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

FORM 10-K

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

For the fiscal year ended **December 31, 2019**

or

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

For the transition period from _____ to _____

Commission File Number: **001-37758**

Moleculin Biotech, Inc.

(Exact name of registrant as specified in its charter)

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

5300 Memorial Drive, Suite 950
Houston, Texas 77007
(713) 300-5160
(Address of Principal Executive Offices, Zip Code and Registrant's Telephone Number)

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

Title of Each Class	**Trading Symbol (s)**	**Name of Each exchange on which registered**
Common Stock, par value $0.001 per share	MBRX	Nasdaq Stock Market LLC

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 ☒ Smaller reporting company ☒
Accelerated filer ☐ 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 $ 48 million. In determining the market value of the voting equity held by non-affiliates, securities of the registrant beneficially owned by directors, officers and 10% or greater shareholders of the registrant have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of shares of the registrant's common stock outstanding as of March 10, 2020 was 53,227,700.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of this registrant's definitive proxy statement for its 2020 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:

- the impact the recent Coronavirus outbreak will have on our ability to commence or continue clinical trials, and our ability to raise future financing;
- our ability to obtain additional funding to commence or continue our clinical trials, fund operations and develop our product candidates;
- our ability to satisfy any requirements imposed by the FDA (or its foreign equivalents) as a condition of our clinical trials proceeding;
- the success, including the ability to recruit patients, of our clinical trials through all phases of clinical development;
- the need to obtain and retain regulatory approval of our drug candidates, both in the United States and in Poland;
- 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 drug candidates in clinical development;
- our ability to commercialize our drug candidates;
- market acceptance of our drug candidates;
- competition from existing therapies or new therapies that may emerge;
- potential product liability claims;
- our dependency on third-party manufacturers to successfully, and timely, supply or manufacture our drug candidates for our preclinical work and our clinical trials;

- 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;
- the effects of future government shutdowns on our ability to raise financing;
- 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", "Moleculin" or "the Company", "we", "our" and "us" are used herein to refer to Moleculin Biotech, Inc.

ITEM 1. BUSINESS

Overview

Our Business

We are 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 MD Anderson Cancer Center ("MD Anderson"). We have three drug candidates that are active in clinical trials. In 2019, those three drug candidates were active in four clinical trials in the US and Poland with a fifth that is expected to begin in the first half of 2020. Of these five clinical trials, two are primarily externally funded. For two of these trials, we successfully concluded the Phase 1 portion recently and are preparing to potentially move into Phase 2 trials. We anticipate laying the groundwork in 2020 for two additional Phase 1 trials expected to begin in 2021 sponsored by us and two other Phase 1 trials we expect to be externally sponsored.

Based on our positive clinical activity thus far, we have narrowed our development focus to our nearest term opportunities. We believe this will allow us to reduce our cash needs until we reach a significant value inflection point, although we will continue to require additional external capital during this period. In addition, institutional support for our technologies has increased and we believe such support may provide outside funding to help reduce future dilution.

Of our three clinical stage drug candidates, Annamycin is being studied for the treatment of relapsed or refractory acute myeloid leukemia ("AML") and cancers metastasized to the lungs. WP1066, an Immune/Transcription Modulator ("p-STAT3 inhibitor") is intended to target a wide range of tumors, including brain tumors and pancreatic cancer. We began and completed a Phase 1 clinical trial in 2019 in Poland for a third drug, WP1220 (a molecule similar to WP1066), for the topical treatment of cutaneous T-cell lymphoma ("CTCL") and we are looking to expand development of this drug into a Moleculin Phase 2 trial. We are also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as Metabolism/Glycosylation Inhibitors.

We consider Annamycin to be a "next generation" anthracycline, unlike any currently approved anthracyclines, as it is designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity (two problems common to all currently approved anthracyclines). We recently received an independent expert cardiology assessment confirming the absence of cardiotoxicity in the first 14 patients treated with Annamycin in both our US and European Phase 1 clinical trials, validating Annamycin's lack of cardiotoxicity. Annamycin is currently in one Phase 1/2 clinical trial in Europe with the Phase 1 portion of another Phase 1/2 AML trial recently concluding in the US. Upon receipt of further data from the European Phase 1 trial, we plan to seek agreement with the FDA for accelerated approval of Annamycin based on a pivotal Phase 2 AML trial sponsored by us, although there is no assurance that the FDA will agree with our proposal.

In 2019, preclinical work on Annamycin demonstrated activity against some cancers metastasized to the lungs. With this new data, we are planning to start a Moleculin-sponsored US Phase 1 trial at MD Anderson for the treatment of cancer metastasized to the lungs with Annamycin.

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-1α. 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. WP1066 is currently in an US physician-sponsored Phase 1 trial for the treatment of glioblastoma ("GBM") and another institutionally sponsored Phase 1 trial should begin soon for the treatment of pediatric brain tumors. Another physician-sponsored Phase 1 trial is being considered for the treatment of GBM with WP1066 in combination with radiation.

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 has the opportunity to become an important drug to potentiate existing therapies, including checkpoint inhibitors. In March 2020, we entered into an agreement with an outside research center who will conduct research on WP1122 for antiviral properties against a range of viruses, including Coronavirus.

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

Mission and Strategy Overview

Moleculin is focused on developing treatments for highly resistant cancers. These include AML, glioblastoma, cutaneous t-cell lymphoma, pancreatic cancer, lung and other vital organ metastases, 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.

In 2019 we announced our out-licensing agreement to WPD Pharmaceuticals, an entity associated with our founder, Dr. Waldemar Priebe. This involved providing territorial rights to certain smaller countries in mainly Eastern Europe and Western Asia in exchange for their agreeing to provide an additional $4 million or more of funding to our development efforts over the next four years. As we are beginning to generate real human data, we intend to pursue additional strategic collaborations.

This increase in potential outside funding should allow us to concentrate our internal resources primarily on Annamycin, and our active p-STAT3 inhibitors, WP1066 and WP1220. This allows us to prioritize our internal funding to core clinical trials that we think may lead to an accelerated approval pathway and/or a strategic licensing opportunity. Accordingly, we have increased our focus on clinical trial pathways for Annamycin and WP1220. We have now seen human activity in both drug candidates that we think is capable of supporting an accelerated approval pathway.

Intellectual Property Overview

Drug development – from discovery to approved drug – can take decades. With this in mind, and in light of the fact that US patent terms begin on the date of filing and run for only 20 years, alternative means of establishing market exclusivity are common in the drug development industry. Orphan Drug designation (“ODD”) from the FDA is available for drugs targeting diseases with less than 200,000 cases per year. ODD may enable market exclusivity of 7 years from the date of approval of a New Drug Application (“NDA”) in the United States. During that period the FDA generally could not approve another product containing the same drug for the same designated indication. Orphan Drug Exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Also available for application from the European Union (“EU”) is ODD where, once granted, extends market exclusivity to 10 years from the date of Marketing Authorization Application (“MAA”). The ODD in the EU is generally available for drug products to treat life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU when the application is made. The 10 year period can be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for the ODD, for example because the product is sufficiently profitable not to justify market exclusivity.

We have been granted royalty-bearing, worldwide, exclusive licenses for the patent and technology rights related to all three of our drug technologies, as these patent rights are owned by MD Anderson. The Annamycin drug substance is no longer covered by any original patent protection, however in June 2019, we submitted new provisional patent applications for synthetic processes for lyophilized Annamycin and for reconstitution of our Annamycin drug product candidate. If the non-provisional patent applications are approved, for which we can provide no assurance, this would potentially provide patent protection for Annamycin through June 2040.

Independently from potential patent protection, in 2018 we received ODD from the FDA for Annamycin for the treatment of AML and, in 2019 we received FDA ODD for WP1066 for the treatment of glioblastoma. Separately, the FDA may also grant market exclusivity of 5 years for newly approved new chemical entities (which our drug candidates are considered to be), which would preclude approval of any generic drug application or 505(b)(2) application attempting to copy our drugs, but there can be no assurance that such exclusivity will be granted or that a third party could apply as an NDA under 505(b)(1). Furthermore, we were granted Fast Track Designation for Annamycin for the treatment of relapsed or refractory AML in April 2019 by the FDA. Fast Track Designation is granted to potentially expedite drug development and approval and is granted to drugs intended to treat serious conditions, where data demonstrate the potential to address an unmet medical need.

The US patents we license from MD Anderson that have been granted expire from 2024 to 2029. MD Anderson manages the patent process related to the technology subject to our license agreements worldwide with advice from us. Additional patents pending, also licensed from MD Anderson, may provide additional potential exclusivity to our drug portfolio, however we can provide no assurance that such patents will be granted.

Our Drug Candidates

Annamycin

One of our lead product candidates is Annamycin, for which FDA allowed an IND to go into effect for a Phase 1/2 trial for the treatment of relapsed or refractory AML and granted Orphan Drug Designation for the treatment of AML, which means the agency believes we have established a medically plausible basis for expecting the drug to be effective. We recently concluded the Phase 1 portion of the US clinical trial and we are planning a potential pivotal Phase 2 trial once we have additional clinical data. A similar Phase 1/2 trial in Europe continues and is in its fourth cohort.

Prior Development

We took over the development of Annamycin after two prior drug development companies, Callisto Pharmaceuticals and Aronex Pharmaceuticals, ceased development work for various clinical and business reasons, leading to the termination of the INDs by the FDA. The basis for our decision to proceed notwithstanding the most recent prior developer's abandoning the project is that we believe the actual clinical data as reported by Dr. Robert Shepard, our Chief Medical Officer and the prior developer's Chief Medical Officer at the time of the clinical trials, to the 2009 Annual Meeting of the American Society of Clinical Oncology, and as further reported by the Principal Investigators of the clinical trials in a peer-reviewed journal article (Clin Lymphoma Myeloma Leuk. 2013 August; 13(4): 430-434. doi:10.1016/j.clml.2013.03.015.), supports further clinical evaluation. In addition, the conclusion published in the 2013 Clinical Lymphoma, Myeloma & Leukemia Journal article was that "Single agent nanomolecular liposomal annamycin appears to be well-tolerated and (demonstrates) evidence of clinical activity as a single agent in refractory adult ALL." As reported in both the ASCO presentation and the 2013 journal article referenced, the definition of efficacy is based on the following Response Criteria: "Response criteria were achievement of CR defined as ≤5% blasts, granulocyte count of ≥1×109/L, and a platelet count of ≥100×109/L. Partial remission was defined the same as CR, except for the presence of 6% to 25% blasts. Hematologic improvement was defined as for CR but platelet count of ≥1×109/L." The summary of patient response from the 2013 journal article reads: "After determining the MTD, a 10-patient phase IIA was conducted. Eight of the patients completed one cycle of the three days of treatment at the MTD. Of these, five (62%) demonstrated encouraging anti-leukemic activity with complete clearing of circulating peripheral blasts. Three of these subjects also cleared bone marrow blasts with one subsequently proceeding onto successful stem cell transplantation. The other two subjects 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 Callisto trial was the second trial to study Annamycin in acute leukemia. The first trial was sponsored by Aronex Pharmaceuticals. When Callisto acquired the technology and made changes in manufacturing methods, they had to conduct another Phase 1 dose ranging trial. Unexpectedly, that trial yielded a significantly different result than the Aronex trial.

The Aronex trial started at 190 mg/m^2, which was expected to be, and in fact was, sub-therapeutic. In accordance with the dose-ranging protocol, dosing was then increased until it reached 350 mg/m^2, where DLTs (dose limiting toxicities) forced a de-escalation back to an MTD (maximum tolerated dose) of 280 mg/m^2. Although the Callisto trial restarted at the same 190 mg/m^2 starting dose used in the Aronex trial, there were immediate instances of DLTs (mucositis), causing the dosing to be reduced instead of escalated. Ultimately, the Callisto trial settled on 150 mg/m^2 as the MTD where, during the expansion (Phase 2a) portion of the trial, therapeutic activity was noted.

The production of liposome formulated anthracyclines is very sensitive to subtle changes in production method and starting materials. It is partly for this reason that, more than 10 years later and with entirely new contractors, we had to run yet another Phase 1 dose ranging study. Although we cannot be sure until the trial is completed, based on our experience to date in our European Phase 1/2 trial, we believe that our product appears to be performing more closely to the Aronex product rather than the Callisto product. This suggests that our Phase 1/2 trial will run longer than originally expected, as we may have to reach 300 mg/m^2 or higher before establishing the MTD.

The Importance of No Cardiotoxicity

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, especially with regard to cardiotoxicity (damage to the heart) , and more effective. Anthracyclines are a class of chemotherapy drugs designed to destroy the DNA of rapidly producing 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 often to induce sufficient remission of patients' blood-born tumor cells to allow for a potentially curative bone marrow transplant.

Two key factors limit the safety and effectiveness of anthracyclines: cardiotoxicity and multidrug resistance. We believe Annamycin may significantly reduce the impact of these two factors. If early human data from the clinical activity thus far is borne out, of which there is no assurance, 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 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 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 1/2 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, especially in relapsed patients.

Additionally, preclinical research in animal models at MD Anderson demonstrated that Annamycin is able to significantly improve survival in an aggressive form of triple negative breast cancer metastasized to the lungs in animal models. Coupled with research in animal models demonstrating that Annamycin is capable of accumulating in the lungs at very high levels, this suggests that Annamycin may be well suited to become a treatment for lung-localized tumors.

