock that have been and may be issued under the Purchase Agreement, which we agreed to file with the Securities and Exchange Commission (the "SEC") pursuant to the Registration Rights Agreement is declared effective by the SEC and a final prospectus in connection therewith is filed and the other conditions set forth in the purchase agreement are satisfied, all of which are outside the control of Lincoln Park. For more information about this transaction, please see discussions elsewhere in this Form 10-K and our Form 8-K filed October 5, 2018, which is incorporated herein.

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, 2018.

ITEM 6. SELECTED CONSOLIDATED 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

Moleculin Biotech, Inc., a Delaware corporation, is a clinical stage pharmaceutical company focused on the treatment of highly resistant cancers. We have three core technologies, all of which are based on discoveries made at M.D. Anderson Cancer Center ("MD Anderson"). We have three drugs in four clinical trials in the US and Poland. Our clinical stage drugs are Annamycin, believed by management to be a "Next Generation" Anthracycline, being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML, and WP1066, an Immune/Transcription Modulator targeting brain tumors, pancreatic cancer and AML. Additionally, a third drug, WP1220 (a molecule similar to WP1066), was approved for a clinical trial in January 2019 in Poland for the topical treatment of cutaneous T-cell lymphoma. We are also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as Metabolism/Glycosylation Inhibitors.

We believe that our Next Generation Anthracycline, Annamycin, is unlike any currently approved anthracyclines, as it is designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity – hence the use of the term "Next Generation." Annamycin has preliminary clinical data suggesting its potential to become the first successful therapy suitable for the majority of relapsed or refractory AML patients and is currently in two Phase I/II clinical trials.

WP1066 is one of several Immune/Transcription Modulators designed to stimulate the immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs) while also inhibiting key oncogenic transcription factors, including p-STAT3, c-Myc and HIF-1 α . These transcription factors are widely sought targets that may also play a role in the inability of immune checkpoint inhibitors to affect more resistant tumors.

We are also developing new compounds designed to exploit the potential uses of inhibitors of glycolysis such as 2-deoxy-D-glucose ("2-DG"), which we believe may provide an opportunity to cut off the fuel supply of tumors by taking advantage of their high level of dependence on glucose in comparison to healthy cells. A key drawback to 2-DG is its lack of drug-like properties, including a short circulation time and poor tissue/organ distribution characteristics. Our lead Metabolism/Glycosylation Inhibitor, WP1122, is a prodrug of 2-DG that appears to improve the drug-like properties of 2-DG by increasing its circulation time and improving tissue/organ distribution. New research also points to the potential for 2-DG to be capable of enhancing the usefulness of checkpoint inhibitors. Considering that 2-DG lacks sufficient drug-like properties to be practical in a clinical setting, we believe WP1122 may also become an important drug to potentiate checkpoint inhibitors.

Mission and Strategy

Moleculin is focused on developing treatments for highly resistant cancers. These include AML, glioblastoma, cutaneous t-cell lymphoma, pancreatic cancer, and others. Our diverse pipeline of technologies was built around the recognition that many highly resistant tumors tend to have a common set of traits, including an increase in multidrug resistant mechanisms, an evasion of the natural immune system, a marked upregulation of certain key oncogenic transcription factors and an increased dependence on glycolysis for energy production. We believe each of these elements may be addressed by the unique and innovative mechanisms introduced by one or more of our three core technologies.

We believe this approach not only provides the opportunity to help the many patients in need of alternative therapies, but also to work in combination with numerous existing technologies that often fail as tumors present immediate or acquired resistance. We believe showing even modest improvements in highly resistant cancers may lead to accelerated approval pathways, potentially reducing the time and capital required to ultimately realize success.

Corporate Overview

We were founded in 2015 in order to combine and consolidate the development efforts involving several oncology technologies, based on license agreements with MD Anderson. 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, on behalf of Moleculin, LLC, we entered into a co-development agreement with Houston Pharmaceuticals, Inc., or HPI, which culminated with the merger of Moleculin, LLC into MBI coincident with our initial public offering allowing us to gain control of the WP1066 Portfolio.

Moleculin, LLC was formed in 2006 and was working to develop the WP1066 Portfolio it licensed from MD Anderson. On May 2, 2016, Moleculin, LLC was merged with and into MBI. As a result of the merger, we issued the holders of Moleculin, LLC equity interests and convertible notes representing in the aggregate approximately 999,931 shares of our common stock. Since Moleculin, LLC commenced operations in 2006, substantially all of its efforts had been focused on research, development and the advancement of the WP1066 Portfolio. Moleculin, LLC did not generate any revenue from product sales and, as a result, incurred significant losses.

In June 2018, we formed Moleculin Australia Pty. Ltd., a wholly-owned subsidiary to oversee pre-clinical development in Australia. The Australian government provides an aggressive incentive for research and development carried out in their country. We believe having an Australian subsidiary could provide a great opportunity to speed up pre-clinical development and reduce the overall cost of our continued drug development efforts.

We do not have manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, we do not have a sales organization.

Technology Overview

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, but 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 (“ODD”) from the FDA for Annamycin for the treatment of AML and, subsequent to December 31, 2018, we received ODD for WP1066 for the treatment of glioblastoma. If we receive approval for either product for the orphan use, we may obtain market exclusivity of 7 years from the date of approval of a New Drug Application (“NDA”) in the United States. During that period FDA generally could not approve another product with the same active moiety 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.

Next Generation Anthracycline

Chemotherapy continues to be a cornerstone of cancer therapy. Despite the progress made with immunotherapy and precision medicine, the first-line treatment for many cancers continues to include chemotherapy. And, in part because of the emphasis placed on alternatives to chemotherapy, we believe that not enough has been done to improve chemotherapeutic agents to make them safer and more effective. Anthracyclines are a class of chemotherapy drugs designed to destroy the DNA of targeted cancer cells. Acute leukemia is one of a number of cancers that are usually treated with anthracyclines. In the case of acute leukemia, anthracyclines are typically used in “induction therapy,” where the goal is to induce sufficient remission of patients’ blood-born tumor cells to allow for a curative bone marrow transplant.

Two key factors limit the safety and effectiveness of anthracyclines: cardiotoxicity (potential to damage the heart) and multidrug resistance. We believe Annamycin may overcome these two factors; if preliminary data are borne out, Annamycin may ultimately provide clinically meaningful benefits over currently approved anthracyclines in treating certain cancers. Preliminary data from very early-stage clinical trials suggest acute leukemia as a potentially opportune indication in which to further study Annamycin.

One of the key dose-limiting toxicities associated with currently available anthracyclines (including the anthracycline in the recently approved drug, Vyxeos) is the propensity to induce life-threatening heart damage (also known as cardiotoxicity). This is a particularly significant risk for pediatric leukemia patients, whose life spans can be severely shortened by the induction therapy intended to cure them of acute leukemia. In the animal model recommended 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. If this characteristic is shown to be the same in humans, it may allow L-Annamycin to be used more aggressively to help patients achieve remission. This would be especially valuable in the case of pediatric acute leukemia (both AML and ALL) because of the potential impact of cardiotoxicity on long-term survival. In our current Phase I/II trial for Annamycin, we are collecting 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).

In addition, the effectiveness of currently approved anthracyclines is limited by their propensity for succumbing to “multidrug resistance.” This can occur where, as a natural defense mechanism, transmembrane proteins acting as transporters (one type of which is referred to as a “P-glycoprotein pump” or “ABCB1 transporter”) develop on the outer surface of cells to expel perceived threats like anthracyclines. In many instances, the likelihood of cardiotoxicity (and other serious side effects) prevents increasing the dosing of current therapies in order to overcome multidrug resistance. As a result, most patients cannot receive current anthracyclines in doses that are adequate to produce lasting remission and thereby qualify for a bone marrow transplant. A laboratory study has suggested that Annamycin may resist being expelled by P-glycoprotein pumps and similar 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.

Immune/Transcription Modulators: Enabling Immune Response and Inhibiting p-STAT3 and other Oncogenic Transcription Factors –

We believe our WP1066 Portfolio (including lead drugs WP1066, WP1220 and WP1732) represents a novel class of agents capable of hitting multiple targets, including the activated form of a key oncogenic transcription factor, STAT3. A substantial body of published research has identified STAT3 as a master regulator of a wide range of tumors and has linked the activated form, p-STAT3, with the survival and progression of these tumors. For this reason, it is widely believed that targeted inhibition of p-STAT3 may be an effective way to reduce or eliminate the progression of these diseases.

The high level of anticancer activity demonstrated in multiple tumors in animal models by WP1066 and WP1732 is potentially related to their ability to also inhibit such important key oncogenic transcription factors like c-Myc and HIF-1 α . In addition to direct anticancer effects not related to the function of the immune system, our lead drug WP1066 has also been shown to boost immune response in animals, in part by inhibiting activity of Regulatory T cells (Tregs), which are coopted by tumors to evade the immune system. We believe the dual effect of (1) directly inhibiting tumor growth and inducing tumor cell death and (2) separately boosting and directing the natural immune response to tumors is therapeutically highly promising. If additional preclinical and clinical data validate the two avenues of apparent activity, this class of drugs may be well-suited to treat a wide range of tumors, both as single agents and as critical elements of successful combination therapies targeting even some of the most difficult-to-treat cancers.

The recent oncology drug landscape has been dominated by immunotherapy, specifically including checkpoint inhibitors. In just the last 5 years, checkpoint inhibitors (such as Opdivo and Keytruda) have reached over \$10 billion in annual revenues. To summarize checkpoint blockade therapy, the T-Cells within an individual's own immune systems should be capable of identifying tumor cells and destroying them before they destroy the individual. Unfortunately, tumors develop the ability to prevent this natural immune response by regulating the expression of certain receptors referred to as "immune checkpoints" that then bind to T-Cells and prevent them from attacking the tumor. Immune checkpoint inhibitors are antibodies that block these receptor mechanisms and allow the T-Cells to act normally and attack the tumor.

In certain types of tumors, like melanoma, checkpoint inhibitors work well and the results can be impressive, creating durable suppression of tumors where no other therapy had succeeded. However, despite the outstanding results in select patients, checkpoint inhibitors benefit only a limited number of patients in certain cancers, and they are essentially not effective in what are called "non-responsive" tumors like glioblastoma and pancreatic cancer, among others. As a result, companies are now focusing heavily on combination therapies, combining immune checkpoint inhibitors with chemotherapy, as well as other agents. There appears to be tremendous demand and we believe there is a clear need for new chemotherapeutic agents that, by their specific mechanism of action, would produce potent combination effects with immune checkpoint inhibitors, and that additionally can boost immune system response on their own. In this regard, there is early nonclinical evidence that WP1066, as a single agent, has the ability to reverse immune tolerance in brain tumor patients (Cancer Res, 67(20), 9630, 2007), and preliminary data in animal models that suggests WP1066 may have a potential for combination use with checkpoint inhibitors.

Recently published research papers have presented several findings that may point to major new opportunities for Moleculin's WP1066 class of drugs. One such article suggested that our STAT3 inhibitor WP1066 abrogated PD-L1/2 expression in cancer cells and may be a useful agent in addition to checkpoint inhibitor immunotherapy in cancer patients (J Clin Exp Hematop, 57(1), 21-25, 2017). Other published results show that CTLA4-induced immune suppression occurs primarily via an intrinsic STAT3 pathway, suggesting that, through its inhibition of activated STAT3, WP1066 might work well in combination with this checkpoint inhibitor (Cancer Res, 77(18), 5118–28, 2017).

A separate paper presents selected key transcription factors as being responsible for the upregulation of an often-targeted checkpoint actor in tumors known as PD-L1. Some of the most important transcription factors identified were HIF-1 α , c-Myc and STAT3, the very targets for which WP1066 was designed (Front Pharmacol, 2018 May 22, 9:536, doi: 10.3389/fphar.2018.00536, eCollection 2018). In summary, although much of the data is nonclinical and all of it is preliminary, we are optimistic that administration of WP1066 could lead to improved treatment results in many patients receiving checkpoint inhibitor therapy.

Metabolism/Glycosylation Inhibitors: Using the Warburg Effect to Starve Tumor Cells to Death –

Science has recognized that many types of cancer cells have a unique metabolism, distinct from that of normal cells. Cancer cells' dependence on glycolysis (a specific way of converting glucose into energy) to proliferate and metastasize has been described as the "sweet tooth of cancer" and is a classic example of how the metabolism of cancer cells and normal cells differ. Glycolysis is a glucose-intensive means of producing energy that is used by normal cells only if oxygen levels are low.

However, many types of tumor cells are essentially addicted to glycolysis even in the presence of abundant oxygen. This is known as the “Warburg Effect” after its discoverer, Dr. Otto Warburg, and such tumors are said to be highly “glycolytic.”

This phenomenon of tumors relying preferentially on glycolysis and the resulting dramatic increase of glucose uptake to fulfill their metabolic demands has already been utilized very effectively in cancer diagnostics. It is the Warburg Effect that enables imaging of actively growing tumors by positron emission tomography (“PET scans”). This diagnostic test uses a fluorine-18 radiolabeled glucose decoy called F18DG that accumulates disproportionately in tumors, using the same process that increases glucose uptake and retention in cancer cells.

The success of PET scanning points to the potential therapeutic benefit of the tumor-specific inhibition of glycolysis that would block energy (adenosine triphosphate (“ATP”)) production and could potentially “starve tumor cells to death” and/or make them sensitive to other existing therapies, including radiotherapy. Unsuccessful attempts to realize this therapeutic potential have been made in the past, using a glucose decoy known as “2-deoxy-D-glucose” (2-DG). Those attempts to target the metabolism of tumor cells have failed, we believe, because of 2-DG’s lack of drug-like properties that include rapid metabolism, short half-life and limited tissue-organ distribution. Essentially, not enough 2-DG could be delivered to its intended target.

We have designed and are studying a novel and patented prodrug of 2-DG (WP1122). We believe WP1122 has the potential for developing into a technology platform for enabling increased cellular uptake, increased drug half-life and, importantly, enabling greater uptake and retention in organs where the most resistant and glycolytic tumors are localized, including the brain and pancreas.

Altering Glycosylation to Enhance Immune Checkpoint Therapy –

A recently published study (Am J Cancer Res, 8(9), 1837-1846, 2018) focused on the analysis of tumor resistance to immune checkpoint therapy. The study found that a process known as glycosylation plays an important role in the ability of checkpoint receptors to suppress immune activity and thereby protect tumors from attack. The researchers discovered that an alteration of the glycosylation of these receptor mechanisms could effectively prevent this evasion of the immune system. This study found that 2-deoxyglucose, or 2-DG, was capable of making this alteration. Although the data are preliminary, the findings suggest that 2-DG could act as an effective anticancer agent in combination with checkpoint inhibitors and potentially with other anticancer therapies.

Attempting to use 2-DG as a drug, however, faces the same problems discussed above. 2-DG’s short circulation time and lack of other drug-like properties mean the drug does not stay in the system long enough or concentrate sufficiently in targeted organs, which severely limits its effectiveness. This suggests a possible role for our patented drug candidate, WP1122. WP1122 is a prodrug of 2-DG, meaning it is a molecule that may be able to be converted into pharmacologically active 2-DG within the body of the patient. The design of WP1122 is intended to allow for a longer circulation time and improved organ distribution, which should provide it a greater opportunity to become an effective drug.

We intend to study WP1122 for both its ability to directly inhibit tumor activity and to potentiate existing therapies via an inhibition of tumor metabolism and to improve the performance of checkpoint inhibitors by reducing the effect of glycosylation and have begun the necessary preclinical work required to file an IND.

Clinical Activity

Annamycin had previously been in clinical trials with a prior drug developer pursuant to an application for Investigational New Drug status (“IND”) that had been filed with the FDA. Due to a lack of development activity by the 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. Patient treatment began in the US in March 2018. We are in the first cohort in our Phase I portion of the trial.

With regard to additional potential Annamycin clinical activity, we received Polish National Office approval in June 2018 for a Clinical Trial authorization (“CTA”) in Poland, which enables us to begin a Phase I/II clinical trial there to study Annamycin for the treatment of relapsed or refractory AML. In Poland, while the clinical trial and the first site were approved in June 2018, we were required to obtain final approval by two different authorities - one in Europe and one in Poland – to ship Annamycin drug product to Poland. Such approval is not necessary for use of Annamycin drug product in the US and we have Annamycin drug product ready and available in the US to treat potential patients. For Poland, we obtained the necessary approvals in November and December 2018 and shipped Annamycin drug product in late December 2018. In January 2019, we began screening patients in Poland.

We continue to recruit and contract with clinics both in the United States and Poland. We can provide no assurance of additional recruitment or that treatments will occur in the near term and on a timely basis, if at all.

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. In July 2018, this trial opened for recruitment in the US. This trial is now in its third cohort of the Phase I portion of the planned protocol. Because this trial is physician led, we are limited in our ability to manage the trial.

With regard to additional potential clinical activity on other drugs, in September 2017 we engaged a 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”). In 2018, we filed a CTA in Poland for this trial, which was approved in January 2019, giving us a third drug in clinic and our fourth clinical trial.

On May 1, 2018, we engaged another CRO to evaluate additional countries for the expansion of our AML clinical trial, specifically Australia and several Western European countries to provide additional clinical sites to improve access for patients to our Phase I/II trial.

We have begun planning and performing the necessary pre-clinical work required to submit an IND for WP1732 and WP1122. In June 2018, we entered into an agreement with The University of Iowa Pharmaceuticals for the development of a formulation for WP1732. This agreement marked the beginning of creating a preclinical package to submit to the FDA in order to request Investigational New Drug status. We have now completed formulation development, and our IND-enabling toxicology work will be progressing via our Australian subsidiary, Moleculin Australia, and we expect to submit an IND in the US in 2019.

We also continue to sponsor ongoing research at MD Anderson in order to improve and expand our drug development pipeline.

Subsequent Events

In addition to subsequent events noted in the discussion above, the following events occurred subsequent to December 31, 2018.

Summary of WPD Agreement

We entered into an agreement with WPD Pharmaceuticals (“WPD”), as described below. Such licensing agreements in Poland, we believe, may provide access to Polish grant money. We have previously entered into similar agreements with Dermis s.p. z o.o. with some of our technologies in the same territories and Dermis has succeeded in obtaining grant funding in Poland benefiting our development objectives. We believe this is a potential non-dilutive source of capital. Furthermore, we believe that an added and extremely important benefit of this approach is that Moleculin does not have to invest its own resources in establishing an EU-based infrastructure that would be required to access such grant funding on our own. We believe this arrangement is consistent with our low overhead, capital efficient approach to development.

On February 19, 2019, we sublicensed certain intellectual property rights, including rights to Annamycin, our WP1122 portfolio, and our WP1066 portfolio to WPD Pharmaceuticals (“WPD”) (the “WPD Agreement”). WPD is affiliated with Dr. Waldemar Priebe, our founder and largest shareholder. Under the WPD Agreement, we granted WPD a royalty-bearing, exclusive license to research, develop, 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 Germany, Poland, Estonia, Latvia, Lithuania, Belarus, Ukraine, Moldova, Romania, Armenia, Azerbaijan, Georgia, Slovakia, Czech Republic, Hungary, Uzbekistan, Kazakhstan, Greece, Austria, Russia, Netherlands, Turkey, Belgium, Switzerland, Sweden, Portugal, Norway, Denmark, Ireland, Finland, Luxembourg, Iceland (“licensed territories”), provided that we have the right to buyback Germany from the licensed territories by making a cash payment \$500,000, or by issuing 235,850 shares of our common stock.

In consideration for entering into the WPD Agreement, WPD agreed that it must use Commercially Reasonable Development Efforts to develop and commercialize products in the licensed territories. For purposes of the WPD Agreement, the term “Commercially Reasonable Development Efforts” means the expenditure by or on behalf of WPD or any of its affiliates of at least: (i) \$2,000,000 during the first two years of the agreement on the research, development and commercialization of products in the licensed territories; and (ii) \$1,000,000 annually for the two years thereafter on the research and development of products in the licensed territories.

In addition, within sixty days we agreed to transfer to WPD certain development data, and, in exchange for such development data, WPD agreed to make a development reimbursement fee to us in the amount of \$300,000 (the “Development Reimbursement Fee”) within the first year of the agreement. Should WPD fail to make the Development Reimbursement Fee, then at our sole discretion: (i) Germany shall no longer be a part of the licensed territories; or (ii) the Commercially Reasonable Development Efforts during the first two years of the agreement shall increase from \$2,000,000 to \$2,500,000.

During the term of the WPD Agreement, to the extent we are required to make any payments to MD Anderson pursuant to our license agreements with MD Anderson, whether a milestone or royalty payment, as a result of the research and development or sale of a sublicensed product, WPD shall be required to advance or reimburse us such payments. In further consideration for the rights granted by us to WPD under the WPD Agreement, WPD agreed to pay us a royalty percentage at a rate equal to the royalty rate we owe MD Anderson under our license agreements with MD Anderson plus an additional royalty (the “override royalty percentage”) equal to 1.0% of net sales of any sublicensed products, provided, however, if WPD spends: (i) more than \$5,000,000 in Commercially Reasonable Development Efforts prior to the fifth anniversary of the date of the agreement and more than \$6,000,000 in Commercially Reasonable Development Efforts prior to the sixth anniversary of the date of the agreement, the override royalty percentage will decrease to 0.75% of net sales; or (ii) more than \$6,000,000 in Commercially Reasonable Development Efforts prior to the fifth anniversary of the date of the agreement and more than \$8,000,000 in Commercially Reasonable Development Efforts prior to the sixth anniversary of the date of the agreement, the override royalty percentage will decrease to 0.5% of net sales.

With certain exceptions, the WPD Agreement will remain in full force and effect until the expiration of the last patent within the sublicensed patents. Notwithstanding the foregoing, we have the right, in our sole discretion, to terminate the WPD Agreement in whole, or to materially amend the agreement by removing a portion of the sublicensed subject matter, in connection with certain fundamental transactions or in connection with the granting to an unaffiliated third party of a license or sublicense to all or to a material portion of the sublicensed subject matter within all or substantially all of the licensed territories (such event, the “buyback event”) by making a payment to WPD equal to a percentage of the consideration after transaction costs we receive in connection with the buyback event. The percentage payable will be the greater of: (i) 2% increasing to 5% upon the completion by WPD of its initial public offering, provided such offering provides WPD with net proceeds of not less than \$2.0 million; or (ii) 10% multiplied by a fraction (A) the numerator of which is the total dollar amount of expenditures made by WPD that represent Commercially Reasonable Development Efforts under the WPD Agreement, up to a maximum of \$2.0 million; and (B) the denominator of which is \$2.0 million. Prior to approval of the WPD Agreement, our board of directors received a fairness opinion from Roth Capital Partners, LLC stating their opinion that the consideration we will receive from WPD pursuant to the WPD Agreement is fair, from a financial point of view, to us.

Animal Life Sciences Licensing Agreement

On February 19, 2019, we sublicensed certain intellectual property rights, including rights to Annamycin, our WP1122 portfolio, and our WP1066 portfolio in the field of non-human animals to Animal Life Sciences, LLC (“ALI”) (the “ALI Agreement”). ALI is affiliated with Dr. Waldemar Priebe, our founder and largest shareholder. Under the ALI Agreement, we granted ALI a worldwide royalty-bearing, exclusive license to research, develop, manufacture, have manufactured, use, import, offer to sell and/or sell products in the field of non-human animals under the licensed intellectual property. During the term of the ALI Agreement, to the extent we are required to make any payments to MD Anderson pursuant to our license agreements with MD Anderson, whether a milestone or royalty payment, as a result of the research and development or sale of a sublicensed product, ALI shall be required to advance or reimburse us such payments. In further consideration for the rights granted by us to ALI under the ALI Agreement, ALI agreed to pay us a royalty percentage at a rate equal to the royalty rate we owe MD Anderson under our license agreements with MD Anderson plus an additional royalty equal to 5.0% of net sales of any sublicensed products. As additional consideration, ALI issued us a 10% ownership interest in ALI. With certain exceptions, the ALI Agreement will remain in full force and effect until the expiration of the last patent within the sublicensed patents.

Sale of Shares to Lincoln Park

During February 2019, the Company sold 600,000 shares to Lincoln Park for an aggregate purchase price of \$0.9 million and 5,367 commitment shares.

Moleculin Biotech, Inc.**Results of Operations for the Year Ended December 31, 2018 as Compared to the Year Ended December 31, 2017**

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

	Year ended December 31,	
	2018	2017
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	9,728	4,545
General and administrative	5,229	4,090
Depreciation	68	18
Total operating expense	15,025	8,653
Loss from operations	(15,025)	(8,653)
Other income (expense):		
Gain (loss) from change in fair value of warrant liability	3,185	(2,548)
Gain from settlement of liability	—	149
Gain from expiration of warrants	—	1,238
Other (expense) income	(40)	9
Interest income (expense), net	4	—
Total other income (expense)	(11,876)	(9,805)
Net loss	\$ (11,876)	\$ (9,805)

Research and Development Expense.

Research and development (“R&D”) expense was \$9.7 million and \$4.5 million for the years ended December 31, 2018 and 2017, respectively. The increase in R&D of approximately \$5.2 million mainly represents an increase of approximately: \$2.9 million related to manufacturing and toxicology; \$1.3 million related sponsored research and license agreements which includes the HPI Out-Licensing Agreement; \$0.3 million associated with clinical trials and \$0.7 million related to an increase in R&D headcount and associated payroll costs. The increase in R&D headcount mainly represents two positions added at the beginning of 2018, a VP/Executive director of Drug Development and a VP/Director of Clinical Operations. These reflect increased clinical and pre-clinical activity for our three core technologies - with emphasis on Annamycin and the WP1066 Portfolio - as compared to 2017.

General and Administrative Expense.

General and administrative (“G&A”) expense was \$5.2 million and \$4.1 million for the years ended December 31, 2018 and 2017, respectively. The increase in G&A of approximately \$1.1 million was mainly attributable to \$1.0 million increase in headcount and associated payroll costs including stock-based compensation expense and approximately \$0.1 million increase in legal, accounting, consulting, and other professional expenses. This increase in headcount was mainly in accounting and finance with the addition of a controller during the third quarter of 2017, a senior accountant in the first quarter of 2018, and a staff accountant and an office manager during the fourth quarter of 2018. These increases reflect the support required by our increase in clinical and pre-clinical activity described above as compared to 2017.

Change in fair value of warrant liability.

We recorded a net gain of \$3.2 million in during the year ended December 31, 2018 as compared to a loss of approximately \$2.5 million, during the year ended December 31, 2017, for the change in fair value on revaluation of our warrant liability associated with our warrants issued in conjunction with our stock offerings in June 2018, February 2018, and February 2017. We are required to revalue certain of the 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 calculated 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. The non-cash gain in 2018 was associated with a decreased fair value calculation and the 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 offerings in 2017 and 2018.

Gain from settlement of liability.

During 2017, 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.

Net Loss.

The net loss for the twelve months ended December 31, 2018 was \$11.9 million which included non-cash expenses of approximately \$1.1 million of stock-based compensation in 2018 as compared to \$0.7 million in 2017.