In all instances, it will be important to develop additional clinical data regarding the early indications from preclinical and early clinical data, as discussed below.

Clinical Trials for Annamycin

We filed our IND application for Annamycin, with the clinical strategy of increasing the MTD mentioned above, in February 2017, which was allowed in September 2017. The FDA limited dosages to patients to a lifetime maximum anthracycline exposure of 550 mg/m2 which in effect limited the maximum dose in our trial to 120 mg/m2. Patient treatment began in the US in March 2018.

In August 2017, we met with the European Medicines Agency ("EMA") to discuss a CTA (Clinical Trial Authorization) in Europe for the study of Annamycin for the treatment of AML. In December 2017, the Ethics Committee in Poland approved our Phase 1/2 trial of Annamycin for the treatment of relapsed or refractory AML. A final approval is required by the Polish National Office which was received in June 2018. This enabled our Phase 1/2 clinical trial there to study Annamycin for the treatment of relapsed or refractory AML to begin. The EMA did not impose a lifetime maximum anthracycline exposure limit in this trial.

In February 2020, we announced that our open label, single arm US Phase 1 portion of a Phase 1/2 trial had concluded its second cohort and met its primary objective of demonstrating the safety of Annamycin in treating relapsed or refractory AML. We also announced an update on interim enrollment, safety and efficacy data in our parallel Phase 1/2 trial in Europe.

We continue to recruit and contract with clinics in our European trial, which is being conducted in 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.

As of February 2020, 12 patients have been dosed in Europe and Annamycin has proven, thus far, to be safe and tolerable and, importantly, there have been no instances of cardiotoxicity in any patient. To date, only one adverse event related to Annamycin has been reported in the European trial; a patient experienced grade 2 mucositis that resolved to grade 1 within 2 days. The European patients have been dosed at levels ranging from 120 mg/m^2 to 210 mg/m^2, with, as of this report, 3 patients having been enrolled in the fourth cohort in Europe receiving a single dose of 210 mg/m^2.

Study Design -

We have been studying Annamycin in both the US and Europe in open label, single arm clinical trials to assess the safety and efficacy of Annamycin for the treatment of adults with relapsed or refractory acute myeloid leukemia. The US and European trials have essentially the same study design, consisting of a Phase 1 intended to establish a "Recommended Phase 2 Dose" (RP2D), to which the studies may then proceed. The Phase 1 studies provide for escalating doses in cohorts of 3 patients each, with each successive cohort receiving the next higher dose level until "dose limiting toxicities" prevent further increases. Cohorts 1, 2 and 3 in Europe received a dose of 120, 150 and 180 mg/m^2, respectively, and the results have permitted moving to Cohort 4 with dosing at 210 mg/m^2, in which all 3 patients have been enrolled and treated. Cohort 1 in the US started at 100 mg/m^2, and the results supported moving to Cohort 2 at 120 mg/m^2, which has now been fully recruited, treated, and evaluated. Beyond this dose level, patients would receive greater than the lifetime maximum anthracycline dose of 550 mg/m^2 allowed by the FDA, so further advancement of the US study must be discussed with the FDA and a meeting for this purpose is expected to occur during the first half of 2020. Once we establish an RP2D in the European trial, the intent is to advance to a Phase 2 arm planned to assess the safety and efficacy of Annamycin in 21 additional patients. We may amend the protocol of either or both studies where appropriate to adapt to new information that may affect patient safety and care. The data reported is preliminary as collected by independent CRO site monitors per standard practice and is subject to subsequent quality assurance review.

We have been and intend to continue reporting top-line results by cohort in each trial, with each announcement also including an update on the other trial. Top-line results will include reporting of any drug-related adverse events (AEs) and assessment of cardiotoxicity, including ECHO (echocardiogram) or MUGA (MUGA stands for multiple-gated acquisition and is also known as radionuclide ventriculography (RVG, RNV) or radionuclide angiography (RNA); it is a type of nuclear imaging test intended to show how well the heart is pumping) scans measuring change in ejection fraction and measuring blood troponin level, which is considered a biomarker for potential long-term cardiovascular impairment. Top-line results will also include the number of partial responses (PRs), complete responses (CRs) and patients deemed capable of progressing to a potentially curative bone marrow transplant, which we term "bridge to transplant" (BTs), each of which is essentially a function of the magnitude of reduction in a patient's bone marrow blasts. For purposes of these clinical trials, a CR means that the patient's bone marrow blasts reduced to 5% or less (with CRi meaning a CR where there was incomplete recovery of white blood cell and/or platelet counts), a PR means the patient's bone marrow blasts reduced by 50% and resulted in a blast count of 25% or less, and a BT means patients are deemed capable of progressing to a potentially curative bone marrow transplant.

The US trial also differs from the European trial in that the FDA would like to review safety data relating to cardiotoxicity from patients treated prior to advancing beyond 120 mg/m^2, as exceeding this dose level would require the patient to exceed the established lifetime maximum exposure to anthracyclines (presuming all anthracyclines are cardiotoxic). We believe that the additional patient safety data gained from the European trial may also assist in the FDA's review of Annamycin's cardiac safety. We plan to discuss with the FDA and EMA our intent to conduct a single arm Phase 2 trial. Our goal is for this trial serve as the basis for accelerated approval of Annamycin in AML and for the FDA to allow us to rely on our European trial to establish a recommended Phase 2 dose. We can provide no assurance that the FDA will permit such reliance and we may be required to conduct additional trials.

Safety of Annamycin in AML Patients -

Our US Phase 1 trial met its primary endpoint, demonstrating the safety of Annamycin in treating AML when delivered to patients at or below the lifetime maximum anthracycline dose established by the FDA. The primary safety signal was the absence of cardiotoxicity, a serious and often treatment-limiting issue prevalent with currently approved anthracyclines. As discussed above, this was determined by echocardiograms, as well as cardiac health biomarkers, principally blood troponin levels, which are considered an indicator of potential long-term heart damage. The data showed no cardiotoxicity in all of the patients evaluated in the US Phase 1 trial.

Additionally, there were no unexpected serious adverse events and no dose limiting toxicities at any dose tested. In February 2020, this was confirmed by an independent assessment of the absence of cardiotoxicity in the first 14 patients treated with Annamycin in both our US and European Phase 1 clinical trials in which an independent expert concluded that he "does not see evidence of cardiotoxicity."

Compared to previous studies of other anthracyclines, we believe this is an important event. For example, a recent review published in Cardiovascular Drugs and Therapy (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5346598/) reported that 65% of patients who received the equivalent of 550 mg/m2 of doxorubicin (a current standard of care anthracycline) exhibited sub-clinical cardiotoxicity, defined as a reduction in left ventricular ejection fraction >10% points to a value <50%. In the 5 patients mentioned above who were treated in our European trial above 550 mg/m2, no evidence of cardiotoxicity was detected. The same published review also suggested that a better long-term indicator of cardiotoxicity may be the measurement of an increase in a biomarker called troponin. When measured as an early biomarker of cancer therapy-related cardiotoxicity, troponin rise occurs consistently in 21% - 40% of patients after treatment with current standard of care anthracycline chemotherapy and, per the published review, such an increase in troponin is associated with an increased risk of heart disease later in life. Overall, some form of cardiotoxicity, short-term or long-term, occurs in 65% of such patients. Of the 17 patients treated thus far in both of our Annamycin clinical trials, none has shown an increase in troponin levels, again supporting the absence of cardiotoxicity.

Preliminary Evidence of Effectiveness -

Although the primary objective of the US Phase 1 trial was to evaluate safety, the study also gathered data to support a preliminary assessment of Annamycin's potential efficacy. Among other things, the study recorded complete response (CR), partial response (PR), and event-free survival. Based on these criteria, efficacy was seen in 2 or 30% of the US patients, even though the drug was dosed at what we considered to be sub-therapeutic levels. The evidence of efficacy consisted of 1 patient who achieved a "morphologically leukemia-free state," which the protocol defined as a CR with incomplete recovery of platelets or neutrophils (CRi), and another patient who had a substantial remission of leukemia cutis (a somewhat rare leukemia symptom), improving from diffuse to 3 small lesions.

We believe to see this kind of activity this early is encouraging, especially since Phase 1 trials are primarily designed to demonstrate safety, not efficacy, and the dosing was therefore at a level we expected to be sub-therapeutic, based on previous data. We are also encouraged because Annamycin is being studied as a single agent, not in combination with any other drugs. We believe this is potentially significant, because we believe the vast majority of relapsed or refractory AML patients do not respond to single agents. Although this is very early data from a small sample size, we are especially encouraged because the dosing was well below our anticipated recommended Phase 2 dose. We believe that, if the level of activity experienced in the US trial can be demonstrated in a larger patient population, we may be well-positioned to seek accelerated approval from the FDA. FDA has granted Fast Track designation, which recognizes that Annamycin shows the potential to address unmet medical needs, which can include providing efficacy comparable to available therapies while avoiding toxicity associated with the existing treatment.

Between the US and European studies, 14 AML patients have been evaluated after receiving Annamycin at or above 120 mg/m^2. When they entered the study, 9 of the 14 patients were considered relapsed and 5 were considered refractory. Although reduction in bone and circulating blasts has been seen in both relapsed and refractory AML patients, each of the 5

patients where efficacy endpoints were met was a relapsed patient. In the 14 patients mentioned, efficacy signals have been demonstrated to date in 55% of the relapsed and 36% of all patients after receiving Annamycin at or above 120 mg/m^2. The efficacy-related data for those patients (which includes the 2 US patients mentioned above) is as follows:

- One patient had a CRi, which the protocol defined as a complete response with incomplete recovery of white blood cells and/or platelets;
- Two patients had PRs (partial responses, meaning that bone marrow blasts were reduced 50% and to below 25%);
- One patient had a substantial remission of their somewhat rare leukemic symptom known as leukemia cutis; and
- One patient was bridged to bone marrow transplant (BT) based on a sufficient reduction in bone marrow blasts.

We refer to Annamycin as a "next generation anthracycline," because it is designed, and thus far has shown clinically, to provide enhanced therapeutic benefits when compared with traditional anthracyclines (like doxorubicin) while reducing the potential for cardiotoxicity, or damage to the heart. This design intent has previously been validated with preclinical toxicology studies in animal models (as required by FDA) demonstrating Annamycin has little to no cardiotoxicity when compared with doxorubicin. Of the 17 patients treated and fully evaluated thus far in both trials, including those treated below 120 mg/m^2, none has shown any evidence of cardiotoxicity. This includes 9 patients in Europe who were treated at levels above the US maximum allowable lifetime cumulative anthracycline dose level (550 mg/m^2), a limitation not imposed on our trial in Europe. If this continues to be confirmed in further studies, this lack of toxicity could be an important differentiator between Annamycin and the currently approved anthracyclines, for which cardiotoxicity is a well-known treatment limitation.

Plans for a Phase 2 Trial -

We intend to discuss with the FDA and EMA our plans to conduct a single arm Phase 2 trial that would serve as the basis for accelerated approval of Annamycin to treat AML. This will follow the establishment of a RP2D in our ongoing Phase 1/2 dose escalation trial in Europe. The FDA has already granted Annamycin Fast Track status and ODD for AML. The benefits of Fast Track include FDA actions to expedite development and review, including "rolling review," where the agency reviews portions of a marketing application before the complete application is submitted.

Most recently, the US Phase 1 study met its primary objective of demonstrating the safety of Annamycin at a dose that was cumulatively at or below the lifetime maximum anthracycline dose established by the FDA. Those results are consistent with results achieved with the parallel Phase 1/2 study being conducted in Europe, which has demonstrated the safety of escalating doses of Annamycin in AML patients, including doses that significantly exceed the maximum lifetime dose of anthracyclines imposed in the US. In both trials, the primary endpoints are aimed at demonstrating the product's safety, primarily the lack of cardiovascular risk.

Based on these results, we will continue to focus our efforts on the European trial to establish an RP2D. Once that is complete, we intend to enter discussions with the FDA and EMA about conducting a single arm Phase 2 study that would be the pivotal trial supporting US and European approval of Annamycin for relapsed or refractory AML. We can provide no assurance that the FDA or their EU or other equivalent will permit such reliance and we may be required to conduct additional trials.

Potential for the Treatment of Lung Metastasis with Annamycin

In April 2019, we announced that our ongoing sponsored research at The University of Texas MD Anderson Cancer Center demonstrated that Annamycin is able to significantly improve survival in an aggressive form of triple negative breast cancer metastasized to the lungs in animal models. We know that Annamycin was previously shown to be significantly more potent than doxorubicin in both Lewis lung carcinoma in vivo and small cell lung cancer in vitro models. In addition to seeing significant activity against animal models of triple negative breast cancer metastasized to the lungs, we are also seeing similar results in colon cancer metastasized to the lungs. The particular animal models used in our testing are considered to represent a very aggressive forms of cancer. We believe our success in increasing the survival rate in mice with these tumor models in combination with the previously observed high uptake of Annamycin by the lungs is a promising indication that supports additional clinical research in lung and metastatic lung cancers.

In October 2019, we announced the expansion of Annamycin to large-scale production to supply the above-mentioned AML clinical trials, as they continue, and a trial for the treatment of lung localized tumors. Our sponsored research at MD Anderson has demonstrated efficacy in lung metastases in different tumor animal models. The latest research has demonstrated that, in animal models, Annamycin accumulates in the lungs at 5- to 6-fold higher concentrations than doxorubicin, the current standard of care for lung metastases. We are now working with MD Anderson to design clinical trials to explore this potential.