Liquidity and Capital Resources

As of December 31, 2018, we had cash and cash equivalents of \$7.1 million and prepaid expenses and other of \$0.9 million. We also had \$1.2 million of accounts payable and \$2.3 million of accrued expenses. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our clinical trials. For the years ended December 31, 2018 and 2017, we used approximately \$12.2 million and \$7.3 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. The increase in 2018 reflects the increase in clinical and preclinical activity over 2017. For the year ended December 31, 2018, net proceeds from financing activities were \$12.0 million, predominately from the sale of our common stock and warrants. In 2017, approximately \$6.0 million was raised through the sale of shares of common stock and approximately \$4.0 million from the exercise of warrants. Cash used in investing activities for the year ended December 31, 2018 was approximately \$0.4 million for the purchase of fixed assets related to the new corporate office space and the implementation of a new financial accounting system.

We believe that our cash resources as of December 31, 2018, along with the additional funding received subsequent to year-end, will be sufficient to meet our projected operating requirements into the third quarter of 2019. This expectation does not consider unplanned preclinical and clinical activity, additional funding, including but not limited to, equity issuances including the use of the Lincoln Park facility described below.

We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to changes we may make in our research and development spending plans. These factors raise substantial doubt about our ability to continue as a going concern for the one year period from the date of filing of this Form 10-K. We believe we have the ability to obtain additional funding through public or private financing or collaborative arrangements with strategic partners to increase the funds available to fund operations. Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

Lincoln Park Transaction

On October 4, 2018, we entered into a purchase agreement ("LP Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park" or "LPC") and a registration rights agreement (the "LP Registration Agreement") pursuant to which Lincoln Park has agreed to purchase from us up to an aggregate of \$20.0 million worth of our common stock. Under the terms and subject to the conditions of the LP Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$20.0 million worth of shares of common stock. Such sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on October 30, 2018 ("Commencement Date") as per the LP Registration Agreement.

Thereafter, under the LP Purchase Agreement, on any business day selected by us, we may direct LPC to purchase up to 100,000 shares of common stock on such business day (each, a “Regular Purchase”), provided, however, that (i) the Regular Purchase may be increased to up to 200,000 shares, provided that the closing sale price of the common stock is not below \$2.25 on the purchase date (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the LP Purchase Agreement) and (ii) the Regular Purchase may be increased to up to 250,000 shares, provided that the closing sale price of the common stock is not below \$2.75 on the purchase date (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the LP Purchase Agreement). In each case, Lincoln Park’s maximum commitment in any single Regular Purchase may not exceed \$1,000,000. In addition, upon the first business day after the Commencement Date, we could have directed a one-time tranche purchase of \$1,000,000 worth of shares to Lincoln Park. We did not act upon this option. The purchase price per share for each such Regular Purchase will be based off of prevailing market prices of our common stock immediately preceding the time of sale without any fixed discount. In addition to Regular Purchases, we may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the LP Purchase Agreement.

Under applicable rules of The NASDAQ Capital Market, in no event may we issue or sell to Lincoln Park under the LP Purchase Agreement more than 19.99% of the shares of our common stock outstanding immediately prior to the execution of the LP Purchase Agreement (which is 5,369,613 shares based on 26,861,497 shares outstanding immediately prior to the execution of the LP Purchase Agreement) (the “Exchange Cap”), unless (i) we obtain stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of common stock to Lincoln Park under the LP Purchase Agreement equals or exceeds \$1.6235, such that issuances and sales of the common stock to Lincoln Park under the LP Purchase Agreement would be exempt from the Exchange Cap limitation under applicable NASDAQ rules. In any event, the LP Purchase Agreement specifically provides that we may not issue or sell any shares of our common stock under the LP Purchase Agreement if such issuance or sale would breach any applicable NASDAQ rules.

Lincoln Park has no right to require us to sell any shares of common stock to LPC, but LPC is obligated to make purchases as we direct, subject to certain conditions. In all instances, we may not sell shares of our common stock to Lincoln Park under the LP Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of our common stock. There are no upper limits on the price per share that Lincoln Park must pay for shares of common stock.

We have agreed with Lincoln Park that we will not enter into any “variable rate” transactions with any third party for a period defined in the Purchase Agreement. We issued to Lincoln Park 243,013 shares of common stock as commitment shares in consideration for entering into the LP Purchase Agreement and may issue an additional 121,507 shares pro-rata when and if Lincoln Park purchases (at our discretion) the \$20,000,000 aggregate commitment.

The extent to which we utilize the LP Purchase Agreement with Lincoln Park as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Lincoln Park under the LP Purchase Agreement on any given day and during the term of the agreement is limited. Additionally, we, as well as Lincoln Park may not effect any sales of shares of our common stock under the purchase agreement during the continuance of an event of default under the purchase agreement.

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 anticipate that 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 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.

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”).

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

	For the Year Ended December 31,	
	2018	2017
Net cash used in operating activities	\$ (12,203)	\$ (7,324)
Net cash used in investing activities	(417)	(28)
Net cash provided by financing activities	12,045	10,059
Effect of exchange rate changes on cash and cash equivalents	(5)	—
Net increase (decrease) in cash and cash equivalents	<u>\$ (580)</u>	<u>\$ 2,707</u>

Cash used in operating activities

Net cash used in operating activities was \$12.2 million for the year ended December 31, 2018 compared to \$7.3 million for the year ended December 31, 2017. This increase in use of cash for operations was due to the increase in R&D associated with: 1) developing, manufacturing 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 increase in G&A support for our 3 core drug technologies as compared to 2017.

Cash used in investing activities

Net cash used in investing activities was \$0.4 million for the twelve months ended December 31, 2018 compared to nil for the twelve months ended December 31, 2017. The only cash used for investing purposes in 2018 was related to the purchase of fixed assets.

Cash provided by financing activities

Net cash provided by financing activities was \$12.0 million for the year ended December 31, 2018 compared to the prior period of \$10.1 million. Net cash provided by financing in 2018 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

Basis of Presentation

The accompanying consolidated 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”).

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 (“Moleculin”) on May 2, 2016, and, going forward our consolidated 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.

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 and drug manufacturing costs;
- 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 estimated useful life over the term of the lease or the estimated useful life, whichever is shorter; computer equipment to have a 2-year life; software to have a 3-year life, machinery and equipment to have a 5-year life and furniture and office equipment to have a 7-year life.

Accounting for warrants

We issued warrants to purchase shares of common stock related to equity transactions in 2017 and 2018. 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, February 2018 and June 2018 Offerings 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 associated with the February 2017 Offering is included in current liabilities on the accompanying financial statements as of December 31, 2017 and December 31, 2018, as warrants are currently being exercised. The liabilities associated with the other offerings described above are shown on the accompanying financial statements in the long-term liability as these warrants are not 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 Brownian 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.

We estimated the fair value of the warrants issued in the February 2018 and June 2018 Offerings under ASC 820 as of their issuance date for financial reporting purposes. We used the Black-Scholes option pricing model (“BSM”) to determine the fair value of the warrants. The BSM model is 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 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 2017-2018.

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, 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 was a provisional amount and a reasonable estimate at December 31, 2017 based upon the best information that was available. The accounting with respect to the implementation of the Tax Act is now complete with no change from the amounts reported at 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. The Company remeasured its deferred taxes based upon the new tax rates as of December 31, 2017 but, as a result of the full valuation allowance against its net deferred tax assets, there was no related impact on the Company's income tax expense.

Recent accounting pronouncements

See Note 2 to the Notes to Consolidated Financial Statements in "Item 8 - Financial Statements and Supplementary Data" in this Annual Report for discussion regarding recent accounting pronouncements.

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, 2018. 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, 2018 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 third quarter 2017 and a Senior Accountant - Reporting in the first quarter 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.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

The following table sets forth the names and ages of all of our directors and executive officers as of February 5, 2019. Our officers are appointed by, and serve at the pleasure of, the Board of Directors.

Name	Age	Position
Walter V. Klemp	59	Chairman of the Board, President and Chief Executive Officer
Jonathan P. Foster	55	Chief Financial Officer and Executive Vice President
Donald Picker	73	Chief Scientific Officer
Robert Shepard	66	Chief Medical Officer
Sandra L. Silberman	64	Chief Medical Officer - New Position
Robert E. George	69	Director
Michael D. Cannon	73	Director
John Climaco	50	Director

Set forth below is biographical information about each of the individuals named in the tables above:

Walter V. Klemp - Chairman of the Board, President and Chief Executive Officer.

Mr. Klemp is a co-founder of our company, and has served as our chairman of the board and chief executive officer since July 2015 and as president since August 2017. Since 2006, Mr. Klemp has served as the chairman, co-founder and part-time chief executive officer of Moleculin, LLC. Since August 2018, Mr. Klemp serves as executive chairman on the board of directors of Soliton, Inc., a medical device company focused on developing new technology for use in aesthetics. From November 2011 to August 2018, Mr. Klemp also served as chief executive officer of Soliton. Mr. Klemp served as president and chief executive officer of Zeno Corporation from 2004 to April 2011, where he developed and marketed dermatology devices and drugs from concept through FDA approval and market launch. From 1987 to 2000, Mr. Klemp served as chief executive officer and chairman of Drypers Corporation, a publicly traded multinational consumer products company that was listed as #1 on the INC 500 List of America's Fastest Growing Companies. We believe that Mr. Klemp's history with our company and background, coupled with his extensive experience in the medical field, provide him with the qualifications to serve as a Chairman of the Board and CEO.

Jonathan P. Foster - Chief Financial Officer and Executive Vice President.

Mr. Foster has served as our chief financial officer and executive vice president since August 2016. Mr. Foster brings more than 30 years in financial experience holding a variety of executive and senior financial positions with public, private, start-up to large corporate and international companies. Since June 2018, Mr. Foster serves as a member on the board of directors of Soliton, Inc., a medical device company focused on developing new technology for use in aesthetics. From February 2012 to August 2016, Mr. Foster served as Chief Financial Officer and Executive Vice President of InfuSystem Holdings, Inc., a national provider of infusion pumps and related services to the healthcare industry. From May 2011 to January 2012, Mr. Foster served as a consultant to the Chief Financial Officer of LSG Sky Chefs, USA, Inc., a subsidiary of Deutsche Lufthansa AG. Mr. Foster served on the Board of Financial Institutions for the State of South Carolina from 2006 to 2012. Mr. Foster is a Certified Public Accountant (South Carolina) and holds the designation of Chartered Global Management Accountant from the American Institute of Certified Public Accountants. He received his BS in Accounting from Clemson University in 1985. We believe that Mr. Foster's history with our company and background, coupled with his experience in the accounting and finance profession, provide him with the qualifications to serve as Chief Financial Officer and Executive Vice President.

Donald Picker, PhD - Chief Scientific Officer.

Dr. Picker has served as our chief scientific officer since August 2017 after serving as our chief operating officer from July 2015 until August 2017 and as our president from January 2016 to August 2017. His employment is on a part-time basis. In 2007, Dr. Picker became the chief executive officer of IntertechBio. From 2006 through 2007, Dr. Picker was the President of Tapestry Pharmaceuticals. From 1998 to 2003, Dr. Picker was CEO of Synergy Pharmaceuticals. Synergy was merged into Callisto Pharmaceuticals where he was vice president of research and development until 2006. Dr. Picker led the development of carboplatin and cisplatin from concept to FDA approval. In 2018, Dr. Picker became an advisor to WPD Pharmaceuticals in Poland. From 2018 to 2019, Dr. Picker served on the board of directors of CNS Pharmaceuticals, Inc. Dr. Picker received his BS degree from Brooklyn Polytechnic University and his PhD from SUNY Albany in 1975. Dr. Picker is currently devoting only part of his work time to us, and provides services as needed to us.

Robert Shepard, MD, FACP, Chief Medical Officer.

Dr. Shepard has served as our chief medical officer, on a part-time basis, since June 2016. From 2013 until 2014, Dr. Shepard served as vice president of scientific and medical affairs for Accelovance. Shepard has extensive research credentials in hematology and oncology and is board certified in oncology, hematology and internal medicine. He has a wide array of experience in translational medicine and clinical research and has been actively involved in oncology research since 1970, responsible for the clinical development of several drugs and immune therapies for biopharmaceutical companies, including serving as the consulting Chief Medical Officer for six companies. Dr. Shepard is a Magna Cum Laude graduate of Harvard University in biochemical sciences and molecular biophysics and studied in the Harvard-M.I.T. Health Sciences program. He held fellowships in hematology and oncology at the Tufts-New England Medical Center where he conducted laboratory research in leukemias, myeloma and myelodysplasia, as well as fellowship in pharmacology and molecular genetics at the Dana-Farber Cancer Center and Harvard Medical School. Dr. Shepard holds academic appointments at Harvard University, Tufts University and the University of Virginia. Dr. Shepard is currently devoting only part of his work time to us, and provides services as needed to us.

Sandra L. Silberman, MD PhD - Chief Medical Officer - New Products.

Dr. Silberman has served as our chief medical officer, on a part-time basis, for new products since November 2017. Dr. Silberman has served as chief medical officer of CNS Pharmaceuticals, Inc. since December 2017 on a part-time basis. In 2018, Dr. Silberman became an advisor to WPD Pharmaceuticals in Poland. Dr. Silberman has served as an Independent Consultant to the Biopharmaceutical Industry for the past four years. Dr. Silberman advanced several original, proprietary compounds into Phases I through III during her work with leading biopharmaceutical companies, including Bristol-Myers Squibb, AstraZeneca, Imclone and Roche. Dr. Silberman is a Hematologist/Oncologist who earned her B.A., Sc.M. and Ph.D. from the Johns Hopkins University School of Arts and Sciences, School of Public Health and School of Medicine, respectively, and her M.D. from Cornell University Medical College, and then completed both a clinical fellowship in Hematology/Oncology as well as a research fellowship in tumor immunology at the Brigham & Women's Hospital and the Dana Farber Cancer Institute in Boston, MA. Dr. Silberman is currently devoting only part of her work time to us, and provides services as needed to us.

Robert E. George - Director.

Mr. George joined our board of directors upon our IPO. He was a partner with the international accounting firm of PricewaterhouseCoopers (PWC) for 27 years until 2010, where his client service sectors included healthcare, among others. Mr. George currently serves as Chairman of the Audit Committee for The University of Texas Health Science Center at Houston and, since June 2011, has been a member of The University of Texas at Austin, McCombs Graduate School of Business accounting faculty. Mr. George graduated with accounting honors from the University of North Texas. We believe Mr. George's deep and broad level of expertise in financial accounting and reporting matters, particularly in the healthcare sector, as a former audit partner at PricewaterhouseCoopers provide him with the qualifications to serve as a director.

Michael D. Cannon - Director.

Mr. Cannon joined our board of directors upon our IPO. Between 1997 and 2004, Mr. Cannon was the Chief Science Officer, EVP and a Director of SICOR, Inc., a U.S. public pharmaceutical company, until its acquisition by Teva Pharmaceutical Industries, Inc. SICOR focused on generic finished dosage injectable pharmaceuticals, active pharmaceutical ingredients and generic biopharmaceuticals. While at SICOR, he oversaw the acquisition and development of the biological business, including initiation and management of international partnerships, as well as on the design, construction, and licensure of protein manufacturing facilities. From July 2005 to December 2009, Mr. Cannon was a member of the scientific advisory board of Trevi Health Ventures LP, a New York investment fund specializing in health care investments. From May 2005 until

December 2011, Mr. Cannon was a partner in a private partnership formed to evaluate and perform preliminary development of intellectual property in the healthcare sector. Since 2005, Mr. Cannon has served as a board member for several private companies. Mr. Cannon currently serves on the boards of directors of three privately held biotech companies. He previously served on the board of directors of Athenex, Inc., a public company traded on the NASDAQ. Mr. Cannon has a degree in chemistry from Fordham College. We believe Mr. Cannon's distinguished career in the biotechnology field, particularly as Chief Science Officer, EVP and a Director of SICOR, a publicly traded company, provide him with the qualifications to serve as a director.

John M. Climaco, Esq. - Director.

Mr. Climaco joined our board of directors in July 2017. Mr. Climaco has served as the chief executive officer of CNS Pharmaceuticals, Inc. since September 2017. Mr. Climaco has served in leadership roles in a variety of healthcare companies. From 2014 until 2017, Mr. Climaco served as the Executive Vice-President of Perma-Fix Medical S.A. From 2002 until 2012, Mr. Climaco served as President and CEO of Axial Biotech, Inc., a DNA diagnostics company. Mr. Climaco currently serves as a director of Digirad, Inc., a leading national provider of imaging services, and Birner Dental Management Services, Inc., a provider of practice management services to the dental industry. Mr. Climaco previously served as a director of PDI, Inc., a provider of outsourced commercial services to pharma companies, and InfuSystem Holdings, Inc., the largest supplier of infusion services to oncologists in the United States. Mr. Climaco obtained his Juris Doctorate Degree from University of California Hastings College of Law, San Francisco, CA and a Bachelors of Philosophy from Middlebury College, Middlebury, VT. Mr. Climaco is active with the State Bar of Utah. We believe Mr. Climaco's vast experience with development stage companies and his legal background provides him with the qualifications to serve as a director.

No director is related to any other director or executive officer of our company or our subsidiaries, and, there are no arrangements or understandings between a director and any other person pursuant to which such person was elected as director.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our executive officers and directors, and persons who own more than ten percent of our common stock, to file reports of ownership and changes in ownership of our common stock with the SEC. Officers, directors, and greater-than-ten-percent stockholders are required by the SEC's regulations to furnish us with copies of all Section 16(a) forms that they file. Based solely upon a review of the Section 16(a) forms furnished to us during the most recent fiscal year, we believe that all such forms required to be filed were timely filed, by the officers, directors, and security holders required to file the forms during the fiscal year ended December 31, 2018.

Code of Ethics

We have adopted a written code of ethics that applies to our directors, principal executive officer, principal financial officer, principal accounting officer or controller and any persons performing similar functions. The code of ethics is on the "Investors - Corporate Governance - Governance Documents" section of our web site at www.moleculin.com. We intend to disclose any future amendments to, or waivers from, the code of ethics within four business days of the waiver or amendment through a website posting or by filing a Current Report on Form 8-K with the SEC.

Nomination of Director Candidates

We receive suggestions for potential director nominees from many sources, including members of the Board, advisors, and stockholders. Any such nominations, together with appropriate biographical information, should be submitted to the Chairperson of the Nominating and Corporate Governance Committee in the manner discussed below. Any candidates submitted by a stockholder or stockholder group are reviewed and considered in the same manner as all other candidates.

Qualifications for consideration as a Board nominee may vary according to the particular areas of expertise being sought as a complement to the existing board composition. However, minimum qualifications include high level leadership experience in business activities, breadth of knowledge about issues affecting the Company, experience on other boards of directors, preferably public company boards, and time available for meetings and consultation on Company matters. Our Nominating and Corporate Governance Committee does not have a formal policy with regard to the consideration of diversity in identifying director candidates, but seeks a diverse group of candidates who possess the background, skills and expertise to make a significant contribution to the Board, to the Company and our stockholders. Candidates whose evaluations are favorable are recommended by our Nominating and Corporate Governance Committee to the full Board for consideration. The full Board selects and recommends candidates for nomination as directors for stockholders to consider and vote upon at the annual meeting.

A stockholder wishing to nominate a candidate for election to our Board of Directors at any annual meeting at which the Board of Directors has determined that one or more directors will be elected must submit a written notice of his or her nomination of a candidate to the Chairperson of the Nominating and Corporate Governance Committee (c/o the Corporate Secretary), providing the candidates name, biographical data and other relevant information together with a consent from the nominee. Pursuant to our Bylaws, the submission must be received at our principal executive offices 120 days prior to the anniversary date of the mailing date of our previous year's proxy statement so as to permit the Board of Directors time to evaluate the qualifications of the nominee.

We have not employed an executive search firm, or paid a fee to any other third party, to locate qualified candidates for director positions.

Audit Committee

The members of the Audit Committee are Robert George (Chairperson), Michael Cannon and John Climaco. Each member of the Audit Committee is independent as defined by the Nasdaq Rules. In addition, each member of the Audit Committee satisfies the additional requirements of the SEC and Nasdaq Rules for audit committee membership, including the additional independence requirements and the financial literacy requirements. The Board has determined that at least one member of the Audit Committee, Mr. George, is an "audit committee financial experts" as defined in the SEC's rules and regulations. The primary purpose of the Audit Committee is to oversee the quality and integrity of our accounting and financial reporting processes and the audit of our financial statements. The Audit Committee is responsible for selecting, compensating, overseeing and terminating the selection of our independent registered public accounting firm.

ITEM 11. EXECUTIVE COMPENSATION

Executive Officer Compensation

Our named executive officers for the years ended December 31, 2018 and 2017, which consist of our principal executive officer and our two other most highly compensated executive officers, are: (i) Walter V. Klemp, our chairman, president and chief executive officer; (ii) Jonathan P. Foster, our chief financial officer; and (ii) Donald Picker, our chief science officer.

Summary Compensation Table - Executive Officers

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option awards (\$ (1))	All other compensation (\$ (2))	Total (\$)
Walter V. Klemp, Chairman, President Chief Executive Officer (3)	2018	402,500	138,250	777,870	27,055	1,345,675
	2017	325,000	93,000	595,000	4,700	1,017,700
Jonathan P. Foster, Executive Vice President and Chief Financial Officer	2018	323,333	104,490	388,290	29,576	845,689
	2017	275,000	75,000	253,750	30,000	633,750
Donald Picker, Chief Scientific Officer	2018	254,167	54,510	96,750	33,980	439,407
	2017	225,000	50,000	105,000	25,000	405,000

(1) Represents the full grant date fair value of the option grant calculated in accordance with FASB ASC Topic 718. These amounts do not necessarily correspond to the actual value that may be realized by the named executive officer. For a summary of the assumptions made in the valuation of the awards, please see Note 6 - Equity to our financial statements as of and for the period ended December 31, 2018 included in Form 10-K.

(2) Represents payments made for medical coverage, dental, vision, short and long-term disability.

(3) Mr. Klemp's employment agreement provided that Mr. Klemp would defer 50% of his salary for 12 months, or until June 1, 2017, which deferred salary will be payable upon Mr. Klemp's termination or on June 1, 2019. The amounts set forth in the table for 2017 consists of \$262,500 that was paid during the year and \$62,500 that represents the deferred portion of Mr. Klemp's salary.

Explanation of Compensation Year; Base Salary

During 2017, we established for compensation purposes a compensation year from June 1 until May 31 of each year. In June of each year, our compensation committee completes its annual review of executive compensation and determines, after researching comparable companies and using a leading industry survey, the compensation arrangements for the next compensation year.

In June 2018, our compensation committee determined, for the 2018/2019 compensation year, to increase Mr. Klemp's base salary to \$440,000, that his targeted cash bonus for such year would be set at 55% of base compensation, and that his targeted option grant value for such compensation year would be set at \$800,000; provided that the cash bonus and option grants for the year are subject to Compensation Committee approval.

In June 2018, our compensation committee determined, for the 2018/2019 compensation year, to increase Mr. Foster's base salary to \$340,000, that his targeted cash bonus for such year would be set at 40% of base compensation, and that his targeted option grant value for such year would be set at \$315,000; provided that the cash bonus and option grants for the year are subject to Compensation Committee approval.

In June 2018, our compensation committee determined, for the 2018/2019 compensation year, to increase Dr. Picker's base salary would continue to be \$275,000, that his targeted cash bonus for such year would be set at 41% of base compensation, and that his targeted option grant value for such year would be set at \$100,000; provided that the cash bonus and option grants for the year are subject to Compensation Committee approval.

Equity Awards

The following table sets forth certain information concerning our outstanding options for our named executive officers at December 31, 2018 and 2017.

Outstanding Equity Awards At Fiscal Year-End

Name	Grant Date of Equity Award	Number of Securities Underlying Unexercised Options (#) Exercisable (1)	Number of Securities Underlying Unexercised Options (#) Unexercisable (1)	Option Exercise Price (\$)	Option Expiration Date
Walter V. Klemp, Chairman, President Chief Executive Officer	6/6/2018	—	603,000	\$ 1.82	6/6/2028
	10/3/2017	85,000	340,000	\$ 2.49	10/3/2027
Jonathan P. Foster, Executive Vice President and Chief Financial Officer	6/6/2018	—	301,000	\$ 1.82	6/6/2018
	10/3/2017	36,250	145,000	\$ 2.49	10/3/2027
	8/19/2016	200,000	200,000	\$ 5.85	8/19/2026
Donald Picker, Chief Scientific Officer	6/6/2018	—	75,000	\$ 1.82	6/6/2028
	10/3/2017	15,000	60,000	\$ 2.49	10/3/2027

(1) The shares underlying the options vest in equal annual installments over a four-year period (i.e., one-quarter of each grant vests on the first, second, third and fourth anniversary of the grant date).

Employment Agreements

Klemp Employment Agreement

On October 13, 2016, we entered into an employment agreement with Mr. Walter Klemp pursuant to which Mr. Klemp agreed to serve as our Chief Executive Officer commencing on such date. The agreement provided for an initial annual salary of \$300,000, provided that Mr. Klemp agreed to defer 50% of his salary for 12 months, which deferred salary will be payable upon Mr. Klemp's termination or on June 1, 2019. Effective June 2018, our compensation committee agreed to increase Mr. Klemp's base salary to \$440,000. If Mr. Klemp's employment is terminated at our election without "cause" (as defined in the

agreement), which requires 30 days advanced notice, or by Mr. Klemp for “good reason” (as defined in the agreement), Mr. Klemp shall be entitled to receive severance payments equal to the greater of 12 months of Mr. Klemp’s base salary or the base salary Mr. Klemp would have received had he remained employed through the third anniversary of the date of the agreement. Mr. Klemp has agreed not to compete with us for 12 months after the termination of his employment. If we determine to retain a new chief executive officer during the term of the agreement, we have the option, at our discretion, to convert Mr. Klemp into a consultant on the same terms as set forth above.

Foster Employment Agreement

On August 19, 2016, we entered into an employment agreement with Mr. Jonathan P. Foster pursuant to which Mr. Foster agreed to serve as our Chief Financial Officer and Executive Vice President commencing on such date for an initial term of three years, which will be automatically renewed for additional one-year terms unless either party chooses not to renew the agreement. The agreement provided for an initial annual salary of \$250,000. Effective June 2018, our compensation committee agreed to increase Mr. Foster’s base salary to \$340,000. Mr. Foster may receive an annual bonus, provided that the final determination on the amount of the annual bonus, if any, will be made by the Compensation Committee of the Board of Directors, based on criteria established by the Compensation Committee.

Under the agreement, Mr. Foster was granted a ten-year option to purchase 400,000 shares at an exercise price per share equal to the closing price of our common stock on the date of execution of his employment agreement, which was \$5.85. The option vests in four equal installments (or 100,000 shares each installment) on each of the succeeding four anniversary dates of the execution of the agreement, provided Mr. Foster is Chief Financial Officer on such vesting date. In the event of a “change of control” (as defined in the agreement) prior to the final vesting of all of the options, all of the unvested options shall immediately vest; provided, however, in the event the acquiring party desires to replace the unvested options with a substitute grant of equal or greater value, such proposed substitution shall be submitted to the Compensation Committee, and the Compensation Committee shall decide whether to allow the unvested options to vest or whether to cancel the unvested options and replace them with the substitute grant proposed by the acquiring party.