Furthermore, a poster was presented entitled, "Liposomal annamycin inhibition of lung localized breast cancer," at the San Antonio Breast Cancer Symposium held in December 2019. The published poster (https://www.moleculin.com/san-antonio-bc-symposium-poster/) shows substantially increased survival in both triple negative breast cancer and colon cancer

lung metastases animal models. It should also be noted that treatment with Annamycin resulted in long-term survival of a significant number of animals, even when cancer was reintroduced into the animals post initial treatment, suggesting the development of beneficial immune memory. A reduction in tumor growth was demonstrated and also a reversal of tumor activity resulting in an almost complete reduction of tumor burden.

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. In 2019, the FDA granted ODD for WP1066 for the treatment of glioblastoma, which means the agency believes we have established a medically plausible basis for expecting the drug to be effective.

Our WP1066 Portfolio (including lead drug candidates WP1066, WP1220 and WP1732), we believe, 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 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-1α. In addition to direct anticancer effects not related to the function of the immune system, our lead drug candidate 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 promising. If additional preclinical and clinical data validate these 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. We believe there is a 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 preclinical evidence that WP1066, as a single agent, may have 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 our 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-1α, 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 preclinical 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.

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 discovery was inspired by a naturally occurring compound (caffeic acid) in propolis (from honeybees). 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-1α. 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 apparent ability in pre-clinical testing 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.

As with other analogs in this portfolio, WP1066 also has a demonstrated in animal models the 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 indicates that WP1066 inhibits tumor growth, blocks angiogenesis (a process that leads to the formation of blood vasculature needed for tumor growth) and increases survival.

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. Additionally, in April 2019 we announced that preclinical data supporting activity of our STAT3-inhibiting Immune/Transcription Modulators was presented by Dr. Waldemar Priebe, our founder and chair of our Scientific Advisory Board, at the 2019 Annual Meeting of the American Association for Cancer Research ("AACR") in Atlanta, GA. The abstract (AACR Abstract: https://www.moleculin.com/inhibition-of-stat3-in-pancreatic-ductal-adenocarcinoma-and-immunotherapeutic-implications/) and presentation included data resulting from preclinical evaluation in pancreatic cancer models of STAT3 inhibitors WP1066 and WP1732. In vitro efficacy of both inhibitors was assessed using proliferation and apoptosis induction assays in a panel of patient-derived and commercially available Pancreatic Ductal Adenocarcinoma ("PDAC") cell lines. Both WP1066 and WP1732 were similarly potent and shown to induce apoptosis and inhibit p-STAT3 and its nuclear localization in all tested PDAC cell lines. Observed IC50 values ranged from 0.5 to 2 μM. WP1732 was well tolerated by mice (LD50 85 mg/kg given IV). Pharmacokinetic and biodistribution studies revealed very high uptake of WP1732 in the pancreas of mice and rats exceeding up to ~30 fold more than the drug levels in plasma. Importantly, both agents show in-vivo efficacy in preliminary experiments when tested alone or in combination with T cell immune checkpoint inhibitors.

Clinical Activity WP1066 -

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 dose-escalation Phase I brain tumor clinical trial via an investigator-initiated IND with MD Anderson Cancer Center has generated pharmacokinetic data for oral dosed WP1066. 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 4th dose escalation cohort in this trial. At an 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 filed and received clearance to proceed with an IND for a trial to treat children with recurrent or refractory malignant brain tumors with WP1066. This trial will be conducted at the Aflac Cancer & Blood Disorders Center at Children's Healthcare of Atlanta. This trial is pending finalization of Emory's internal administrative

documents and procedures. Although we can provide no assurance regarding the likelihood and timing of such trial, we expect the first patient to be treated in the first half of 2020.

The Phase 1 trial at MD Anderson with WP1066 drug is being supported by $2 million in private grant funding 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 our financial statements, but instead are applied to the cost of preclinical and clinical activities at and conducted by MD Anderson.

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 two Polish drug development companies. One is Dermin, which has received previously Polish government grant money to develop WP1220 in Poland for the topical treatment of early stage CTCL patients, and the other is WPD Pharmaceuticals, which is applying for Polish government grant money. CTCL is a potentially deadly form of skin cancer for which there are limited treatment options.

On March 16, 2020, we entered into a material transfer agreement with The University of Texas Medical Branch at Galveston, d/b/a UTMB Health ("UTMB"), a health institution of The University of Texas System ("System"), an agency of the State of Texas (the "Agreement"). Pursuant to the Agreement, we agreed to provide research material(s) to UTMB. The materials will be used by UTMB to conduct research, specifically to test the effects of 2 Deoxy D-Glucose (2DG) and analogues thereof on the infectivity of viruses, including Coronoavirus. The materials to be provided pursuant to the Agreement are subject to patent and technology license agreements we have with MD Anderson Cancer Center. In the event that use of the materials results in an invention, improvement, substance, or information, whether or not patentable, and patent applications and patents, if any, which result therefrom (the "Developed Technology"), UTMB has agreed to disclose such Developed Technology, in confidence, to us. At our expense, we have the right to file for and obtain patent protection in the name of UTMB, if solely invented by UTMB, or in the name of both parties if jointly invented, for Developed Technology or request UTMB to do so. Any Developed Technology conceived, invented, expressed and/or reduced to practice solely by UTMB in accordance with UTMB's research shall be solely owned by UTMB. For those inventions determined to be solely owned by UTMB, we have been granted an option to negotiate a license in such Developed Technology on a worldwide, exclusive basis the terms of which shall be negotiated by and between the parties in good faith. Any Developed Technology conceived, invented, expressed and/or reduced to practice jointly by UTMB and us in accordance with the research performed hereunder shall be deemed Jointly Developed Technology and shall be owned jointly us and UTMB.

Clinical Activity WP1220 –

In August 2019, we completed full enrollment in a proof-of-concept clinical trial in Poland to study WP1220 for the treatment of CTCL. Polish authorities approved our CTA for this use in January 2019, and the trial began enrolling patients in March 2019. In February 2020, we announced the final data from our CTCL clinical trial of WP1220, which was published and presented by Dr. M. Sokolowska-Wojdylo in conjunction with the 4th Annual World Congress of Cutaneous Lymphomas in Barcelona, Spain on February 13, 2020. The final results supported the safety of topical WP1220 and demonstrated a median improvement in the Composite Assessment of Index Lesion Severity ("CAILS") score of 56% in treated (index) lesions for patients completing the study. We plan to meet with the FDA and EMA to discuss a Phase 2 Trial with WP1220 for the treatment of CTCL.

Mycosis Fungoides or MF, the most common variant of CTCL, is a disease with symptomatic, disfiguring skin lesions. STAT3, an oncogenic transcription factor, has been identified as a critical regulator of MF, whereby the activation of STAT3 through phosphorylation (p-STAT3) has been linked to tumor proliferation and suppression of immune responses. Preclinical testing demonstrated that WP1220, a synthetic compound, potently inhibits the activity of p-STAT3 and the growth of CTCL cell lines. This Phase 1 study was designed to demonstrate the safety and efficacy of WP1220 after topical treatment of CTCL.

Of 5 subjects enrolled, 9 lesions were assessed according to the CAILS scoring system. The only adverse event (AE) was mild contact dermatitis in one subject felt not to be related to the drug. 4 of the 5 subjects improved in CAILS scores on index lesions, with a median reduction of 56% (range 25-94%). Improvement was noted within 7 days of treatment initiation and maintained 1 month after discontinuation. Independent dermatologic review based on photographic documentation was conducted and corroborated these findings.

WP1220, an inhibitor of p-STAT3, demonstrated safety and efficacy in MF after topical treatment. We believe this is the first demonstration in humans suggesting that inhibition of p-STAT3 with topical therapy has efficacy in CTCL. A larger Phase 2 study is now being planned.

IV Formulation for the WP1066 Portfolio

Currently WP1066 is dosed orally. WP1220 is topically applied. In February 2018, we announced that, pursuant to our continued collaboration with MD Anderson we had developed and licensed 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.

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 may make it well suitable 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 preclinical work to develop an IV formula for WP1066 and WP1732. This data is required to submit an IND or its foreign equivalent for an intravenous formulation of WP1066. We expect to submit an IND in 2021. We are working with The University of Iowa Pharmaceuticals and developers in Poland to develop an IV formulation.

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. 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 23,890 new cases of brain and other nervous system cancers will occur in the United States in 2020, resulting in 18,020 deaths. Despite the severity and poor prognosis of these tumors, there are few FDA-approved drugs on the market.

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 2020, nearly 1.8 million new cases will be diagnosed and over 600,000 Americans will die from cancer.

Digestive, reproductive, breast and respiratory cancers comprise 58% of expected cancer diagnoses in 2020, 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 19,940 of the estimated 60,530 new cases expected in the United States in 2020.

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 approved anthracyclines most commonly used 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 $153 million in 2016, and it is estimated that this number is

increasing with the increase in approved AML treatments. Of this worldwide amount, 67% is estimated to be attributed to the US market.

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.

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, 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 consists of combining seven injections of Cytarbine with 3 infusions of an anthracycline to induce remission (a complete response, or "CR"). This therapy had not improved since it was first used in the 1970s and we estimate that this induction therapy had a success rate of about 20% to 25%. A revision to this therapy was 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 potentially curative bone marrow transplant and unfortunately most patients 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.

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 $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 $0.2 million and $0.3 million for the year ended December 31, 2019 and 2018, respectively.

We have a sponsored research agreement with MD Anderson that currently runs until the end of October 2021. The expenses recognized under the MD Anderson agreement with regards to the sponsored research agreement were $0.5 million and $0.4 million for the year ended December 31, 2019 and 2018, respectively.

Annamycin

On June 29, 2017, we 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 US government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the US government. The terms and payments of which are included in the summary above.

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 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

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 of $0.5 million. On July 30, 2019, we entered into an agreement that satisfied the foregoing buyback right, and as such, Germany is no longer considered part of the licensed territories.

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.

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 $0.3 million (the "Development Reimbursement Fee") within the first year of the agreement. WPD did not pay the Development

Reimbursement Fee, so the Commercially Reasonable Development Efforts during the first two years of the agreement increased from $2.0 million to $2.5 million.

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 $5.0 million in Commercially Reasonable Development Efforts prior to the fifth anniversary of the date of the agreement and more than $6.0 million 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 $6.0 million in Commercially Reasonable Development Efforts prior to the fifth anniversary of the date of the agreement and more than $8.0 million 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. This license is subject to the terms in the prior agreements entered into by the Company and MDA. ALI granted us the right to name an observer to ALI's board of directors. On August 8, 2019, the Company named its Chairman and CEO Walter V. Klemp to that position.

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.

Other Licenses

In 2015, we obtained the rights and obligations for certain patent and technology development and license agreements with Dermin sp. z o.o. ("Dermin"). In connection with such agreements, certain intellectual property rights related to Annamycin, our WP1122 portfolio, and our WP1066 portfolio were licensed to Dermin and Dermin was 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 had 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 agreed to pay a royalty for the sale of any licensed product in the licensed territories and agreed to 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. In July 2019, Dermin assigned its rights under the foregoing license agreements to an affiliated entity, Exploration Invest Pte Ltd. ("Exploration"). On July 30, 2019, we and Exploration entered into a License Modification Agreement pursuant to which we agreed to issue Exploration shares of Company common stock valued at $0.5 million (based on the greater of the closing price of the common stock on the date of the agreement or the 10-day average closing price prior to the date of the agreement) in exchange for the modifying the license agreements to: (i) limit the licensed territory solely to Poland; and (ii) limit the patent rights and technology rights licensed to Exploration to the patent rights and technology rights that existed on the date the original license agreements were entered into with Dermin. On August 8, 2019, we issued 429,978 shares of common stock to Exploration to satisfy this commitment.

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 the development efforts involving several oncology technologies, based on license agreements with MD Anderson. 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. followed by the acquisition of the license rights to the WP1122 Portfolio from IntertechBio Corporation. Further, on behalf of Moleculin, LLC, we entered into a co-development agreement with Houston Pharmaceuticals, Inc., 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.

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 for quality, 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 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 US 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 and in accordance with the Animal Welfare Act 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, laws 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 data 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 safety or effectiveness compared to marketed products. The FDA will move more quickly in its review of such products in an effort to complete the review four months sooner than a standard review. Additionally, accelerated approval may be available for a product intended to treat a serious condition that provides a meaningful therapeutic benefit over existing treatments, which means the product may be approved on the basis of clinical data establishing an effect on a surrogate endpoint or 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 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 US Department of Justice and/or US 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 US 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 US 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.

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 do 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.

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, 2019, we had eleven full-time employees and five 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 Related to Regulatory Approval and the Development and Commercialization of our Drug Candidates

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 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 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.

There are limited suppliers for active pharmaceutical ingredients ("API") used in 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 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 are currently conducting a Phase 1 trial to attempt to increase the maximum tolerable dose (“MTD”) for Annamycin, 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 US and non-US 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 received Orphan Drug designation for Annamycin and WP1066, but it may not effectively prevent approval of a competing product.