If Mr. Foster’s employment is terminated at our election without “cause” (as defined in the agreement), which requires 90 days advance notice, or by Mr. Foster for “good reason” (as defined in the agreement), Mr. Foster shall be entitled to receive severance payments equal to nine months of Mr. Foster’s base salary and a pro rata portion of the target bonus, if any, for the year in which such termination occurs. In addition, if Mr. Foster’s employment is terminated prior to the end of the term of the agreement by us without cause or by Mr. Foster for good reason, and such termination occurs within three months prior to a change in control, in contemplation of a change in control or within six months after a change in control, Mr. Foster shall be entitled to receive, in addition to the severance discussed above, an acceleration of the vesting of the option grant described in the prior paragraph. Mr. Foster agreed not to compete with us until nine months after the termination of his employment.

Director Compensation

In April 2018, our compensation committee engaged Pay Governance LLC, an independent compensation consultant, to advise them on matters relating to our non-employee director compensation program. Based on a review of a compensation study prepared by Pay Governance, our compensation committee recommended to our Board and our Board approved the following policy for compensating non-employee members of the Board:

- Each non-employee director shall receive annual cash compensation of \$35,000. In addition, the chairperson of the Audit Committee, Compensation Committee and Nominating and Governance Committee shall receive an annual compensation of \$15,000, \$10,000 and \$7,500, respectively; the other members of such committees shall receive an annual compensation of \$7,500, \$5,000 and \$3,750, respectively; and the Lead Independent Director shall receive an annual compensation of \$15,000. All payments will be made within 15 days after calendar quarter end.

- Upon the initial appointment (or election) of non-employee directors to the Board, the director will be issued a 10-year option to purchase 40,000 shares of our common stock, under our 2015 Stock Plan, with 3-year annual vesting and an exercise price equal the closing price of our common stock on the date of the appointment (or election). Prior to April 2018, the initial appointment option grant consisted of an option to purchase 20,000 shares of common stock. Consistent with the Pay Governance compensation study, the Committee determined that the increase from 20,000 shares to 40,000 shares approximates the median initial appointment award value provided by a representative peer group of publicly traded companies. Correspondingly, each of our current non-employee directors will receive an additional 20,000 share option grant on the date of the 2018 annual meeting to adhere to the new initial appointment policy.

- Annually, on the date of our annual meeting, each non-employee director that is re-elected at the annual meeting will be issued, upon a motion and approval of the Board of Directors, a 10-year option to purchase 15,000 shares of our common stock, under our 2015 Stock Plan, with 3-year annual vesting and an exercise price equal the closing price of our common stock on the date of the annual meeting.

In December 2018, our compensation committee engaged Pay Governance LLC, an independent compensation consultant, to advise them on matters relating to our non-employee director compensation program. Their report is expected to be released to the committee by May 2019.

The following table sets forth the total compensation earned by our non-employee directors in 2018 (Mr. Klemp did not earn additional compensation during 2018 for his services on the Board, and his compensation is fully reflected in the “- Summary Compensation Table” above):

Summary Compensation Table for Non-Employee Directors

Name	Year	Fees earned or paid in cash (\$)	Option awards (\$ (1))	Total (\$)
Michael D. Cannon	2018	\$ 56,250	\$ 44,450	\$ 100,700
Robert E. George	2018	\$ 62,500	\$ 44,450	\$ 106,950
John Climaco	2018	\$ 66,250	\$ 44,450	\$ 110,700

(1) Represents the full grant date fair value of the option award our board approved and granted to each non-employee director, calculated in accordance with FASB ASC Topic 718. These amounts do not necessarily correspond to the actual value that may be realized by the director. For a summary of the assumptions made in the valuation of the awards, please see Note 7 to our financial statements as of and for the period ended December 31, 2018 included in this Form 10-K. As of December 31, 2018, the aggregate number of shares outstanding under all options to purchase our common stock held by our non-employee directors were: Mr. Cannon - 70,000 shares; Mr. George - 70,000 shares; and Mr. Climaco - 55,000 shares. None of our non-employee directors held stock awards other than options as of December 31, 2018.

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

The following table sets forth information, as of February 5, 2019, regarding beneficial ownership of our common stock by:

- each of our directors;
- each of our executive officers;
- all directors and executive officers as a group; and
- each person, or group of affiliated persons, known by us to beneficially own more than five percent of our shares of common stock.

Beneficial ownership is determined according to the rules of the SEC, and generally means that person has beneficial ownership of a security if he or she possesses sole or shared voting or investment power of that security, and includes options that are currently exercisable or exercisable within 60 days. Each director or officer, as the case may be, has furnished us with information with respect to beneficial ownership. Except as otherwise indicated, we believe that the beneficial owners of common stock listed below, based on the information each of them has given to us, have sole investment and voting power with respect to their shares, except where community property laws may apply. Except as otherwise noted below, the address for each person or entity listed in the table is c/o Moleculin Biotech, Inc., 5300 Memorial Drive, Suite 950, Houston, Texas 77007.

Name and Address of Beneficial Owner	As of February 5, 2019	
	Shares beneficially owned	Percent of Class (1)
Walter V. Klemp	2,477,724 (2)	9.1 %
Donald Picker	1,113,635 (3)	4.1 %
Jonathan P. Foster	246,250 (4)	Less than 1%
Robert George	14,750 (5)	Less than 1%
Michael Cannon	13,750 (6)	Less than 1%
John Climaco	5,000 (6)	Less than 1%
<i>Directors and Named Executive Officers as a Group (8 persons)</i>	3,871,109 (7)	14.3 %
<i>5% or greater shareholders</i>		
Waldemar Priebe	4,040,573 (8)	14.9 %
AnnaMed, Inc.	1,425,000 (9)	5.3 %

(1) Based on 27,129,510 shares of common stock outstanding as of February 5, 2019.

(2) Includes 1,425,000 shares held by AnnaMed, Inc. that have been included in the amount for Mr. Klemp. Mr. Klemp has voting and dispositive power over the shares held by AnnaMed, Inc. Includes 85,000 shares underlying options exercisable within 60 days of February 5, 2019.

(3) Of the amount in the table, 630,000 shares held by IntertechBio Corp. have been included in the amounts for Drs. Picker and Priebe. Drs. Picker and Priebe have voting and dispositive power over the shares held by IntertechBio Corp. Includes 15,000 shares underlying options exercisable within 60 days of February 5, 2019.

(4) Includes 236,250 shares underlying options exercisable within 60 days of February 5, 2019.

(5) Includes 13,750 shares underlying options exercisable within 60 days of February 5, 2019.

(6) Consists solely of shares underlying options exercisable within 60 days of February 5, 2019.

(7) Consists of the shares identified in footnotes (2)-(6).

(8) Of the amount in the table, 629,000 shares held by Houston Pharmaceuticals, Inc. have been included in the amount for Dr. Priebe. Dr. Priebe has voting and dispositive power over the shares held by Houston Pharmaceuticals, Inc. Of the amount in the table, 630,000 shares held by IntertechBio Corp. have been included in the amounts for Drs. Picker and Priebe. Drs. Picker and Priebe have voting and dispositive power over the shares held by IntertechBio Corp.

(9) Mr. Klemp has voting and dispositive power over the shares held by AnnaMed, Inc.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information regarding our equity compensation plans at December 31, 2018:

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)	2,794,000	\$ 1.82	1,706,000
Equity compensation plans not approved by security holders (2)	107,802	\$ 7.50	—
Equity compensation plans not approved by security holders (3)	250,000	\$ 2.76	—
Total	3,151,802		1,706,000

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.

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

Director Independence

The rules of the Nasdaq Stock Market, or the Nasdaq Rules, require a majority of a listed company's board of directors to be composed of independent directors. In addition, the Nasdaq Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent. Under the Nasdaq Rules, a director will only qualify as an independent director if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The Nasdaq Rules also require that audit committee members satisfy independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In considering the independence of compensation committee members, the Nasdaq Rules require that our board of directors must consider additional factors relevant to the duties of a compensation committee member, including the source of any compensation we pay to the director and any affiliations with our company.

Our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Mr. Klemp, are independent as defined under the Nasdaq Rules.

Related Party Transactions

Prior to our IPO, we merged with Moleculin, LLC. Moleculin, LLC was the holder of the license agreement with MD Anderson covering our WP 1066 Portfolio. As a result of the merger, we issued the equity interests holders of Moleculin, LLC an aggregate of 999,931 shares of our common stock. Waldemar Priebe, Walter Klemp and Don Picker were members of Moleculin, LLC and received 6,046 shares, 22,795 shares and 6,046 shares, respectively, of our common stock as a result of the merger. In addition, Walter Klemp and Don Picker were members of the board of Moleculin, LLC.

In connection with the acquisition of Moleculin, LLC, we also negotiated on behalf of Moleculin, LLC two agreements with HPI. Waldemar Priebe and Don Picker are shareholders of HPI, and Dr. Priebe has the voting and dispositive power over our shares held by HPI. Under the first agreement, HPI's option to obtain an 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 this amount, all has been paid as of December 31, 2018 except for \$75,000 which was due and paid in January 2019 and an additional payment is due on May 15, 2019. At that time the \$1.0 million payment to conclude this out-licensing agreement is due. 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, 2018, 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 may 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.

We currently employ Lindsey Picker, the daughter of Don Picker, our president and chief operating officer, as a clinical research assistant on an at-will basis with an annual salary of \$75,000.

In February 2019, we entered into sublicense agreements with WPD Pharmaceuticals, Inc. and Animal Lifesciences, LLC. Dr. Priebe is affiliated with both WPD Pharmaceuticals, Inc. and Animal Lifesciences, LLC. For more information on the terms of these agreements, please see Item 1 – Business-Our Licensing Agreements above. In addition, Dr. Picker and Dr. Silberman have in the past and may in the future perform consulting work for WPD Pharmaceuticals.]

In August 2018, CNS Pharmaceuticals, Inc. entered into sublicense agreements with WPD Pharmaceuticals, Inc. and Animal Lifesciences, LLC pursuant to which CNS Pharmaceuticals, Inc. licensed the rights to their lead drug candidate, Berubicin, an anthracycline. Mr. Climaco is the chief executive officer of CNS Pharmaceuticals, Inc. and Dr. Silberman is the part-time chief medical officer for CNS Pharmaceuticals, Inc. In addition, Dr. Picker was previously a director of CNS Pharmaceuticals, Inc. Dr. Priebe is the majority shareholder of CNS Pharmaceuticals, Inc.]

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or as a director or executive officer of any other company or enterprise to which the person provides services at our request. We believe that these charter provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may decline in value to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Policies and Procedures for Related Party Transactions

Our audit committee charter provides that our audit committee is responsible for reviewing and approving in advance any related party transaction. This will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds \$120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. All of the transactions described in this section occurred prior to the creation of our audit committee and the adoption of this policy.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our proxy statement for the 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2018, and is incorporated into this Annual Report on Form 10-K by reference.

PART IV

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 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 75.

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

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)
4.2	Form of Warrant Agreement issued in February 2018 offering (incorporated by reference to Exhibit 4.1 of the Form 8-K filed February 16, 2018)
4.3	Form of Warrant Agreement issued in June 2018 offering (incorporated by reference to Exhibit 4.1 of the Form 8-K filed June 21, 2018)
10.1 **	Moleculin Biotech, Inc. Amended and Restated 2015 Stock Plan (incorporated by reference to Annex B to the definitive proxy statement filed April 27, 2018)
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 Molculin 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 Molculin 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 Molculin 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)
10.17	Lease Agreement for 5300 Memorial (incorporated by reference to Exhibit 10.1 of the Form 10-Q filed May 14, 2018)
10.18+	Patent And Technology License Agreement dated February 12, 2018 by and between The Board of Regents of The University Of Texas System on behalf of The University Of Texas M. D. Anderson Cancer Center and Molculin Biotech, Inc. (incorporated by reference to Exhibit 10.2 of the Form 10-Q filed May 14, 2018)
10.19	Purchase Agreement, dated as of October 4, 2018, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 of the Form 8-K filed October 5, 2018)
10.20	Registration Rights Agreement, dated as of October 4, 2018, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 of the Form 8-K filed October 5, 2018)
10.21*	Sublicense Agreement dated as of February 19, 2019 entered into between the Company and WPD
10.22*	Sublicense Agreement dated as of February 19, 2019 entered into between the Company and Animal Life Sciences, LLC
21*	Subsidiaries of the Registrant
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.
+	Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

ITEM 16. FORM 10-K SUMMARY

None.

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: February 21, 2019

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
<u>/s/ Walter V. Klemp</u> Walter V. Klemp	Chief Executive Officer and Chairman (Principal Executive Officer)	February 21, 2019
<u>/s/ Jonathan P. Foster</u> Jonathan P. Foster	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 21, 2019
<u>/s/ Robert George</u> Robert George	Director	February 21, 2019
<u>/s/ Michael Cannon</u> Michael Cannon	Director	February 21, 2019
<u>/s/ John Climaco</u> John Climaco	Director	February 21, 2019

Moleculin Biotech, Inc.
Index to Consolidated Financial Statements

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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 consolidated balance sheets of Moleculin Biotech, Inc. (a Delaware corporation) and subsidiary (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, 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 \$26.4 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
February 21, 2019

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

	December 31,	
	2018	2017
Assets		
Current Assets:		
Cash and cash equivalents	\$ 7,134	\$ 7,714
Prepaid expenses and other	840	588
Total current assets	7,974	8,302
Furniture and equipment, net of accumulated depreciation of \$93 and \$21, respectively	463	33
Intangible assets	11,148	11,148
Total Assets	<u>\$ 19,585</u>	<u>\$ 19,483</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,246	\$ 810
Accrued expenses and other current liabilities	2,302	902
Deferred compensation - related party	150	—
Warrant liability - current	180	503
Total current liabilities	3,878	2,215
Long-term deferred compensation – related party	—	150
Deferred rent - long-term	107	—
Warrant liability - long-term	1,328	—
Total Liabilities	<u>5,313</u>	<u>2,365</u>
Commitments and contingencies (Note 8)		
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, 28,528,663 and 21,469,109 shares outstanding at December 31, 2018 and December 31, 2017, respectively	29	21
Additional paid-in capital	40,564	31,577
Accumulated other comprehensive income	35	—
Accumulated deficit	(26,356)	(14,480)
Total stockholders' equity	<u>14,272</u>	<u>17,118</u>
Total liabilities and stockholders' equity	<u>\$ 19,585</u>	<u>\$ 19,483</u>

See accompanying notes to the financial statements.