In 2017, we received notice that the FDA granted Orphan Drug designation ("ODD") for Annamycin for the treatment of AML. In February 2019, we received notice that the FDA granted ODD for WP1066 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 regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we and our collaborators must demonstrate with substantial evidence from well controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for a product candidate are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the United States. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

We have received Fast Track designation for one of our product candidates and may seek the same designation for one of more of our other product candidates. Even if we receive designation, such designation may not actually lead to a faster development or regulatory review or approval process.

If a product is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. If we seek Fast Track designation for a product candidate, we may not receive it from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA’s priority review procedures.

Risks Related to our Intellectual Property

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 US 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 US government. As a result, the US 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 US 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 US and substantially manufactured outside the US without the US 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 US). The US 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 US 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 US 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 US 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.

Risks Relating to Our Business and Our Financial Condition

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 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 INDs 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. Based on the results of our Annamycin Phase 1 clinical trials, we intend to enter discussions with the FDA and EMA about conducting a single arm Phase 2 study that would be the pivotal trial supporting US and European approval of Annamycin for relapsed or refractory AML. We can provide no assurance that the FDA will permit such reliance and we may be required to conduct additional trials. If the FDA or its EU equivalent requires that we perform additional nonclinical studies or clinical trials, 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.

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 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 the results of our clinical trials will be announced on a timely basis and, when announced, whether such results are in accordance with our expectations or our announced milestones;
- whether the FDA and EMA will allow us to conduct a single arm Phase 2 study that would be the pivotal trial supporting US and European approval of Annamycin for relapsed or refractory AML;

- 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 third quarter of 2020, 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 or our ATM. 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. Our existing capital resources are not sufficient to enable us to complete the development and commercialization of Annamycin, WP1066, and WP1220, if approved, or to initiate any clinical trials or additional development work needed for any other drug candidates. Accordingly, we will need to raise additional funds in the near 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 US 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 or our ATM 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 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, preparing several drugs for authorization to conduct clinical trials and commencing Phase 1 clinical trials. We have only recently commenced Phase 1 clinical trials 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 candidates 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 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.

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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.

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, 2019, we incurred a net loss of $13.2 million. We had an accumulated deficit of $39.6 million as of December 31, 2019.

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.

We conduct 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. We applied for a refundable tax credit and received in 2019 for $0.2 million

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.

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, 2019. 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 we will record a noncash impairment loss on our 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.

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. 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. In 2019, some of these rights were transferred to WPD Pharmaceuticals, Inc. via an additional sublicense. The territories covered by these sublicense agreements are primarily Poland and lesser surrounding countries, but not including any of the major European markets (UK, Germany, France, Spain and Italy).

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 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, 2019, we had eleven full-time and five 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. 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.

Our business and operations would suffer in the event of third-party computer system failures, cyber-attacks on third-party systems or deficiency in our cyber security.

We rely on information technology ("IT") systems, including third-party "cloud based" service providers, to keep financial records, maintain laboratory data, clinical data, and corporate records, to communicate with staff and external parties and to operate other critical functions. This includes critical systems such as email, other communication tools, electronic document repositories and archives. If any of these third-party information technology providers are compromised due to computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication failures, electrical failures, cyber-attacks or cyber-intrusions over the internet, then sensitive emails or documents could be exposed or deleted. Similarly, we could incur business disruption if our access to the internet is compromised and we are unable to connect with third-party IT providers. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, we rely on those third parties to safeguard important confidential personal data regarding our employees and patients enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in a third-party IT provider's operation, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidates could be delayed, or could fail.

The recent coronavirus pandemic may impact our business including, but not limited to, the progress of clinical trials and the the production of our drug, which the latter could adversely affect our clinical trials if we are unable to obtain sufficient supply.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China. As of February 2020, the virus has spread to Italy, which reportedly has the highest number of coronavirus infections outside Asia. We currently source the production of Annamycin in Italy. Additionally, some clinics in Poland have put limitations on access to the monitoring our clinical trials, which for now has not limited the progress of our trials, but this could change at any time. The impact of the coronavirus has been so widespread and increasing, that not all future impacts can be predicted. As such, the outbreak of the coronavirus worldwide could have a material adverse effect on our business, financial condition and results of operations. These effects could include travel bans or restrictions, limited access to required facilities, disruptions from the temporary closure of third-party supplier and manufacturer facilities, or restrictions on the export or shipment of products. The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot

be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

We are subject to US data protection laws and regulations (i.e., laws and regulations that address privacy and data security) at both the federal and state levels. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. Numerous federal and state laws, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, and disclosure of health-related and other personal information. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under Health Insurance Portability and Accountability Act of 1996, or HIPAA. Although we are not directly subject to HIPAA-other than potentially with respect to providing certain employee benefits-we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Finally, a data breach affecting sensitive personal information, including health information, could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

EU Member States, Switzerland and other countries have also adopted data protection laws and regulations, which impose significant compliance obligations. For example, the collection and use of personal health data in the EU is governed by the provisions of the EU Data Protection Directive, or the Directive. The Directive and the national implementing legislation of the EU Member States impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. Data protection authorities from the different E.U. Member States may interpret the Directive and national laws differently and impose additional requirements, which add to the complexity of processing personal data in the EU.

Guidance on implementation and compliance practices are often updated or otherwise revised. For example, the EU Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, that are not considered by the European Commission to provide an adequate level of data protection. These countries include the United States.

The judgment by the Court of Justice of the EU in the Schrems case (Case C-362/14 Maximillian Schrems v. Data Protection Commissioner) determined the US-EU Safe Harbor Framework, which was relied upon by many US entities as a basis for transfer of personal data from the EU to the US, to be invalid. US entities therefore, had only the possibility to rely on the alternate procedures for such data transfer provided in the EU Data Protection Directive.

On February 29, 2016, however, the European Commission announced an agreement with the U.S. Department of Commerce, or DOC, to replace the invalidated Safe Harbor framework with a new EU-US "Privacy Shield". On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the Court of Justice of the EU in its Schrems judgment by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and the Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. US companies have been able to certify to the DOC their compliance with the privacy principles of the Privacy Shield since August 1, 2016 and rely on the Privacy Shield certification to transfer of personal data from the EU to the US.

On September 16, 2016, the Irish privacy advocacy group Digital Rights Ireland brought an action for annulment of the European Commission decision on the adequacy of the Privacy Shield before the Court of Justice of the E.U. (Case T-670/16). Case T-670/16 is still pending. If the Court of Justice of the EU invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to transfer personal data from the EU to entities in the US. Adherence to the Privacy Shield is not, however, mandatory. US-based companies are permitted to rely either on their adherence to the EU-US Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the EU Data Protection Directive.

In addition, the EU Data Protection Regulation, intended to replace the current EU Data Protection Directive entered into force on May 24, 2016 and will apply from May 25, 2018. The EU Data Protection Regulation will introduce new data protection requirements in the E.U. and substantial fines for breaches of the data protection rules. The EU Data Protection

Regulation will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules.

Our failure to comply with these laws, or changes in the way in which these laws are implemented, could lead to government enforcement actions and significant penalties against us, and adversely impact our business.

We depend on our information technology and infrastructure.

We rely on the efficient and uninterrupted operation of information technology systems, including mobile technologies, to manage our operations, to process, transmit and store electronic and financial information, and to comply with regulatory, legal and tax requirements. We also depend on our information technology infrastructure for communications among our personnel, contractors, consultants and vendors. System failures or outages could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition.

In addition, we depend on third parties to operate and support our information technology systems. These third parties vary from multi-disciplined to boutique providers, and they may or could have access to our computer networks, mobile networks, and our confidential information. Many of these third parties subcontract or outsource some of their responsibilities to other third parties. As a result, our information technology systems, including those functions that are performed by third parties who are involved with or have access to those systems, are very large and complex. Failure by any of these third-party providers to adequately deliver the contracted services, or maintain confidentiality, could have an adverse effect on our business, which in turn may materially adversely affect our operating results and financial condition. All information technology systems, despite implementation of security measures, may be vulnerable to disability, failures or unauthorized access. If our information technology systems were to fail or be breached, such failure or breach could materially adversely affect our ability to perform critical business functions and sensitive and confidential data could be compromised.

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 $0.32, 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 100,000,000 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, 2019, we had a material number of outstanding options and warrants to purchase shares of common stock. As of December 31, 2019, we had warrants and options outstanding to purchase an aggregate of 10,763,995 shares of common stock at an average exercise price of $1.97 per share. 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.

As of December 31, 2019, our founders, directors and executive officers beneficially own and are able to vote in the aggregate 15.1% 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. As of March 11, 2020, our founders, directors and executive officers beneficially own and are able to vote in the aggregate 13.0% of our outstanding common stock

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 $0.32. 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.

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.

Since February 6, 2020, we have been trading below the $1.00 minimum closing bid price requirement set forth in NASDAQ Listing Rule 5550(a)(2). On March 18, we traded below that minimum for a total of 30 consecutive days, so we are out of compliance with NASDAQ, and will receive notice of noncompliance from NASDAQ. To regain compliance, we must trade at or above $1.00 per share or greater for the 10 consecutive business days during the six months following receipt of such notice.

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.

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, 2019, 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, 2019 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, 2019, 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 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.

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. In March 2018, we entered into a Lease Agreement (the “Lease”) which we use 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. We are required to remit base monthly rent 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.

In August 2019, we entered into an Amended Lease Agreement (the "Lab Lease") which our lab space. The term of the Lab Lease began in September 2019 and will continue for an initial term of 35 months, with no further right or option to renew. We are required to remit base monthly rent which will increase at an average approximate rate of 3% each year. The Lab Lease is classified as an operating lease. In August 2019, we entered into a sublease with Houston Pharmaceuticals, Inc. ("HPI"), which is affiliated with Dr. Priebe. We granted HPI access to all of the Lab Lease space and HPI has agreed to pay us 50% of the rent payable under the Lab Lease less 50% of any benefits from any sublease or other lab service agreement we may receive from its Lab Lease. Although HPI has access to the space, it is the intent of the parties that they equally share the Lab Lease space for research purposes. 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 March 4, 2020, the closing price reported on the NASDAQ Capital Market for our common stock was $0.70.

Holders

As of March 4, 2020, there were approximately 149 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

All information related to equity securities sold by us during the period covered by this report that were not registered under the Securities Act have been included in our Form 10-Q filings or in a Form 8-K filing. We did not issue any equity securities during the fourth quarter of 2019 that were not registered under the Securities Act.

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, 2019.

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

Our Business

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 MD Anderson Cancer Center ("MD Anderson"). We have three drug candidates that are active in clinical trials. In 2019, those three drug candidates were active in four clinical trials in the US and Poland with a fifth that is expected to begin in the first half of 2020. Of these five clinical trials, two are primarily externally funded. For two of these trials, we successfully concluded the Phase 1

portion recently and are preparing to potentially move into Phase 2 trials. We anticipate laying the groundwork in 2020 for two additional Phase 1 trials expected to begin in 2021 sponsored by us and two other Phase 1 trials we expect to be externally sponsored.

Based on our positive clinical activity thus far, we have narrowed our development focus to our nearest term opportunities. We believe this will allow us to reduce our cash needs until we reach a significant value inflection point, although we will continue to require additional external capital during this period. In addition, institutional support for our technologies has increased and we believe such support may provide outside funding to help reduce future dilution.

Of our three clinical stage drug candidates, Annamycin is being studied for the treatment of relapsed or refractory acute myeloid leukemia (“AML”) and cancers metastasized to the lungs. WP1066, an Immune/Transcription Modulator ("p-STAT3 inhibitor") is intended to target a wide range of tumors, including brain tumors and pancreatic cancer. We began and completed a Phase 1 clinical trial in 2019 in Poland for a third drug, WP1220 (a molecule similar to WP1066), for the topical treatment of cutaneous T-cell lymphoma ("CTCL") and we are looking to expand development of this drug into a Moleculin Phase 2 trial. We are also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as Metabolism/Glycosylation Inhibitors.

We consider Annamycin to be a "next generation" anthracycline, unlike any currently approved anthracyclines, as it is designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity (two problems common to all currently approved anthracyclines). We recently received an independent expert cardiology assessment confirming the absence of cardiotoxicity in the first 14 patients treated with Annamycin in both our US and European Phase 1 clinical trials, validating Annamycin's lack of cardiotoxicity. Annamycin is currently in one Phase 1/2 clinical trial in Europe with the Phase 1 portion of another Phase 1/2 AML trial recently concluding in the US. Upon receipt of further data from the European Phase 1 trial, we plan to seek agreement with the FDA for accelerated approval of Annamycin based on a pivotal Phase 2 AML trial sponsored by us, although there is no assurance that the FDA will agree with our proposal.

In 2019, preclinical work on Annamycin demonstrated activity against some cancers metastasized to the lungs. With this new data, we are planning to start a Moleculin-sponsored US Phase 1 trial at MD Anderson for the treatment of cancer metastasized to the lungs with Annamycin.

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-1α. 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. WP1066 is currently in a US physician-sponsored Phase 1 trial for the treatment of glioblastoma ("GBM") and another institutionally sponsored Phase 1 trial should begin soon for the treatment of pediatric brain tumors. Another physician-sponsored Phase 1 trial is being considered for the treatment of GBM with WP1066 in combination with radiation.

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 has the opportunity to become an important drug to potentiate existing therapies, including checkpoint inhibitors. In March 2020, we entered into an agreement with an outside research center who will conduct research on WP1122 for antiviral properties against a range of viruses, including Coronavirus.