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

	December 31,	
	2018	2017
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	9,728	4,545
General and administrative	5,229	4,090
Depreciation	68	18
Total operating expenses	15,025	8,653
Loss from operations	(15,025)	(8,653)
Other income (expense):		
Gain (loss) from change in fair value of warrant liability	3,185	(2,548)
Gain from settlement of liability	—	149
Gain from expiration of warrants	—	1,238
Other (expense) income	(40)	9
Interest income (expense), net	4	—
Net loss	<u>\$ (11,876)</u>	<u>\$ (9,805)</u>
Net loss per common share - basic and diluted	<u>\$ (0.46)</u>	<u>\$ (0.53)</u>
Weighted average common shares outstanding, basic and diluted	<u>25,904,170</u>	<u>18,569,193</u>
Comprehensive loss:		
Net loss	\$ (11,876)	\$ (9,805)
Other comprehensive income (loss):		
Foreign currency translation	\$ 35	\$ —
Comprehensive loss	<u>\$ (11,841)</u>	<u>\$ (9,805)</u>

See accompanying notes to the financial statements.

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

	December 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (11,876)	\$ (9,805)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	68	18
Stock-based compensation	1,140	707
Deferred compensation - related party	—	62
Change in fair value of warrant liability	(3,185)	2,548
Gain in settlement of liability	—	(149)
Gain from expiration of warrants	—	(1,238)
Loss on foreign currency transactions	40	—
Other	—	(9)
Changes in operating assets and liabilities:		
Prepaid expenses	(252)	(364)
Accounts payable	436	411
Accrued expenses and other current liabilities	1,400	495
Other long-term liabilities	26	—
Net cash used in operating activities	<u>(12,203)</u>	<u>(7,324)</u>
Cash flows from investing activities:		
Purchase of fixed assets	(417)	(28)
Net cash used in investing activities	<u>(417)</u>	<u>(28)</u>
Cash flows from financing activities:		
Proceeds from exercise of stock options	5	—
Proceeds from exercise of warrants	15	3,988
Proceeds from sale of common stock, net of cash stock issuance costs	12,025	6,071
Net cash provided by financing activities	<u>12,045</u>	<u>10,059</u>
Effect of exchange rate changes on cash and cash equivalents	(5)	—
Net change in cash and cash equivalents	(580)	2,707
Cash and cash equivalents, at beginning of year	7,714	5,007
Cash and cash equivalents, at end of year	<u><u>\$ 7,134</u></u>	<u><u>\$ 7,714</u></u>
Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ 5	\$ 3
Cash paid for income taxes	\$ —	\$ —
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued liabilities	\$ 23	\$ —
Leasehold improvements paid by landlord	\$ 82	\$ —
Common stock issued for conversion of debt	\$ —	\$ 302
Warrants issued for services provided	\$ —	\$ 104
Common stock issued for services provided	\$ —	\$ 89

See accompanying notes to the financial statements.

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

	Common Stock						
	Shares	Par Value Amount	Additional Paid-In-Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Stockholders' Equity	
Balance, December 31, 2016	12,164,852	\$ 12	\$ 19,623	\$ (4,675)	\$ —	\$ 14,960	
Issued for cash - sale of units	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, December 31, 2017	21,469,109	21	31,577	(14,480)	—	17,118	
Issued for cash - sale of common stock in February 2018, net of issuance costs of \$809	4,290,000	5	5,117	—	—	5,122	
Issued for cash - sale of common stock in June 2018, net of issuance costs of \$232	1,092,636	1	957	—	—	958	
Issued to Lincoln Park - sale of common stock, net of issuance costs of \$380	1,642,166	2	1,754	—	—	1,756	
Stock options exercised	25,000	—	4	—	—	4	
Warrants exercised	9,752	—	15	—	—	15	
Stock-based compensation	—	—	1,140	—	—	1,140	
Net loss	—	—	—	(11,876)	—	(11,876)	
Cumulative translation adjustment	—	—	—	—	35	35	
Balance, December 31, 2018	28,528,663	\$ 29	\$ 40,564	\$ (26,356)	\$ 35	\$ 14,272	

See accompanying notes to the financial statements.

Moleculin Biotech, Inc.
Notes to the Consolidated Financial Statements

1. Nature of Business

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, with its focus on the treatment of highly resistant cancers via the development of its 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 formed Moleculin Australia Pty. Ltd., (MAPL), a wholly-owned subsidiary in June 2018, to begin preclinical development in Australia for WP1732, an analog of WP1066. This may enable the Company to enjoy the benefits of certain research and development tax credits in Australia.

Core Technologies - MBI has three core technologies with six drug candidates, all of which are based on discoveries made at MD Anderson. These core technologies are 1) Annamycin, 2) its Immune/Transcription Modulators portfolio and 3) its Metabolism/Glycosylation Inhibitor portfolio. The Company’s clinical stage drugs are Annamycin, an anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML and WP1066, an Immune/Transcription Modulator targeting brain tumors, pancreatic cancer and AML. Subsequent to December 31, 2018, WP1220 was approved for a clinical trial in Poland for the treatment of a form of skin cancer, cutaneous T-cell lymphoma (CTCL). WP1220 is part its Immune/Transcription Modulators portfolio. MBI is also engaged in preclinical development of additional drug candidates, including other Immune/Transcription Modulators, as well as Metabolism/Glycosylation Inhibitors. With the approval of the Polish clinical trial in January 2019 for WP1220 for the treatment of a type of skin cancer, the Company now has three drugs in four clinical trials.

The Company believes Annamycin is a "Next Generation Anthracycline" since it is designed to avoid multidrug resistance mechanisms and to affect little to no cardiotoxicity. Annamycin is currently in two Phase I/II clinical trials, and preliminary clinical data suggests that it may have the potential to become the first therapy suitable for the majority of relapsed or refractory AML patients.

WP1066 is one of several Immune/Transcription Modulators that appear capable of stimulating immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs) while also inhibiting key oncogenic transcription factors, including p-STAT3, c-Myc and HIF-1 α . These transcription factors are widely sought targets that may also play a role in the inability of immune checkpoint inhibitors to affect more resistant tumors.

The Company is also developing new prodrugs to exploit the potential uses of inhibitors of glycolysis. Its lead Metabolism/Glycosylation Inhibitor compound, WP1122, provides an opportunity to cut off the fuel supply of tumors by taking advantage of their overdependence on glucose as compared with healthy cells. New research also points to the potential for the glucose decoy (2-DG) within WP1122 to be capable of enhancing the usefulness of checkpoint inhibitors.

Drug Candidates - Within the Company's core technologies, it currently has six drug candidates representing three substantially different approaches to treating cancer. Annamycin, is a chemotherapy designed to inhibit the replication of DNA of rapidly dividing cells and is the Company's most mature drug candidate. Annamycin had been in clinical trials pursuant to an investigational 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, the Company resubmitted a new IND for a Phase I/II trial for the treatment of relapsed or refractory AML in August 2017, which the FDA allowed to go into effect in September 2017. The Company has trials open in the US and Poland and is actively recruiting in both countries.

The Company has five other drug development projects:

- WP1066 has an approved physician-sponsored clinical trial open for enrollment and dosing patients for the treatment of brain tumors and is also being evaluated for potential treatment of pediatric brain tumors, as well as AML and pancreatic cancer,
- WP1220, an analog of WP1066, is being studied for the topical treatment of CTCL and MBI filed a Clinical Trial Application ("CTA") in Poland which was approved in January 2019,
- WP1732, another analog of WP1066, that the Company believes is particularly well suited for intravenous administration, is being evaluated for potential treatment of AML, pancreatic and other cancers, and MBI has begun pre-clinical work which it expects to generate sufficient data for an IND filing in 2019, and
- WP1122 and WP1234 are being evaluated for their potential to treat brain tumors and pancreatic cancer via their ability to inhibit glycolysis.

Clinical Trials - The Company believes that patient recruitment for its Annamycin clinical trial in the US has been slow due to the high number of competitive clinical trials, combined with the FDA's requirement to set the initial dose level relatively low in comparison with previous Annamycin clinical trials. Additionally, the Company believes that patient recruitment for its clinical trial in Poland will be more successful than in the US due to a comparatively lower number of competitive clinical trials and the protocol there being approved to start at a significantly higher dose than in the US with fewer enrollment screening limitations.

On May 1, 2018, the Company engaged another contract research organization ("CRO") to evaluate additional countries for the expansion of its AML clinical trial, specifically Australia and several Western European countries to provide additional clinical sites to improve access to patients for MBI's trial. This evaluation is ongoing.

In July 2018, the physician-sponsored WP1066 Phase I clinical trial for the treatment of glioblastoma opened for recruitment and began treating patients in September 2018.

In September 2017, the Company engaged a CRO to prepare for a proof-of-concept clinical trial in Poland to study its drug candidate WP1220, a part of the WP1066 portfolio, for the treatment of CTCL. The Company filed a CTA in Poland for this use, which was approved subsequent to December 31, 2018, and gave the Company its third drug in its fourth clinical trial.

Licenses - The Company has been granted royalty-bearing, worldwide, exclusive licenses for the patent and technology rights related to all of MBI's drug technologies, as these intellectual property rights are owned in part or entirely by MD Anderson. The Annamycin drug substance is no longer covered by any existing patent protection, however, the Company intends to submit patent applications for formulation, synthetic process and reconstitution related to MBI's Annamycin drug product candidate, although there is no assurance that the Company will be successful in obtaining such patent protection. Such technology is also licensed from MD Anderson. Independently from potential patent protection, MBI has received Orphan Drug designation (ODD) from the FDA for Annamycin for the treatment of AML and, subsequent to December 31, 2018, for WP1066 for the treatment of glioblastoma. ODD may provide tax and other benefits during product development, and if either product is approved, may lead to a grant of seven-year market exclusivity. Under that exclusivity, which runs from the date of the approval of the New Drug Application (NDA) in the United States, the FDA generally (there are important exceptions) could not approve another for the designated indication. The Company also intends to apply for similar status in the European Union (EU) where market exclusivity could extend to 10 years from the date of Marketing Authorization Application (MAA) approval. Separately, the FDA may also grant market exclusivity of 5 years for newly approved new chemical entities (which the Company believes Annamycin would be one), but there can be no assurance that such exclusivity will be granted.

Moleculin, LLC - Prior to MBI's initial public offering, the Company 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. Basis of presentation, principles of consolidation and significant accounting policies

Basis of Presentation - The accompanying consolidated 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").

Acquisition - We acquired Moleculin, LLC ("Moleculin") on May 2, 2016, and, going forward our consolidated 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.

Principles of consolidation - The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation. The company views its operations and manages its business in one operating segment. All material long-lived assets of the Company reside in the United States. 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.

Use of Estimates - The preparation of these consolidated financial statements 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 expenses during the reporting period. Actual results could differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of financial statements. Estimates are used in the following areas, among others: fair value estimates on intangible assets, warrants, and stock-based compensation expense, accrued expenses and taxes.

Going Concern - These consolidated 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, 2018, the Company has incurred a consolidated accumulated deficit of \$26.4 million since inception and had not yet generated any revenue from operations. Additionally, management anticipates that its consolidated cash on hand as of December 31, 2018 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 consolidated 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.

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
Software	3 years
Machinery and equipment	5 years
Furniture and office equipment	7 years

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 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.

Rent and Deferred rent - The Company recognizes rent expense for leases with increasing annual rents on a straight-line basis over the term of the lease. The amount of rent expense in excess of cash payments is classified as deferred rent. Any lease incentives received are deferred and amortized over the term of the lease.

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 5. The following table provides the financial assets and liabilities reported at fair value and measured on a recurring basis at December 31, 2018 and December 31, 2017, respectively. (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:				
December 31, 2018	\$ 1,508	\$ —	\$ —	\$ 1,508
December 31, 2017	\$ 503	\$ —	\$ —	\$ 503

The following table provides a summary of changes in fair value associated with the Level 3 liabilities for the years ended December 31, 2017 and 2018 (in thousands):

	Warrant Liability – Current	Warrant Liability – Long-Term	Warrant Liability – Total
December 31, 2016	\$ —	\$ —	\$ —
Issuance 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
Exercise of warrants	(5,201)	251	(4,950)
Expiration of warrants	(1,238)	—	(1,238)
December 31, 2017	503	—	503
Issuance of warrants	—	4,203	4,203
Change in fair value - net	(310)	(2,875)	(3,185)
Exercise of warrants	(13)	—	(13)
December 31, 2018	\$ 180	\$ 1,328	\$ 1,508

The above table of Level 3 liabilities begins with the initial valuation given the warrant issuances that occurred in 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.

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.

Translation of Foreign Currencies - The functional currency for our foreign subsidiary is the local currency. For our non-U.S. Subsidiary that transacts in a functional currency other than the U.S. dollar, assets and liabilities are translated at current rates of exchange at the balance sheet date. Income and expense items are translated at the average foreign currency rates for the period. Adjustments resulting from the translation of the financial statements of our foreign operations into U.S. dollars are excluded from the determination of net income and are recorded in accumulated other comprehensive income, a separate component of equity.

Stock-based Compensation - Stock-based compensation expense includes the estimated fair value of equity awards vested or expected to vest during the reporting period. The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, Compensation—Stock Compensation ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options and modifications to existing stock options, to be recognized in the consolidated statements of operations based on their fair values. The Company uses the Black-Scholes option pricing model to determine the fair value of options granted. The awards are subject to service vesting conditions. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Compensation expense related to awards to non-employees with service-based vesting conditions is recognized based on the then-current fair value at each financial reporting date prior to the measurement date over the associated service period of the award, which is generally the vesting term.

Loss Per Common Share - Basic net loss per common share is 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, 2018, the Company's potentially dilutive shares, which were not included in the calculation of net loss per share, included options to purchase 2,794,000 common shares and warrants to purchase 3,784,515 common shares. 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.

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 consolidated financial statements were issued for subsequent event disclosure consideration as described in Note 9.

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, 2018. The Company is currently evaluating the impact that this standard will have on its consolidated 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. This topic is not applicable until after 2018.

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 adoption of this pronouncement did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued Topic 842, Leases, by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. The new leasing standards generally requires lessees to recognize operating and financing lease liabilities and corresponding right-of-use assets on the consolidated balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. We will adopt the new standard effective January 1, 2019 and will not restate comparative periods. Presentation of leases within the consolidated statements of operations and consolidated statements of cash flows will be generally consistent with the current lease accounting guidance. We will elect the package of practical expedients permitted under the transition guidance and as such, the adoption of this ASU will not change the classification of any of our leases. We will elect to combine lease and non-lease components, elect not to record leases with an initial term of 12 months or less on the balance sheet and recognize the associated lease payments in the consolidated statements of operations on a straight-line basis over the lease term. We estimate that approximately \$0.2 million will be recognized as total right-of-use asset and a lease liability on our consolidated balance sheet as of January 1, 2019. Otherwise, we do not expect the new standard to have a material impact on our consolidated 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 consolidated 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. The adoption of this standard on January 1, 2018 did not have a significant impact on the Company's consolidated 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. 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 adoption of this pronouncement did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718) Improvements to Non-employee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 affects all entities that enter into share-based payment transactions for acquiring goods and services from non-employees. The amendments in this ASU expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The amendments in this ASU are effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption permitted, but no earlier than an entity's adoption date of Topic 606. The adoption of this pronouncement did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820) ("ASU 2018-13"). ASU 2018-13 modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement, based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of this Update. The Company is currently evaluating the impact that this standard will have, if any, 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 \$6.0 million, 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 \$0.1 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. 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, 2018, 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 \$0.75 million 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. When we decide to exercise the buy-out right from HPI, we will need to raise additional funds. We cannot assure that such additional funding will be available on satisfactory terms, or at all.

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.

Intangible assets consisted of the following at December 31, 2018 and December 31, 2017 (in thousands):

	December 31,	
	2018	2017
Intangibles acquired from Moleculin, LLC	\$ 11,148	\$ 11,148

4. Accrued expenses and other current liabilities

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

	December 31,	
	2018	2017
Accrued license fees and sponsored research agreements	\$ 1,147	\$ 260
Accrued drug manufacturing costs	400	—
Accrued payroll	342	250
Accrued clinical testing	95	320
Accrued legal and professional fees	91	50
Accrued other	227	22
Total accrued expenses and other current liabilities	\$ 2,302	\$ 902

5. Warrant Liability

The basis of value of the warrant liability 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 used the Black-Scholes option pricing model (“BSM”) to determine the fair value of the Series A and Series B Warrants from the February 2017 Issuance, described below, along with the warrants issued in the February 2018 Issuance and June 2018 Issuance. The Company used a Monte Carlo simulation (“MCM”) with regard to the Series C Warrants from the February 2017 Issuance because of the path dependent vesting terms of the contract.

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 issuance date.

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

June 2018 Issuance of Warrants

On June 22, 2018, the Company entered into a definitive agreement with institutional investors for a registered direct offering of securities for the sale of 1,092,636 shares of its common stock, at a purchase price of \$2.105 per share. Concurrently with the sale of the common shares, pursuant to the agreement, the Company also sold warrants to purchase 710,212 shares of common stock. The total number of warrants issued were 742,991, which includes the Roth Warrants below. The Company sold the common shares and warrants for aggregate gross proceeds of approximately \$2.3 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 \$2.02 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 agreement occurred on June 22, 2018.

The Company 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. The Company 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, the Company also issued Roth warrants to purchase up to 3% of the aggregate number of shares of common stock sold in the transactions (the “Roth Warrants”) or 32,779 shares. The Roth Warrants have substantially the same terms as the investor warrants described above, except that the Roth Warrants will expire on June 21, 2023 and have an exercise price of \$2.3155 per share. 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. The Company also reimbursed Roth for its expenses of \$50,000. The Company agreed to give Roth a nine month right of first refusal to act as its lead underwriter or exclusive placement agent for any further capital raising transactions the Company undertakes. With certain exceptions, the Company 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 MBI with further capital during such six-month period following termination of its engagement of Roth.

The assumptions used in the BSM model for the June 2018 Warrants are as follows:

	Year Ended December 31,			
	2018		2017	
Risk-free interest rate	2.5 %	to	2.51%	N/A
Volatility	75 %	to	80%	N/A
Expected life (years)	4.47	to	4.98	N/A
Dividend yield	—%			N/A

A summary of the Company's June 2018 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 as of January 1, 2018	—	—	—	—	—
Granted	742,991	\$ 2.02	to \$ 2.32	\$ 2.03	4.97
Exercised	—	—	—	—	—
Expired	—	—	—	—	—
Balance as of December 31, 2018	<u>742,991</u>	\$ 2.02	to \$ 2.32	\$ 2.03	4.97
Vested and exercisable at December 31, 2018	<u>742,991</u>	\$ 2.02	to \$ 2.32	\$ 2.03	4.97

February 2018 Issuance of Warrants

On February 16, 2018, the Company entered into a Securities Purchase Agreement with certain institutional investors for the sale of 4,290,000 shares of its common stock, at a purchase price of \$2.10 per share. Concurrently with the sale of the common shares, pursuant to the Purchase Agreement, the Company also sold warrants to purchase 2,145,000 shares of common stock. The total number of warrants issued were 2,273,700 which includes the Roth Warrants below. The Company sold the common shares and warrants for aggregate gross proceeds of approximately \$9.0 million. Subject to certain beneficial ownership limitations, the warrants became 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 warrants and the shares issuable upon exercise of the warrants were sold without registration under the Securities Act of 1933 ("Securities Act") 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.

The Company also entered into a placement agent agreement with Roth, pursuant to which Roth agreed to serve as exclusive placement agent for the issuance and sale of the common shares and warrants. The Company 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, the Company also issued Roth warrants to purchase up to 3% of the aggregate number of shares of common stock sold in the transactions (the "Roth Warrants") or 128,700 shares. The Roth Warrants have substantially the same terms as the investor warrants described above, 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. The Company also reimbursed Roth for its expenses of \$75,000. The Company agreed to give Roth a nine-month right of first refusal to act as its lead underwriter or exclusive placement agent for any further capital raising transactions it undertakes. With certain exceptions, the Company 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 MBI with further capital during such 6-month period following termination of its engagement of Roth.

The assumptions used in the BSM model for the February 2018 Warrants are as follows:

	Year Ended December 31,			
	2018		2017	
Risk-free interest rate	2.49 %	to	2.50%	N/A
Volatility	75.0 %	to	77.5%	N/A
Expected life (years)	4.13	to	4.63	N/A
Dividend yield	—%			N/A

A summary of the Company's February 2018 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, 2018	—	—	—	—
Granted	2,273,700	\$ 2.80	\$2.80	4.64
Exercised	—	—	—	—
Expired	—	—	—	—
Balance at December 31, 2018	2,273,700	\$ 2.80	\$2.80	4.64
Vested and Exercisable at December 31, 2018	2,273,700	\$ 2.80	\$2.80	4.64

February 2017 Issuance of Warrants

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. All Series B and unvested Series C warrants expired on May 15, 2017.

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 assumptions used in the BSM and MCM models for the February 2017 Warrants are as follows:

	Year Ended December 31,			
	2018	2017		
Risk-free interest rate	2.46%	1.68 %	to	1.86%
Volatility	75.0%	80.0 %	to	160.11%
Expected life (years)	3.12	0.5	to	5.00
Dividend yield	—%	—%		

A summary of our February 2017 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 December 31, 2017	419,772	\$ 1.50	\$ 1.46	4.38
Granted	—	—	—	—
Exercised	(9,752)	\$ 1.50	\$ 1.50	—
Expired	—	—	—	—
Balance at December 31, 2018	410,020	\$ 1.50	\$ 1.50	3.13
Vested and Exercisable - December 31, 2018	410,020	\$ 1.50	\$ 1.50	3.13

6. Equity

We are authorized to issue 5,000,000 shares of preferred stock and 75,000,000 shares of common stock.

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, 2018, there was no issued preferred stock.

Common Stock

Lincoln Park Transaction

On October 4, 2018, the Company entered into a purchase agreement (the "Purchase Agreement") and a registration rights agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$20.0 million of our common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement. Pursuant to the terms of the Registration Rights Agreement, we filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Pursuant to the terms of the Purchase Agreement, at the time we signed the Purchase Agreement and the Registration Rights Agreement, we issued 243,013 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement and may issue an additional 121,507 commitment shares pro-rata when and if Lincoln Park purchases (at the Company's discretion) the \$20.0 million aggregate commitment. The commitment shares were valued at \$337,788, recorded as an addition to equity for the issuance of common stock and treated as a reduction to equity as a cost of capital to be raised under the Purchase Agreement.

During the fourth quarter, the Company issued 1,399,153 shares to Lincoln Park which included 10,918 commitment shares for \$1.8 million.

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.

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 5 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.

During the year ended December 31, 2018, the Company did not sell any shares under this ATM Agreement.

Consulting Agreement

In 2017, the Company entered into a consulting agreement for its investor relations operations. The consulting agreement initially covered a period of twelve months from the commencement date of July 29, 2017 and was extended in April 2018 until March 31, 2019. Pursuant to the original consulting agreement, in exchange for the consulting services, the Company issued 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. Each of the Warrants vests over a 12-month period in equal monthly installments starting July 29, 2017, provided that the consultant is providing services to the Company pursuant to the consulting agreement on each vesting date. The Warrants became initially exercisable in August 2017, and expire five years from the initial exercise date. The Company recorded stock compensation expense for the non-employee consulting agreement of \$113,273 and \$104,000 during the years ended December 31, 2018 and 2017 based on the fair value of the warrants vested at December 31 of each year. In connection with the extension of the consulting agreement, the Company issued the consultant a 3-year warrant to purchase 100,000 shares of common stock at an exercise price of \$3.00 per share vesting in four quarterly installments. In addition the Company paid out \$20,000 per quarter pursuant to the amendment to the consulting agreement.

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 and April 6, 2018. 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 4,500,000 shares. The awards under the 2015 Stock Plan can be in the form of stock options, stock awards or stock unit awards. On June 6, 2018, the stockholders approved an amendment to the 2015 Plan to, among other things, increase the number of shares of common stock authorized for issuance under the 2015 Plan by 2,000,000 shares.

Stock option activity for the years ended December 31, 2018 and 2017 is as follows:

	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, 2017	1,345,000	\$ 1.93	\$ 3.50	9.07	\$ 83,000
Granted	1,479,000	\$ 1.32	\$ 1.79		
Exercised	(25,000)	\$ 0.13	\$ 0.20		
Canceled	(5,000)	\$ 1.75	\$ 2.49		
Outstanding, December 31, 2018	<u>2,794,000</u>	\$ 1.78	\$ 2.61	9.43	\$ 21,200
Exercisable, December 31, 2018	<u>512,500</u>	\$ 2.61	\$ 3.51	8.00	<u>\$ 21,000</u>

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

	Year Ended December 31,	
	2018	2017
Risk-free interest rate	0.95 % to 2.24%	1.83 % to 1.95%
Volatility	70.18% to 89.11%	80%
Expected life (years)	5.0 to 6.25	5.0 to 6.25
Expected dividend yield	—%	—%

Stock-based compensation expense is as follows (in thousands):

	Year Ended December 31,	
	2018	2017
General and administrative	\$ 976	\$ 684
Research and development	164	23
Total	\$ 1,140	\$ 707

In 2018, the Company granted each of the two members of its science advisory board options in the aggregate to purchase 10,000 shares of the Company's common stock with a weighted average exercise price of \$1.46 per share, a term of 10 years, and a vesting period of 4 years.

Options granted during 2018 have an aggregated fair value of \$1.9 million that was calculated using the Black-Scholes option-pricing model. At December 31, 2018, total compensation cost not yet recognized was \$3.2 million and the weighted average period over which this amount is expected to be recognized is 2.8 years. The aggregate fair value of options vesting in the years ended December 31, 2018 and 2017 was \$1.9 million and \$3.1 million, respectively. No options were exercised in 2017. 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.