Recent Developments

Offering

On February 6, 2020, we entered into subscription agreements with certain institutional investors for the sale of up to 7,500,000 shares of our common stock and warrants to purchase 5,625,000 shares of common stock at a combined public offering price of $0.80 per share and related warrant. The warrants will be exercisable six months from the date of issuance at a price of $1.05 per share and will expire five years from the date they are first exercisable. The offering closed on February 10, 2020 and gross proceeds of the offering were approximately $6.0 million, prior to deducting the placement agent fees and other estimated offering expenses.

Entry into a Material Definitive Agreement

On March 16, 2020, we entered into a material transfer agreement with The University of Texas Medical Branch at Galveston, d/b/a UTMB Health ("UTMB"), a health institution of The University of Texas System ("System"), an agency of the State of Texas (the "Agreement"). Pursuant to the Agreement, we agreed to provide research material(s) to UTMB. The materials will be used by UTMB to conduct research, specifically to test the effects of 2 deoxyglucose (2DG) and analogues thereof on the infectivity of viruses, including Coronoavirus. The materials to be provided pursuant to the Agreement are subject to patent and technology license agreements we have with MD Anderson Cancer Center.

Moleculin Biotech, Inc.

Results of Operations for the Year Ended December 31, 2019 as Compared to the Year Ended December 31, 2018

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

	Year ended December 31,	
	2019	**2018**
Revenue	$ —	$ —
Operating expenses:		
Research and development	11,013	9,728
General and administrative	6,312	5,229
Depreciation and amortization	199	68
Total operating expense	17,524	15,025
Loss from operations	(17,524)	(15,025)
Other income (expense):		
Gain from change in fair value of warrant liability	4,062	3,185
Other income (expense)	15	(40)
Interest income, net	13	4
Net loss before taxes	(13,434)	(11,876)
Income tax benefit	$ 229	$ —
Net loss	$ (13,205)	$ (11,876)

Research and Development Expense.

Research and development ("R&D") expense was $11.0 million and $9.7 million for the years ended December 31, 2019 and 2018, respectively. The increase in R&D of approximately $1.3 million mainly relates to: increased clinical trial activity (2 drugs in 3 clinical trials in 2018, versus 3 drugs in 4 clinical trials in 2019) including the manufacturing of additional drug product and the issuance of common stock for $0.5 million, related to the exercise of the option to reacquire certain license rights in Germany under the Dermin License Agreements. These increases were offset by a reduction in various other R&D expenses.

General and Administrative Expense.

General and administrative ("G&A") expense was $6.3 million and $5.2 million for the years ended December 31, 2019 and 2018, respectively. The increase in G&A of approximately $1.1 million was mainly attributable to increase in payroll costs for additional finance and office staff, stock-based compensation expense for vested warrants issued to a consultant, and annual employee stock options.

Gain from Change in Fair Value of Warrant Liability.

We recorded a gain of $4.1 million during the year ended December 31, 2019 as compared to a gain of approximately $3.2 million, during the year ended December 31, 2018, for the change in fair value on revaluation of our warrant liability associated with our warrants issued in conjunction with our stock offerings. 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 model. 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.

Net Loss.

The net loss for the year ended December 31, 2019 was $13.2 million, which included non-cash gains of $4.1 million on warrants in 2019 as compared to $3.2 million in the prior year and approximately $1.5 million of stock-based compensation expense in 2019 as compared to $1.1 million in 2018.

Liquidity and Capital Resources

As of December 31, 2019, we had cash and cash equivalents of $10.7 million and prepaid expenses and other of $2.7 million. We also had $2.2 million of accounts payable and $1.4 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, 2019 and 2018, we used approximately $17.2 million and $12.2 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 2019 reflects the increase in clinical and preclinical activity over 2018. For the year ended December 31, 2019, net proceeds from financing activities were $20.9 million, predominately from the sale of our common stock and warrants. In 2018, approximately $12.0 million was raised predominately through the sale of shares of common stock and the exercise of warrants. Cash used in investing activities for the year ended December 31, 2019 was approximately $0.05 million primarily for the purchases of employee computer equipment and office furniture.

We believe that our cash resources as of December 31, 2019, along with the additional funding received subsequent to year-end, will be sufficient to meet our projected operating requirements towards the end of the third quarter of 2020. 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 or ATM facilities.

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.

On October 4, 2018, we entered into a purchase agreement ("LP Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") and a registration rights 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. As of December 31, 2019 we have utilized $2.8 million under the LP Purchase Agreement.

In July 2019, we entered into an at-the-market equity agreement (the “ATM Agreement”) with Oppenheimer & Co. Inc. (the “Agent”). Pursuant tothe terms of the ATM Agreement, we may sell from time to time through the Agent shares of our common stock, with an aggregate sales price of up to $15 million, subject to certain terms and conditions. The offering of the shares pursuant to the ATM Agreement will terminate upon the sale of shares in an aggregate offering amount equal to $15 million, or sooner if either we or the Agent terminate the ATM Agreement pursuant to its terms. We will pay a commission to the Agent of 3.0% of the gross proceeds of the sale of the shares sold under the ATM Agreement and reimburse the Agent for certain expenses. We provided the Agent with customary indemnification rights. We have not sold any shares under the ATM Agreement.

As mentioned above, subsequent to year-end in February 2020 we entered into subscription agreements with certain institutional investors for the sale of up to 7,500,000 shares of our common stock and warrants to purchase 5,625,000 shares of common stock at a combined public offering price of $0.80 per share and related warrant. The warrants will be exercisable six months from the date of issuance at a price of $1.05 per share and will expire five years from the date they are first exercisable. The offering closed on February 10, 2020 and gross proceeds of the offering were approximately $6.0 million, prior to deducting the placement agent fees and other estimated offering expenses.

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

	For the Year Ended December 31,	
	2019	2018
Net cash used in operating activities	$ (17,198)	$ (12,203)
Net cash used in investing activities	(51)	(417)
Net cash provided by financing activities	20,854	12,045
Effect of exchange rate changes on cash and cash equivalents	(4)	(5)
Net change in cash and cash equivalents	$ 3,601	$ (580)

Cash used in operating activities

Net cash used in operating activities was $17.2 million for the year ended December 31, 2019 compared to $12.2 million for the year ended December 31, 2018. This increase in use of cash for operations was mainly due to: 1) payments for developing, manufacturing and testing drug product as we prepared for clinical trials, including the $1.0 million payment to HPI; 2) an increase in R&D employee and contractor headcount and associated payroll costs; 3) an increase in paid sponsored research and related expenses; and 4) an increase in license fees. These are all a reflection of the ongoing clinical and pre-clinical activity and the associated increase in G&A support for our three core drug technologies.

Cash used in investing activities

Net cash used in investing activities was $0.05 million for the year ended December 31, 2019 compared to $0.4 million for the year ended December 31, 2018. The decrease relates to purchases in 2018 related to furniture and fixtures and leasehold improvements on the new office location, as well as the installation of a new accounting system in 2018.

Cash provided by financing activities

Net cash provided by financing activities was $20.9 million for the year ended December 31, 2019 compared to the prior period of $12.0 million. Net cash provided by financing in 2019 consisted primarily of $19.3 million net proceeds from issuance of common stock, and $1.6 million net proceeds from the exercise of warrants. The prior period financing activities consisted primarily of net proceeds from issuance of common stock.

Off-Balance Sheet Transactions

We do not engage in off-balance sheet transactions.

JOBS Act and Recent Accounting Pronouncements

The 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 ("US 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**.**

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 and 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 evaluates the recoverability of its property and equipment and amortizable intangible assets for possible impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable or at a minimum annually during the fourth quarter of the year. Recoverability of these assets is measured by a comparison of the carrying amounts to the future undiscounted cash flows the assets are expected to generate. If such review indicates that the carrying amount of property and equipment and amortizable intangible assets is not recoverable, the carrying amount of such asset is reduced to fair value.

Acquired in-process research and development ("IPR&D") assets are considered indefinite lived until the completion or abandonment of the associated research and development efforts. Management evaluates the recoverability of its IPR&D assets for possible impairment annually during the fourth quarter or whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of IPR&D assets is measured by a comparison of the carrying amounts its fair value. If such review indicates that the carrying amount of IPR&D assets is not recoverable, the carrying amount of such asset is reduced to fair 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 2 to 5 year life and furniture and office equipment to have a 2 to 7 year life.

Accounting for warrants

We issued warrants to purchase shares of common stock related to equity transactions in 2017, 2018, and 2019. 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 certain of our warrants to purchase shares of common stock related to equity transactions in 2017, 2018 and 2019 meet the criteria for classification as a liability. Accordingly, the warrants were classified as a warrant liability and are subject to fair value remeasurement at each transaction and 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.

Our financial instruments consist primarily of non-trade receivables, account payables, accrued expenses, and a warrant liability. The carrying amount of non-trade receivables, 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, February 2018, June 2018, March 2019, and April 2019 Offerings ("Offerings") are included in long-term liabilities on the accompanying financial statements as of December 31, 2019. As of December 31, 2018, the fair value of the warrant liability associated with the February 2017 Offering was included in current liabilities, and the liabilities associated with the other offerings were included in long-term liabilities.

We estimated the fair value of the warrant liability issued in our 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 US 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 combined with our own due to the lack of sufficient historical data of our stock price during 2017-2019. In 2019 we began utilizing some our stock's own volatility in the estimated volatility in the BSM. Beginning in 2020, only the volatility of our stock will be used in the BSM as we now have sufficient historic data in our stock price.

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, and the fair value of restricted stock units using the closing price of our common stock as reported on the date of grant. The Black-Scholes estimate uses assumptions regarding a number of inputs that require us to make significant estimates and judgments. In 2019 we began utilizing some our stock's own volatility in the estimated volatility in the BSM. Beginning in 2020, only the volatility of our stock will be used in the BSM as we now have sufficient historic data in our stock price.

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.

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, 2019. 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, 2019 due to a material weakness in our internal controls due to the lack of segregation of duties as described below:

- Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible, however segregation of duties has been implemented, with regards to the initiation of transactions, the custody of assets and the recording of transactions performed by separate individuals.
- A number of the prior issues related to segregation of duties were remediated with new information technology systems and policies during 2019 and further improvements are planned for 2020.

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 above, 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.

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 additional accounting and IT personnel in 2019 and implemented a new accounting software system, accounting policies, and banking controls. Management intends to further enhance its accounting staff and enhance the controls surrounding its system of financial accounting and reporting, as soon as economically feasible and sustainable, to further remediate this material weakness.

There has been no change in our internal control over financial reporting, other than what is described above, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, or our certificate of incorporation or the bylaws, and (iv) any action asserting a claim against us governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or Securities Act.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, a court could find these provisions of our certificate of incorporation to be inapplicable or unenforceable in respect of one or more of the specified types of actions or proceedings, which may require us to incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our proxy statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019 and is incorporated into this Annual Report on Form 10-K by reference.

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

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our proxy statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019 and is incorporated into this Annual Report on Form 10-K by reference.

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

The information required by this item is incorporated by reference to our proxy statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019 and is incorporated into this Annual Report on Form 10-K by reference.

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

The information required by this item is incorporated by reference to our proxy statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019 and is incorporated into this Annual Report on Form 10-K by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our proxy statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019 and is incorporated into this Annual Report on Form 10-K by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

ı. 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 62.

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	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Moleculin Biotech, Inc. (incorporated by reference to Exhibit 3.1 of the Form 8-K filed May 24, 2019)
3.3	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)
4.4	Form of Warrant Agreement issued in March 2019 offering (incorporated by reference to Exhibit 4.1 of the Form 8-K filed March 28, 2019)
4.5	Form of Underwriter Warrant Agreement issued in March 2019 offering (incorporated by reference to Exhibit 4.2 of the Form 8-K filed March 28, 2019)
4.6	Form of Warrant Agreement issued in April 2019 offering (incorporated by reference to Exhibit 4.1 of the Form 8-K filed April 24, 2019)
4.7	Form of Placement Agent Warrant Agreement issued in April 2019 offering (incorporated by reference to Exhibit 4.2 of the Form 8-K filed April 24, 2019)
4.8	Form of Warrant Agreement issued in February 2020 offering (incorporated by reference to Exhibit 4.1 of the Form 8-K filed February 6, 2020)
4.9	Form of Placement Agent Warrant Agreement issued in February 2020 offering (incorporated by reference to Exhibit 4.2 of the Form 8-K filed February 6, 2020)
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 April 2, 2012 by and between The Board of Regents of the University of Texas System and IntertechBio Corporation (incorporated by reference to exhibit 10.6 of the Form S-1/A filed March 21, 2016)
10.7	Patent and Technology Development and License Agreement June 28, 2012 by and between Annamed, Inc. and Dermin Sp. z.o.o (incorporated by reference to exhibit 10.7 of the Form S-1/A filed April 15, 2016)
10.8	Patent and Technology Development and License Agreement dated April 15, 2011 by and between IntertechBio Corporation and Dermin Sp. z.o.o (incorporated by reference to exhibit 10.8 of the Form S-1/A filed March 21, 2016)