7. Income Taxes

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

	Year Ended December 31,	
	2018	2017
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):

	Year Ended December 31,	
	2018	2017
Valuation allowance at beginning of period	\$ 2,561	\$ 1,397
Income tax benefit	3,294	1,164
Release of valuation allowance	—	—
Valuation allowance at end of period	<u>\$ 5,855</u>	<u>\$ 2,561</u>

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):

	Year Ended December 31,			
	2018		2017	
	Amount	Percent	Amount	Percent
Federal tax benefit at statutory rate	\$ 2,494	21.00 %	\$ 3,334	34.00 %
State tax benefit net of federal	18	.15 %	(117)	(1.20)%
Foreign rate differential	43	0.36 %	—	— %
IPO costs	(112)	(.94)%	(76)	(.77)%
Stock warrant costs	669	5.63 %	(395)	(4.03)%
Other permanent differences	(8)	(.07)%	(9)	(.09)%
Permanent PTR items	190	1.60 %	—	— %
Change in deferred tax rate due to tax reform	—	— %	(1,562)	(15.93)%
Other	—	— %	(11)	(.11)%
Increase in valuation allowance	(3,294)	(27.73)%	(1,164)	(11.87)%
Total tax (expense) benefit	<u>\$ —</u>	<u>— %</u>	<u>\$ —</u>	<u>— %</u>

The principal components of the Company's deferred tax assets and liabilities consist of the following (in thousands):

	Year Ended December 31,	
	2018	2017
Deferred tax assets:		
Start-up costs	\$ 1,962	\$ 1,105
Federal net operating loss carryforwards	3,153	1,275
State tax loss carryforwards	21	9
Foreign net operating loss carryforwards	182	—
Tax credit carryforward	190	—
Interest limitation	1	—
Deferred compensation	418	176
Total deferred tax assets	<u>\$ 5,927</u>	<u>\$ 2,565</u>
Less valuation allowance	<u>(5,855)</u>	<u>(2,561)</u>
Net deferred tax assets	<u>\$ 72</u>	<u>\$ 4</u>
Deferred tax liabilities:		
Fixed assets	<u>(72)</u>	<u>(4)</u>
Total deferred tax liabilities	<u>\$ (72)</u>	<u>\$ (4)</u>
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

The Company has incurred net operating losses since inception. As of December 31, 2018, the Company had total federal operating loss carry forwards of approximately \$15.1 million. Of this, \$6.1 million will expire commencing in 2037,

with the rest having no set expiration date. 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. Under the new tax laws, net operating loss carry forwards will not expire beginning for losses generated in the 2018 tax year. However, these net operating losses will only be able to offset 80% of future taxable income. 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, 2018, the Company had state operating losses of approximately \$13.3 million which expire commencing in 2038. 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, 2018. 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 \$5.9 million and \$2.56 million has been established at December 31, 2018 and 2017, respectively. The change in the valuation allowance for the year ended December 31, 2018 was primarily 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.

The Company participates in significant Research and Development Activities, and expects to receive a benefit from both a federal and foreign Research and Development Tax Credit. Currently, we have not recognized the tax credit for the 2018 tax year and will wait for completion of the full study for the federal credit. The company has recognized the federal Research and Development tax credit claimed on the 2017 tax return, for approximately \$0.2 million. While the company is fully reserved, we expect a reserve of 20% for this credit claimed.

The company has a liability for unrecognized tax benefits of \$38,000 (excluding accrued interest and penalties) as of December 31, 2018. A reconciliation of the beginning and ending unrecognized tax benefits excluding interest and penalties is as follows (in thousands):

	Year Ended December 31,	
	2018	2017
Balance, beginning of year	\$ —	\$ —
Additions for tax positions related to the current year	—	—
Additions for tax positions related to prior years	38	—
Reductions due to lapse of statutes of limitations	—	—
Decreases related to settlements with tax authorities	—	—
Balance, end of year	<u>\$ 38</u>	<u>\$ —</u>

The Company also participates in significant research and development activities in Australia. The Australian government provides a refundable tax credit based on whether the business and the activities it is conducting are eligible. While the Company was not pre-approved for this credit, approval for the year ended December 31, 2018 is expected. The amount of benefit is estimated to be around A\$0.4 million. This will not be booked until approval has been received.

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, 2018.

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 was a provisional amount and a reasonable estimate at December 31, 2017 based upon the best information that was available. The accounting with respect to the implementation of the Tax Act is now complete with no change from the amounts reported at 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. The Company remeasured its deferred taxes based upon the new tax rates as of December 31, 2017 but, as a result of the full valuation allowance against its net deferred tax assets, there was no related impact on the Company's income tax expense.

8. Commitments and Contingencies

Lease Obligations Payable

On March 22, 2018, the Company entered into a Lease Agreement (the "Lease") with IPX Memorial Drive Investors, LLC (the "Landlord") in Houston, Texas which is being used for corporate office space and headquarters. The term of the Lease began in August 2018 and will continue for an initial term of 66 months, which may be renewed for an additional 5 years. The Company is required to remit base monthly rent of approximately \$4,300 which will increase at an average approximate rate of 3% each year. Rent expense is being recognized on a straight-line basis over the life of the lease and the difference between rent expense and rent paid is being recorded as deferred rent. The Company is responsible for certain charges incurred by the Landlord. Rent expense also includes lab space, which is on a month-to-month lease.

Rent expense was \$54,000 and \$29,000 for the years ended December 31, 2018 and 2017, respectively.

Minimum aggregate future lease commitments at December 31, 2018 are as follows (in thousands):

Year Ended	Minimum Lease Payments
2019	\$ 48
2020	53
2021	54
2022	55
2023	56
Thereafter	5
Total minimum lease payments	\$ 271

MD Anderson

Under agreements associated with Annamycin, the WP1122 Portfolio, and the WP1066 Portfolio, which includes WP1732, all described below, the Company is responsible for certain license, milestone and royalty payments over the course of the agreements. Annual license fees can cost as high as \$0.1 million depending upon the anniversary. Milestone payments for the commencement of phase II and phase III clinical trials can cost as high as \$0.5 million. Other milestone payments for submission of an NDA to the FDA and receipt of first marketing approval for sale of a license product can be as high as \$0.6 million. Royalty payments can range in the single digits as a percent of net sales on drug products or flat fees as high as \$0.6 million, depending upon certain terms and conditions. Not all of these payments are applicable to every drug. Total expenses under these agreements were \$0.3 million and \$0.2 million for the years ended December 31, 2018 and 2017, respectively. On

June 29, 2017, the Company entered into an agreement with MD Anderson licensing certain technology related to the method of preparing Liposomal Annamycin.

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 MBI. Therefore, MBI has 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.

WP1066 Portfolio

The rights and obligations to a June 2010 Patent and Technology License Agreement entered into by and between Molculin LLC and MD Anderson (the "Molculin Agreement") have been assigned MBI. Therefore, MBI has 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 the Company has obtained pursuant to the assignment of the Molculin 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.

MBI 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 MBI does not exercise 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.

During the year, management concluded that it was more likely than not that the Company will pay in the near term the HPI Repurchase Payment. The \$1.0 million accrual for this payment is recorded on the balance sheet as a liability as of December 31, 2018 under "Accrued expenses and other liabilities" and expensed under "Research and development" during the period. License fees expensed related to HPI and the accrual for the HPI Repurchase Payment were \$1.3 million and \$0.2 million respectively, for the year ended December 31, 2018 and 2017.

In February 2018, we entered into a license agreement with MD Anderson covering a new group of molecules recently discovered in connection with research it has been sponsoring there called WP1732, a part of the WP1066 Portfolio.

Sponsored Research Agreements with MD Anderson

On January 9, 2017, MBI amended our Sponsored Laboratory Study Agreement with MD Anderson whereby we paid \$0.3 million in 2017, and the agreement was extended to October 31, 2018. On December 4, 2017, MBI extended this Agreement until October 31, 2019 for total payment amount of \$0.35 million spread over that period of time. Of this amount, \$0.24 million was paid in the first quarter of 2018 and the final payment of \$0.11 million was paid in the third quarter of 2018. On September 25, 2018, we extended this Agreement until October 31, 2020 for total payment amount of \$0.4 million spread over that period of time. Of this amount, \$0.27 million was paid in the fourth quarter of 2018, and the final payment of \$0.13 million was paid in 2019. The expenses recognized under the MD Anderson agreement with regards to the Sponsored Laboratory Study were \$0.4 million and \$0.2 million for the years ended December 31, 2018 and 2017, respectively.

Other Licenses

In 2015, we obtained the rights and obligations for certain patent and technology development and license agreements with Dermin Sp. Zoo ("Dermin"). In connection with such agreements, certain intellectual property rights related to Annamycin, our WP1122 portfolio, and our WP1066 portfolio 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. With respect to Annamycin, the license is limited to 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; provided that we have the right to remove Germany from the list of covered territories with a \$0.5 million payment. With respect to WP1122, the license is limited to the countries of Belarus, Russia, Kazakhstan, Uzbekistan, Turkmenistan, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Ukraine. With respect to WP1066, the license is limited to the countries of Belarus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Ukraine. In each case, Dermin will pay a royalty for the sale of any licensed product in the licensed territories and will pay all out-of-pocket expenses incurred in filing, prosecuting and maintaining the licensed patents for which the license has been granted in the licensed territories. Dermin also agreed to provide a percentage of certain consideration that Dermin receives pursuant to sublicense agreements.

Employment Agreements

The Company has agreements with nine employees to provide certain benefits in the event of termination where the base salary and certain other benefits would aggregate approximately \$1.2 million using the rate of compensation in effect at December 31, 2018.

9. Subsequent Events

In addition to the subsequent events discussed elsewhere in these notes, see below for a discussion of our subsequent events occurring after December 31, 2018.

Summary of WPD Agreement

On February 19, 2019, we sublicensed certain intellectual property rights, including rights to Annamycin, our WP1122 portfolio, and our WP1066 portfolio to WPD Pharmaceuticals ("WPD") (the "WPD Agreement"). WPD is affiliated with Dr. Waldemar Priebe, our founder and largest shareholder. Under the WPD Agreement, we granted WPD a royalty-bearing, exclusive license to research, develop, 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 Germany, Poland, Estonia, Latvia, Lithuania, Belarus, Ukraine, Moldova, Romania, Armenia, Azerbaijan, Georgia, Slovakia, Czech Republic, Hungary, Uzbekistan, Kazakhstan, Greece, Austria, Russia, Netherlands, Turkey, Belgium, Switzerland, Sweden, Portugal, Norway, Denmark, Ireland, Finland, Luxembourg, Iceland ("licensed territories"), provided that we have the right to buyback Germany from the licensed territories by making a payment \$0.5 million, or by issuing 235,850 shares of our common stock.

In consideration for entering into the WPD Agreement, WPD agreed that it must use Commercially Reasonable Development Efforts to develop and commercialize products in the licensed territories. For purposes of the WPD Agreement, the term "Commercially Reasonable Development Efforts" means the expenditure by or on behalf of WPD or any of its affiliates of at least: (i) \$2.0 million during the first two years of the agreement on the research, development and commercialization of products in the licensed territories; and (ii) \$1.0 million annually for the two years thereafter on the research and development of products in the licensed territories.

Prior to approval of the WPD Agreement, our board of directors received a fairness opinion from Roth Capital Partners, LLC that stated that it was their opinion that the consideration we will receive from WPD pursuant to the WPD Agreement is fair, from a financial point of view, to us.

Summary of Animal Life Sciences Agreement

On February 19, 2019, we sublicensed certain intellectual property rights, including rights to Annamycin, our WP1122 portfolio, and our WP1066 portfolio in the field of non-human animals to Animal Life Sciences, LLC ("ALI") (the "ALI Agreement"). ALI is affiliated with Dr. Waldemar Priebe, our founder and largest shareholder. Under the ALI Agreement, we granted ALI a worldwide royalty-bearing, exclusive license to research, develop, manufacture, have manufactured, use, import, offer to sell and/or sell products in the field of non-human animals under the licensed intellectual property.

During the term of the ALI Agreement, to the extent we are required to make any payments to MD Anderson pursuant to our license agreements with MD Anderson, whether a milestone or royalty payment, as a result of the research and development or sale of a sublicensed product, ALI shall be required to advance or reimburse us such payments. In further consideration for the rights granted by us to ALI under the ALI Agreement, ALI agreed to pay us a royalty percentage at a rate equal to the royalty rate we owe MD Anderson under our license agreements with MD Anderson plus an additional royalty equal to 5.0% of net sales of any sublicensed products. As additional consideration, ALI issued us a 10.0% ownership interest in ALI.

With certain exceptions, the ALI Agreement will remain in full force and effect until the expiration of the last patent within the sublicensed patents.

Sale of Shares to Lincoln Park

During February 2019, the Company sold 600,000 shares to Lincoln Park for an aggregate purchase price of \$0.9 million and 5,367 commitment shares.

CORPORATE INFORMATION

EXECUTIVE OFFICERS

Walter V. Klemm
*President, Chief Executive Officer
and Chairman*

Jonathan P. Foster, CPA, CGMA
*Executive Vice-President,
Chief Financial Officer*

Donald Picker, PhD
Chief Science Officer

Robert Shepard, MD, FACP
Chief Medical Officer

Sandra L. Silberman, MD, PhD
Chief Medical Officer - New Products

BOARD OF DIRECTORS

Walter V. Klemm

Robert E. George

Michael D. Cannon

John M. Climaco, Esq.

SCIENCE ADVISORY BOARD

Waldemar Priebe, PhD.
*Founder, Founding Scientist and
Science Advisory Board Chairman*

Dr. James L. Abbruzzese
*Chief of the Division of Medical
Oncology at Duke University*

Dr. Jorge Cortes
*Deputy Chair and Professor of
Medicine in the Department of
Leukemia at MD Anderson Cancer
Center*

Dr. Elihu Estey
*Professor of Medicine, Division
of Hematology, University of
Washington School of Medicine*

Dr. Martin Tallman
*Chief of Leukemia for Memorial
Sloan Kettering Cancer Center*

Dr. John Paul Waymack
*Chief Medical Officer, Kitov
Pharmaceuticals*

HEADQUARTERS

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STOCK LISTING

Nasdaq: MBRX

ANNUAL MEETING

The Annual Meeting of
Stockholders will be held at
1:30 p.m. Central Time on
Wednesday, May 22, 2019 at
the corporate offices of Molculin
Biotech, Inc., 5300 Memorial Drive,
Suite 950, Houston, TX 77007

AUDITORS

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FORWARD-LOOKING STATEMENTS

Important Note About Forward-Looking Statements.

Some of the statements contained herein are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements contained herein include, without limitation, the ability of Molculin to successfully recruit sufficient patients to complete its current clinical trials and the ability of Molculin's drug candidates to show safety and efficacy in patients. Although Molculin Biotech believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Molculin Biotech has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under Item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC") and updated from time to time in our Form 10-Q filings and in our other public filings with the SEC. Any forward-looking statements contained herein speak only as of its date. We undertake no obligation to update any forward-looking statements contained herein to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

Moleculin Biotech, Inc.
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