10.9	Patent and Technology Development and License Agreement dated October 27, 2010 by and between Moleculin, LLC and Dermin Sp. z.o.o (incorporated by reference to exhibit 10.9 of the Form S-1/A filed March 21, 2016)
10.10	Rights Transfer Agreement dated between Moleculin Biotech, Inc. and IntertechBio Corporation dated August 11, 2015 (incorporated by reference to exhibit 10.10 of the Form S-1/A filed March 21, 2016)
10.11	Agreement and Plan of Merger between Moleculin Biotech, Inc. and Moleculin, LLC (incorporated by reference to exhibit 10.11 of the Form S-1/A filed March 21, 2016)
10.12	Technology Rights and Development License Agreement to be entered into by Moleculin Biotech, Inc. and Houston Pharmaceuticals, Inc. (incorporated by reference to exhibit 10.13 of the Form S-1/A filed April 15, 2016)
10.13 **	Employment Agreement between Moleculin Biotech, Inc. and Jonathan P. Foster dated August 19, 2016 (incorporated by reference to Exhibit 10.1 of the Form 8-K filed August 25, 2016)
10.14 **	Executive Employment Agreement between Moleculin Biotech, Inc. and Walter Klemp dated October 13, 2016 (incorporated by reference to Exhibit 10.1 of the Form 8-K filed October 13, 2016)
10.15 **	General Release and Separation Agreement between Moleculin Biotech, Inc. and Louis Ploth dated October 7, 2016 (incorporated by reference to Exhibit 10.2 of the Form 8-K filed October 13, 2016)
10.16	Development Collaboration Agreement between Moleculin Biotech, Inc. and Dermin Sp. Z o. o. dated September 30, 2016 (incorporated by reference to Exhibit 10.4 of the Form 10-Q filed November 21, 2016)
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 Moleculin 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 Pharmaceuticals. (incorporated by reference to Exhibit 10.21 of the Form 10-K filed February 21, 2019)
10.22	Sublicense Agreement dated as of February 19, 2019 entered into between the Company and Animal Life Sciences, LLC (incorporated by reference to Exhibit 10.22 of the Form 10-K filed February 21, 2019)
10.23	At Market Issuance Sales Agreement, dated July 23, 2019, by and among the Company and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 1.1 of the Form 8-K filed July 24, 2019)
10.24*	Consulting Agreement, dated March 16, 2020, entered into between the Company and Houston Pharmaceuticals, Inc. (HPI)
10.25*	Equipment Lab Letter, dated March 16, 2020, entered into between the Company and Houston Pharmaceuticals, Inc. (HPI)
10.26*	Scientific Advisory Board Agreement, dated February 28, 2020, entered into between the Company and Waldemar Priebe, PhD

21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21 of the Form 10-K filed February 21, 2019)
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: March 19, 2020

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

Signature	Title	Date
/s/ Walter V. Klemp Walter V. Klemp	Chief Executive Officer and Chairman (Principal Executive Officer)	March 19, 2020
/s/ Jonathan P. Foster Jonathan P. Foster	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 19, 2020
/s/ Robert George Robert George	Director	March 19, 2020
/s/ Michael Cannon Michael Cannon	Director	March 19, 2020
/s/ John Climaco John Climaco	Director	March 19, 2020

Moleculin Biotech, Inc.
Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Moleculin Biotech, Inc.

Opinion on the financial statements
We have audited the accompanying consolidated balance sheets of Moleculin Biotech, Inc. (a Delaware corporation) and subsidiary (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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 $39.6 million since inception and has not generated any revenue from operations. These conditions, along with other matters as set forth in Note 2, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

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

/s/ GRANT THORNTON LLP

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

Houston, Texas
March 19, 2020

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

	December 31,	
	2019	**2018**
Assets		
Current Assets:		
Cash and cash equivalents	$ 10,735	$ 7,134
Prepaid expenses and other current assets	2,749	840
Total current assets	13,484	7,974
Furniture and equipment, net of accumulated depreciation of $284 and $93, respectively	316	463
Intangible assets	11,148	11,148
Operating lease right-of-use asset	287	—
Total Assets	$ 25,235	$ 19,585
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 2,153	$ 1,246
Accrued expenses and other current liabilities	1,417	2,452
Warrant liability - current	—	180
Total current liabilities	3,570	3,878
Operating lease liability - long-term, net of current portion	276	—
Deferred rent - long-term	—	107
Warrant liability - long-term	5,818	1,328
Total Liabilities	9,664	5,313
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; 100,000,000 and 75,000,000 authorized as of December 31, 2019 and December 31, 2018, 45,727,700 and 28,528,663 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	46	29
Additional paid-in capital	55,055	40,564
Accumulated other comprehensive income	31	35
Accumulated deficit	(39,561)	(26,356)
Total stockholders' equity	15,571	14,272
Total liabilities and stockholders' equity	$ 25,235	$ 19,585

See accompanying notes to these consolidated financial statements.

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

	December 31,	
	2019	**2018**
Revenue	$ —	$ —
Operating expenses:		
Research and development	11,013	9,728
General and administrative	6,312	5,229
Depreciation and amortization	199	68
Total operating expenses	17,524	15,025
Loss from operations	(17,524)	(15,025)
Other income (expense):		
Gain from change in fair value of warrant liability	4,062	3,185
Other income (expense)	15	(40)
Interest income, net	13	4
Net loss before taxes	(13,434)	(11,876)
Income tax benefit	229	—
Net loss	$ (13,205)	$ (11,876)
Net loss per common share - basic and diluted	$ (0.32)	$ (0.46)
Weighted average common shares outstanding, basic and diluted	40,721,406	25,904,170
Comprehensive loss:		
Net loss	$ (13,205)	$ (11,876)
Other comprehensive income (loss):		
Foreign currency translation	$ (4)	$ 35
Comprehensive loss	$ (13,209)	$ (11,841)

See accompanying notes to these consolidated financial statements.

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

	December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (13,205)	$ (11,876)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	199	68
Stock-based compensation	1,537	1,140
License rights expense settled in stock	490	—
Gain from sale of fixed assets	(1)	—
Gain from change in fair value of warrant liability	(4,062)	(3,185)
Operating lease, net of sublease receipts	(14)	—
Loss on foreign currency transactions	—	40
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,909)	(252)
Accounts payable	907	436
Accrued expenses and other current liabilities	(1,140)	1,400
Other long-term liabilities	—	26
Net cash used in operating activities	(17,198)	(12,203)
Cash flows from investing activities:		
Purchase of fixed assets	(52)	(417)
Proceeds from sale of fixed assets	1	—
Net cash used in investing activities	(51)	(417)
Cash flows from financing activities:		
Proceeds from exercise of stock options	5	5
Proceeds from exercise of warrants	1,557	15
Proceeds from sale of common stock, net of issuance costs	19,292	12,025
Net cash provided by financing activities	20,854	12,045
Effect of exchange rate changes on cash and cash equivalents	(4)	(5)
Net change in cash and cash equivalents	3,601	(580)
Cash and cash equivalents, at beginning of year	7,134	7,714
Cash and cash equivalents, at end of year	$ 10,735	$ 7,134
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 1	$ 5
Cash paid for taxes	$ 19	$ 21
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued liabilities	$ 22	$ 23
Leasehold improvements paid by landlord	$ —	$ 82
Research and development costs settled in stock	$ 490	$ —

See accompanying notes to these consolidated 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 at 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
Consolidated net loss	—	—	—	(11,876)	—	(11,876)
Cumulative translation adjustment	—	—	—	—	35	35
Balance at December 31, 2018	28,528,663	$ 29	$ 40,564	$ (26,356)	$ 35	$ 14,272
Issued for cash - sale of common stock in March 2019, net of issuance costs of $617	5,250,000	5	3,221	—	—	3,226
Issued to Lincoln Park - sale of common stock, net of $59 issuance costs	706,041	—	935	—	—	935
Issued for cash - sale of common stock in April 2019, net of issuance costs of $1,300	9,375,000	9	3,575	—	—	3,584
Common stock issued for license rights	429,978	1	489	—	—	490
Warrants exercised	1,413,018	2	4,729	—	—	4,731
Stock options exercised	25,000	—	5	—	—	5
Stock based compensation	—	—	1,537	—	—	1,537
Consolidated net loss	—	—	—	(13,205)	—	(13,205)
Cumulative translation adjustment	—	—	—		(4)	$ (4)
Balance at December 31, 2019	45,727,700	$ 46	$ 55,055	$ (39,561)	$ 31	$ 15,571

See accompanying notes to these 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 MD 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 enables the Company to enjoy the benefits of certain research and development tax credits in Australia. In February 2019, the Company entered into an agreement with Animal Life Sciences, LLC ("ALI"), where the Company has granted a sublicense to ALI to research, develop, make, have made, use, offer to sell, sell, export or import and commercialize certain licensed products for non-human use and share development data. ALI issued to the Company a 10% interest in ALI. ALI converted into a corporation and became Animal Life Sciences, Inc.

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 STAT3 Immune/Transcription Modulators, or simply "Immune/Transcription Modulators" WP1066 portfolio and 3) its Metabolism/Glycosylation Inhibitor portfolio, WP1122. The Company’s clinical stage drugs are Annamycin, an anthracycline which is in two Phase 1/2 studies for the treatment of relapsed or refractory acute myeloid leukemia ("AML"), WP1066, an Immune/Transcription Modulator, which is in a Phase 1 clinical trial in the US for the treatment in glioblastoma, and WP1220, a member of the WP1066 portfolio of drugs, which has completed a Phase 1 proof-of-concept clinical trial for the topical treatment of cutaneous T-cell lymphoma ("CTCL"), a form of skin cancer. A fifth Phase 1 trial for the treatment of pediatric brain tumors at Emory University has been approved by the US Food and Drug Administration ("FDA") and is expected to begin in 2020.

The Company believes Annamycin is a "Next Generation Anthracycline" since it is designed to avoid multidrug resistance mechanisms that typically defeat currently approved anthracyclines, as well as to be non-cardiotoxic, which is the dose limiting toxicity of all currently approved anthracyclines. Annamycin is currently in two Phase 1/2 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 regardless of gene mutations. During 2019, these trials have so far demonstrated the safety, including little to no cardiotoxicity, and has begun to show some initial efficacy. Additionally, preclinical research in animal models at MD Anderson demonstrated that Annamycin is able to significantly improve survival in an aggressive form of triple negative breast cancer metastasized to the lungs. Coupled with research demonstrating that Annamycin is capable of accumulating in the lungs at very high levels, this suggests that Annamycin may be well suited to become a treatment for lung-localized tumors.

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-1α. These transcription factors are widely sought targets that may also play a role in the lack of efficacy of immune checkpoint inhibitors in certain resistant tumors. The Phase 1 trial for WP1220 demonstrated safety and efficacy and is being studies for a Phase 2 trial going forward.

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. In March 2020, we entered into an agreement with an outside research center who will conduct research on WP1122 for antiviral properties against a range of viruses, including Coronavirus.

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 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 1/2 trial for the treatment of relapsed or refractory AML in 2017, which the FDA allowed to go into effect in September 2017. The Company has trials opened in the US and Poland. The US Phase 1 portion of the Phase 1/2 trial reached key safety end points in early 2020 and the Company plans to discuss next steps with the FDA. The Phase 1/2 trial in Poland continues its dose escalation and is in its fourth cohort. So far both trials have proven Annamycin, to date, is safe and is non-cardiotoxic. The trials have demonstrated initial efficacy as well.

The Company has five other drug development projects, two of which are also in clinical trials:

• WP1066 has an approved physician-sponsored clinical trial open for enrollment and dosing patients for the treatment of brain tumors and is close to having a second Phase 1 trial for another physical-sponsored clinical trial for the potential treatment of pediatric brain tumors, as well as AML and pancreatic cancer,

• WP1220 is an analog of WP1066 for which Polish authorities approved the Company's Clinical Trial Application (CTA) in 2019 for a Phase 1"proof-of-concept" clinical trial to study the topical treatment of CTCL, which was completed and demonstrated sufficient efficacy to justify, the Company believes, moving to a Phase 2 trial in the near future,

• WP1732, another analog of WP1066, is being evaluated along with WP1066 for the potential treatment of AML, pancreatic and other cancers, and MBI has begun pre-clinical work that it expects to generate sufficient data for an IND for an intravenous formulation of one of its STAT3 inhibitors, which filing is expected to be submitted in 2021, 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 has concluded the initial Phase 1 portion of its Phase 1/2 trial in the US due to 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. This trial is in its fourth cohort in the dose ranging Phase 1 portion of the trial. In September 2018, the physician sponsored WP1066 Phase I clinical trial for the treatment of glioblastoma and melanoma metastasized to the brain, which opened for recruitment in July 2018, began treating patients. In August 2019, the Company completed its proof-of-concept Phase 1 clinical trial in Poland to study WP1220, a part of the WP1066 portfolio, for the treatment of CTCL. This trial demonstrated the safety of WP1220 and also demonstrated initial efficacy sufficient, the Company believes, to move forward into a Phase 2 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 filed new patent applications in July 2019 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 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 product containing the same drug 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), which would preclude approval of any other annamycin product, but there can be no assurance that such exclusivity will be granted. In April 2019, FDA approved the Company's request for Fast Track Designation for Annamycin for the treatment of relapsed or refractory AML. Fast Track Designation, the purpose of which is to expedite drug development and approval, is granted to drugs intended to treat serious conditions and where data demonstrate the potential to address an unmet medical need.

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").

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 asone 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, as well as 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, 2019, the Company has incurred a consolidated accumulated deficit of $39.6 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, 2019 plus the additional cash generated from its equity offering subsequent to year-end, discussed further in Note 9. Subsequent Events, within these notes to the consolidated 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.

Prepaid Expenses and Other Current Assets - Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2019	2018
Vendor prepayments and deposits	$ 1,857	$ 238
Prepaid insurance	352	171
Non-trade receivables	1	56
Related party receivables	10	—
Other	529	375
Total prepaid expenses and other current assets	$ 2,749	$ 840

Vendor prepayments includes approximately $1.5 million for the expansion of Annamycin production commitments on a commercial scale to be delivered in 2020, which will be used in clinical trials.

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	2 to 5 years
Furniture and office equipment	2 to 7 years

Intangible assets - Intangible assets with finite lives are amortized using the straight-line method over their estimated period of benefit. Acquired intangible assets identified as in-process research and development ("IPR&D") assets, are considered indefinite lived until the completion or abandonment of the associated research and development efforts. If the associated research and development effort is abandoned, the related IPR&D 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.

Operating Lease Right-of-Use Asset - The Company determines if an arrangement is a lease at contract inception or during modifications or renewal of an existing lease. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. The lease payments used to determine the Company's operating lease assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized in the Company's operating lease assets in the Company's condensed consolidated balance sheet. The Company has elected the practical expedient and does not separate lease components from nonlease components for its leases. The Company's operating leases are reflected in operating lease right-of-use asset ("ROU"), accrued expenses and other current liabilities, and operating lease liability - long-term in the Company's consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Short-term leases, defined as leases that have a lease term of 12 months or less at the commencement date, are excluded from this treatment and are recognized on a straight-line basis over the term of the lease. Refer to Note 8 - Commitments and Contingencies - Lease Obligations Payable for additional information related to the Company’s operating leases.

Cost Method Investment - The Company's cost method investment consists of an investment in a private company in which it does not have the ability to exercise significant influence over its operating and financial activities. Management evaluates this investment for possible impairment quarterly.

Fair Value of Financial instruments - The Company's financial instruments consist primarily of non-trade receivables, account payables, accrued expenses and a warrant liability. The carrying amount of non-trade receivables, accounts payables, and accrued expenses approximates their fair value because of the short-term maturity of such. The Company has categorized its 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, 2019 and 2018 (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, 2019	$ 5,818	$ —	$ —	$ 5,818
December 31, 2018	$ 1,508	$ —	$ —	$ 1,508

The following table provides a summary of changes in fair value associated with the Level 3 liabilities for the years ended December 31, 2019 and 2018 (in thousands):

	Warrant Liability Current	Warrant Liability Long-Term	Warrant Liability Total
December 31, 2017	$ 503	$ —	$ 503
Issuances 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
Reclass of liability between long-term and current	(4,490)	4,490	—
Exercise of warrants	(3,174)	—	(3,174)
Issuances of warrants	11,546	—	11,546
Change in fair value - net	(4,062)	—	(4,062)
December 31, 2019	$ —	$ 5,818	$ 5,818

The above table of Level 3 liabilities begins with the valuation as of December 31, 2017 and adjusts the balances for changes that occurred during the years. 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 in 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, restricted stock units, and modifications to existing stock options, to be recognized in the consolidated statements of operations based on their fair values. The grant date fair value of stock options is determined using the Black-Scholes option pricing model and the grant date fair value of restricted stock awards is determined using the closing price of the Company's common stock on the date of grant. 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. For purposes of this calculation, options to purchase common stock, restricted stock units subject to vesting and warrants to purchase common stock were considered to be common stock equivalents. 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. For the years ended December 31, 2019, and 2018, approximately 12.2 million and approximately 5.4 million, respectively, of potentially dilutive shares were excluded from the computation of diluted earnings per share due to their antidilutive effect.

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

Reclassifications - A reclassification was made to the prior period financial statements to conform to the 2019 presentation. Such reclassification did not affect net loss as previously reported.

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 February 2016, the FASB issued ASU No. 2016-02, Leases ("Topic 842") ("ASU 2016-02"). Under ASU 2016-02, an entity will be required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. ASU 2016-02 offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. The Company adopted this standard on January 1, 2019 using the modified retrospective transition method. Therefore, prior period financial information before adoption has not been adjusted and continues to be reflected in accordance with the Company's historical accounting policy. Upon adoption, the Company recognized a ROU asset of $0.1 million, an operating lease liability of $0.2 million and there was no cumulative-effect adjustment to the opening balance of retained earnings as of January 1, 2019. The standard establishes a ROU asset model that requires the lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. (see Note 8 Commitments and Contingencies)

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 Company adoption of this pronouncement effective January 1, 2018 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. The Company adoption of this pronouncement effective January 1, 2018 did not have a material impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740) ("ASU 2019-12"). ASU 2019-12 modifies the requirements for the timing of adoption of enacted change in tax law. The effects of changes on taxes currently payable or refundable for the current year must be reflected in the computation of annual effective tax rate in the first interim period that includes the enactment date of the new legislation, beginning after December 15, 2020. Early adoption is permitted upon issuance of this ASU. 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

In conjunction with its acquisition of Moleculin, LLC in 2016, the Company recognized an intangible asset for acquired in-process research and development ("IPR&D) related to the acquired WP1066 portfolio. As our WP1066 portfolio is currently in development, the Company's IPR&D intangible asset will not be amortized until development is complete. If the associated research and development effort is abandoned, the Company's IPR&D intangible asset 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. IPR&D was $11.1 million as of December 31, 2019 and 2018, respectively.

4. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities at December 31, 2019 and 2018 consist of the following components (in thousands):

	December 31,	
	2019	**2018**
Accrued payroll and bonuses	$ 436	$ 492
Accrued legal and professional fees	272	91
Accrued license fees and sponsored research agreements	201	1,147
Accrued other	164	227
Operating lease liability - current	103	—
Related party payable	99	—
Accrued clinical testing	93	95
Accrued drug manufacturing costs	49	400
	$ 1,417	$ 2,452

5. Warrants

Upon its issuance of warrants to purchase shares of common stock, the Company evaluates the terms of the warrant issue to determine the appropriate accounting and classification of the warrant issue pursuant to FASB ASC Topic 480, Distinguishing Liabilities from Equity, FASB ASC Topic 505, Equity, FASB ASC 815, Derivatives and Hedging, and ASC 718. Warrants are classified as liabilities when the Company may be required to settle a warrant exercise in cash and classified as equity when the Company settles a warrant exercise in shares of its common stock.

Liability classified warrants are valued at fair value at the date of issue and at each reporting date pursuant to FASB ASC 820, Fair Value Measurement, ("ASC 820") and is reflected as a warrant liability on our consolidated balance sheet with the change in the warrant liability during each reporting period is reflected as a gain (loss) from change in fair value of warrant liability in our consolidated statement of operations.

Equity classified warrants issued to non-employees in exchange for services are accounted for in accordance with ASC 718 which requires all stock-based payments be recognized in the consolidated statements of operations based on their fair value. For further information, see Note 2. Basis of presentation, principles of consolidation and significant accounting policies – Stock-based Compensation.

At December 31, 2019 and 2018, the Company has the following warrants outstanding,

	Number of Shares Under Outstanding Warrants at December 31, 2019	Number of Shares Under Outstanding Warrants at December 31, 2018	Weighted Average Exercise Price at December 31, 2019 $	Remaining Contractual Life at December 31, 2019 (No.Years)
Liability Classified Warrants [1]				
Issued February 2017	404,002	410,020	$ 1.50	2.13
Issued February 2018	2,273,700	2,273,700	$ 2.80	3.61
Issued June 2018 [2]	742,991	742,991	$ 2.03	3.94
Issued March 2019	1,585,500	—	$ 1.10	4.24
Issued April 2019	5,250,000	—	$ 1.75	4.32
	10,256,193	3,426,711	$ 1.89	
Equity Classified Warrants				
Issued May 2016 - Bonwick	107,802	107,802	$ 7.50	1.34
Issued July 2017 - Consulting [3]	150,000	150,000	$ 2.61	2.58
Issued April 2018 - Consulting	100,000	100,000	$ 3.00	1.25
Issued August 2019 - Consulting	150,000	—	$ 1.64	2.61
	507,802	357,802	$ 3.44	
Balance outstanding and exercisable	10,763,995	3,784,513	$ 1.97	

[1] If the Company subdivides (by any stock split, stock dividend, recapitalization or otherwise) its outstanding shares of its common stock into a smaller number of shares, the warrant exercise price is proportionately reduced and the number of shares under outstanding warrants is proportionately increased. Additionally, if the Company combines (by combination, reverse stock split or otherwise) its outstanding shares of common stock into a smaller number of shares, the warrant exercise price is proportionately increased and the number of shares under outstanding warrants is proportionately decreased. Also, the Company may voluntarily reduce the warrant exercise price for its warrants issued in March 2019 and February 2017 and may voluntarily extend the contractual term of its warrants issued in February 2017.

[2] Includes warrants to purchase 710,212 shares at an exercise price of $2.02, expiring December 22, 2023, and warrants to purchase 32,779 shares at an exercise price of $2.32, expiring June 21, 2023.

[3] Includes warrants to purchase 100,000 shares at an exercise price of $2.41 and warrants to purchase 50,000 shares at an exercise price of $3.00.

Liability Classified Warrants

The Company uses the Black-Scholes option pricing model to determine the fair value of its warrants at the date of issue and outstanding at each reporting date.

The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds linearly interpolated to obtain a maturity period commensurate with the term of the warrants.

Estimated volatility is a measure of the amount by which the Company's stock price is expected to fluctuate each year during the expected life of the warrants. Where appropriate, the Company uses the historical volatility of peer entities combined with our own common stock due to the lack of sufficient historical data of our stock price during the years 2017 to 2019.

The assumptions used in determining the fair value of the Company’s outstanding liability classified warrants are as follows:

	Year Ended December 31,					
	2019			2018		
Risk-free interest rate	1.58%	to	1.67 %	2.46 %	to	2.51 %
Volatility	97.50%	to	107.50 %	75.00 %	to	80.00 %
Expected life (years)	2.12	to	4.32	3.12	to	4.98
Dividend yield	—%			—%		

A summary of the Company's liability classified warrant activity during the year ended December 31, 2019 and related information follows:

	Number of Shares Under Warrant	Range of Warrant Exercise Price per Share			Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Outstanding at December 31, 2018	3,426,711	$ 1.50	to	$ 2.80	$ 2.48	4.53
Granted	8,242,500	$ 1.10	to	$ 1.75	$ 1.51	—
Exercised	(1,413,018)	$ 1.10	to	$ 1.50	$ 1.10	—
Expired	—	$ —		$ —	$ —	—
Outstanding at December 31, 2019	10,256,193	$ 1.10	to	$ 2.80	$ 1.89	4.04
Vested and Exercisable at December 31, 2019	10,256,193	$ 1.10	to	$ 2.80	$ 1.89	4.04

In connection with the Company's stock offering that closed on April 25, 2019, the Company issued warrants to purchase 4,687,500 shares of its common stock that are immediately exercisable at a price of $1.75 per share, subject to adjustment in certain circumstances, and expire five years from the date of issuance, and issued Oppenheimer & Co. Inc. a warrant to purchase up to 562,500 shares of its common stock with an exercise price of $1.75 per share, subject to adjustment in certain circumstances, which expires on April 23, 2024.

In connection with the Company's stock offering that closed on March 29, 2019, the Company issued warrants to purchase 2,625,000 shares that are immediately exercisable at a price of $1.10 per share, subject to adjustment in certain circumstances, and expire five years from the date of issuance and issued Oppenheimer & Co. Inc. a warrant to purchase up to 367,500 shares of its common stock with an exercise price at $1.10 per share, subject to adjustment in certain circumstances, which expires on March 27, 2024. For a summary of the changes in fair value associated with our warrant liability for the years ended December 31, 2019 and 2018, see Note 2. Basis of presentation, principles of consolidation and significant accounting policies – Fair Value of Financial Instruments.

Equity Classified Warrants

The Company has entered into a consulting agreement, as amended, in which it has issued warrants in exchange for services. Pursuant to this agreement, in August 2019, the Company issued the consultant a fully vested three-year warrant to purchase 150,000 shares of its common stock at an exercise price of $1.64 per share and expiring August 2022.

Additionally, in April 2018, the Company issued the consultant a three-year warrant to purchase 100,000 shares of its common stock with an exercise price of $3.00 per share, vesting in four equal quarterly installments provided that the consultant is providing advisory services to the Company pursuant to the consulting agreement on each vesting date. Also, in July 2017, the Company issued two warrants to the consultant to purchase 100,000 and 50,000 shares of its common stock at exercise prices of $2.41 and $3.00 per share, respectively. Each of the warrants vested over a 12-month period in equal monthly installments starting upon issuance 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 $0.1 million for the years ended December 31, 2019 and 2018, respectively. At December 31, 2019, there was no unrecognized stock compensation expense related to this consulting agreement.

6. Equity

The Company is authorized to issue 105,000,000 shares of which 5,000,000 shares of preferred stock are authorized and 100,000,000 shares of common stock are authorized.

Preferred Stock

Our certificate of incorporation authorizes the Company 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, 2019, the Company has not issued any preferred stock.

Common Stock

April 2019 Stock Offering

In April 2019, the Company entered into subscription agreements with certain institutional investors (the "Investors") for the sale by the Company of up to 9,375,000 units with each unit consisting of (i) one share of the Company's common stock, $0.001 par value per share, and (ii) 0.5 of a warrant to purchase one share of common stock. The public offering price of the units was $1.60 per unit. The shares of common stock were offered together with the warrants, but the securities comprising the units were issued separately and are separately transferable. The Company received total proceeds of $15.0 million, net of $1.3 million in transaction expenses.

The warrants issued in this offering to purchase 4,687,500 shares of the Company's common stock were immediately exercisable at a price of $1.75 per share and expire 5 years from the date of issuance. Additionally, the Company issued Oppenheimer & Co. Inc. a warrant which was immediately exercisable to purchase up to 562,500 shares of its common stock at an exercise price of $1.75 per share which expires on April 23, 2024.

March 2019 Stock Offering

In March 2019, the "Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Oppenheimer & Co. Inc. relating to an underwritten offering of 5,250,000 units, each unit consisting of (i) one share of the Company's common stock, and (ii) 0.5 of a warrant to purchase one share of common stock. The public offering price of the Units was $1.00 per Unit, and on March 29, 2019 the Underwriter purchased the units from the Company pursuant to the Underwriting Agreement at a price of $0.93 per unit. The shares of common stock were offered together with the warrants, but the securities comprising the units were issued separately and are separately transferable. The Underwriter purchased the units from the Company pursuant to the Underwriting Agreement at a price of $0.93 per unit for total proceeds of $5.3 million, net of $0.6 million in transaction expenses.

The warrants issued in this offering to purchase 2,625,000 shares of the Company's common stock were immediately exercisable at a price of $1.10 per share, subject to adjustment in certain circumstances, and expire 5 years from the date of issuance. Additionally, the Company issued Oppenheimer & Co. Inc. a warrant which was immediately exercisable to purchase up to 367,500 shares of its common stock at an exercise price of $1.10 per share which expires on March 27, 2024.

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 $0.3 million, 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 year ended December 31, 2019, the Company issued706,041 shares, which included 6,041 commitment shares for $1.0 million. During the year ended 2018, the Company issued 1,399,153 shares to Lincoln Park which included10,918 commitment shares for $1.8 million.

At Market Issuance Sales Agreements (ATM)

In September 2017, the Company entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with Roth Capital Partners, LLC and National Securities Corporation (collectively, the "Agents"). Pursuant to the terms of the Agreement, the Company was permitted to 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. In June 2019, the Company canceled the ATM Agreement. The Company did not sell any shares under this ATM Agreement in 2019 or 2018.

Subsequent to canceling the ATM Agreement with Roth and National, the Company entered into an At Market Issuance Sales Agreement (the "Opco Agreement") with Oppenheimer & Co. Inc. (the "Agent") on July 23, 2019. Pursuant to the terms of the Opco Agreement, the Company may sell from time to time through the Agent shares of the Company's common stock, with an aggregate sales price of up to $15 million (the "Shares"). Any sales of Shares pursuant to the Opco Agreement will be made under the Company's effective "shelf" registration statement (the "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"). Under the Opco Agreement, the Company may sell Shares through the 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. Sales of the Shares, if any, 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 Agent, 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 $15 million, or sooner if either the Company or the Agent terminate the Agreement pursuant to its terms. The Company will pay a commission to the Agent of 3.0% of the gross proceeds of the sale of the Shares sold under the Agreement and reimburse the Agent for certain expenses. The Company has also provided the Agent with customary indemnification rights. The Company has not sold any shares under the Opco 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 in April 2016 and April 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, including the 2018 amendment. The awards under the 2015 Stock Plan can be in the form of stock options, stock awards, stock unit awards, or stock appreciation rights. 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-based Compensation and Outstanding Awards

Under the terms of the Company's 2015 Stock Plan, as amended, and approved by its stockholders on June 6, 2018,4.5 million shares of the Company's common stock are available for grant to employees, non-employee directors and consultants. The 2015 Stock Plan provides for the grant of stock options, stock awards, stock unit awards, or stock appreciation rights. As of December 31, 2019, there were 297,093 shares remaining to be issued under the 2015 Stock Plan.

Stock-based compensation expense for the years ended December 31, 2019 and 2018 is as follows (in thousands):

	Year Ended December 31,	
	2019	2018
General and administrative	$ 1,324	$ 976
Research and development	213	164
Total Stock-Based Compensation	$ 1,537	$ 1,140

Each of the Company's stock-based compensation arrangements are discussed below.

Stock Options

Stock option awards are generally granted with an exercise price equal to the market price of the Company's stock at the date of grant. Stock option awards generally have a 10-year contractual term and vest over a 4-year period for employees and over a 1 to 3-year period for directors from the grant date on a straight-line basis over the requisite service period. The grant-date fair value of stock options is determined using the Black-Scholes option-pricing model. Additionally, the Company's stock options provide for full vesting of unvested outstanding options, in the event of a change of control of the Company.

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 below. The expected term of the stock option awards was computed using the "plain vanilla" method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin 107 because the Company does 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 due to the lack of sufficient historical data of its stock price. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

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

	Year Ended December 31,					
	2019			2018		
Risk-free interest rate	1.56%	to	2.20%	0.95%	to	2.24%
Volatility	85%	to	110%	70.18%	to	89.11%
Expected life (years)	5.31	to	6.25	5	to	6.25
Expected dividend yield		—%			—%	

Stock option activity for the year ended December 31, 2019 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, 2018	2,794,000	$ 1.78	$ 2.61	9.43	$ 21,200
Granted	1,170,000	$ 1.03	$ 1.29		
Exercised	(25,000)	$ 0.13	$ 0.20		$ 15,750
Forfeited	(103,000)	$ 1.29	$ 1.82		
Outstanding, December 31, 2019	3,836,000	$ 1.59	$ 2.26	8.34	$ —
Exercisable, December 31, 2019	1,194,335	$ 2.16	$ 3.22	7.49	$ —

Options granted during 2019 have an aggregated fair value of $1.2 million that was calculated using the Black-Scholes option-pricing model. At December 31, 2019, total compensation cost not yet recognized was $2.9 million and the weighted average period over which this amount is expected to be recognized is 2.49 years. The aggregate fair value of options vesting in the years ended December 31, 2019 and 2018 was $1.3 million and $0.8 million, respectively. Cash received from the exercise of stock options was $5,000 for the year ended December 31, 2019.

Restricted Stock

In July 2019, the Company granted 316,907 restricted stock units, which vest annually in four equal installments. The weighted average grant date fair value of $1.31 per unit was determined using the closing price of the Company's common stock on the grant date. Prior to 2019, the Company had not granted any restricted stock awards. Additionally, the Company's restricted stock unit agreements provide for full vesting of the restricted stock award in the event of a change of control of the Company. During the year ended December 31, 2019, no restricted stock units vested or were forfeited.

As of December 31, 2019, total compensation cost not yet recognized was $0.4 million and the weighted average period over which this amount is expected to be recognized is 3.5 years.

7. Income Taxes

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

	Year Ended December 31,	
	2019	2018
Current expense (benefit):		
Federal	$ —	$ —
State	—	—
Foreign	(229)	—
Current income tax benefit	(229)	—
Deferred expense (benefit):		
Federal	—	—
State	—	—
Foreign	—	—
Deferred income tax expense	—	—
Total	$ (229)	$ —

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

	Year Ended December 31,	
	2019	2018
Valuation allowance at beginning of period	$ 5,855	$ 2,561
Income tax benefit	3,563	3,294
Release of valuation allowance	—	—
Valuation allowance at end of period	$ 9,418	$ 5,855

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,			
	2019		2018	
	Amount	Percent	Amount	Percent
Federal tax benefit at statutory rate	$ 2,773	21.00 %	$ 2,494	21.00 %
State tax benefit net of federal	(4)	(0.03)%	18	0.15 %
Foreign rate differential	11	0.09 %	43	0.36 %
IPO costs	—	— %	(112)	(0.94)%
Stock warrant costs	853	6.46 %	669	5.63 %
Other permanent differences	(72)	(0.54)%	(8)	(0.07)%
Permanent PTR items	107	0.81 %	190	1.60 %
Stock compensation change	(34)	(0.26)%	—	— %
Research and development tax credits	229	1.73 %	—	— %
Uncertain tax provision	(33)	(0.26)%	—	— %
Other	(38)	(0.29)%	—	— %
Increase in valuation allowance	(3,563)	(26.98)%	(3,294)	(27.73)%
Total tax (expense) benefit	$ 229	1.73 %	$ —	— %

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

	Year Ended December 31,	
	2019	2018
Deferred tax assets:		
Start-up costs	$ 2,991	$ 1,962
Federal net operating loss carryforwards	5,376	3,153
State tax loss carryforwards	19	21
Foreign net operating loss carryforwards	51	182
Tax credit carryforward	405	190
Interest limitation	—	1
Deferred compensation	609	418
Total deferred tax assets	$ 9,451	$ 5,927
Less valuation allowance	(9,418)	(5,855)
Net deferred tax assets	$ 33	$ 72
Deferred tax liabilities:		
Fixed assets	(33)	(72)
Total deferred tax liabilities	$ (33)	$ (72)
Net deferred taxes	$ —	$ —

The Company has incurred net operating losses since inception. As of December 31, 2019, the Company had total U.S. federal operating loss carry forwards of approximately $25.6 million. Of this, $6.0 million will expire commencing in 2035, 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, 2019, the Company had state operating losses of approximately $0.7 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 for 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, 2019. 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 $9.4 million and $5.9 million has been established at December 31, 2019 and 2018, respectively. The change in the valuation allowance for the year ended December 31, 2019 was primarily due to additional operating losses and capitalized research costs.

The Company undertakes research and development (R&D) activities that qualify for certain tax credits for US and Australian income tax purposes. The Company has a full valuation allowance against its U.S. federal R&D tax credits. For the 2018 tax year, the Company claimed an Australian credit of approximately $0.2 million on its 2018 Australian tax return. For the 2019 tax year, the potential U.S. and Australian research and development tax credits are not expected to be significant.

The company has a liability for unrecognized tax benefits of $0.1 million (excluding accrued interest and penalties) as of December 31, 2019.

A reconciliation of the beginning and ending unrecognized tax benefits excluding interest and penalties is as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Balance, beginning of year	$ 38	$ —
Additions for tax positions related to the current year	—	—
Additions for tax positions related to prior years	34	38
Reductions due to lapse of statutes of limitations	—	—
Decreases related to settlements with tax authorities	—	—
Balance, end of year	$ 72	$ 38

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, 2019 within the next year..

8. Commitments and Contingencies

Lease Obligations Payable

Effective January 1, 2019, the Company adopted ASC 842, which requires recognition of a right-of use asset and a lease liability for all leases at the commencement date based on the present value of the lease payment over the lease term.

In March 2018, the Company entered into a Lease Agreement (the “Lease”) which it uses for its 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 additional5 years. The Company is required to remit base monthly rent which will increase at an average approximate rate of 3% each year. The Company is also required to pay additional rent in the form of its pro-rata share of certain specified operating expenses of the Landlord. The leased space is located in Houston, Texas. The corporate office lease is classified as an operating lease.

In August 2019, the Company entered into an Amended Lease Agreement (the "Lab Lease") which it uses for lab space. The term of the Lease began in September 2019 and will continue for an initial term of 35 months, with no further right or option to renew. The Company is required to remit base monthly rent which will increase at an average approximate rate of 3% each year. The Lab Lease is classified as an operating lease. In August 2019, the Company entered into a sublease with Houston Pharmaceuticals, Inc. ("HPI"). The Company has granted HPI access to all of its Lab Lease space and HPI has agreed to pay the Company 50% of the Company's rent payable under the Lab Lease less 50% of any benefits from any sublease or other lab service agreement the Company may receive from its Lab Lease. Although HPI has access to the Company's Lab Lease space, it is the intent of the parties that they equally share the Lab Lease space for research purposes. The Company recorded approximately $0.01 million in sublease income from the related party for the year ended December 31, 2019. Sublease income is recorded as other income on the Company's condensed consolidated statement of operations and comprehensive loss. The Company recorded lease costs of $0.06 million for the year ended December 31, 2019.

The Company made an accounting policy election not to apply the recognition requirements to short-term leases. The Company recognizes the lease payments for short-term leases in profit or loss on a straight-line basis over the lease term, and variable lease payments in the period in which the obligation for those payments is incurred. The Company recorded total expenses for its short-term leases of $0.04 million for the year ended December 31, 2019. The Company recorded lease costs for variable lease payments of $0.03 million for the year ended December 31, 2019.

Other supplemental cash flow information for operating leases is as follows (in thousands):

	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 74
Right-of-use assets obtained in exchange for lease liabilities:	
Operating leases	$ 321

As of December 31, 2019, future minimum leases under ASC 842 under the Company's operating leases were as follows (in thousands):

Maturity of lease liabilities	As of December 31, 2019
2020	$ 134
2021	138
2022	105
2023	56
2024	10
2025 and thereafter	—
Total lease payments	$ 443
Less: imputed interest	(64)
Present value of operating lease liabilities	$ 379

As of December 31, 2019, the weighted average remaining lease term is4.17 and 2.58 for the Lease and Lab Lease, respectively, and the weighted average discount rate is 9.6%. The interest rate implicit in lease contracts is typically not readily determinable and as such, the Company uses an incremental borrowing rate based on a peer analysis using information available at the commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment. During the year ended December 31, 2019, in addition to the initial adoption of the lease standard, the Company amended its Lab Lease which required additional right of use assets and liabilities to be recorded.

Licenses

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 $0.2 million and $0.3 million, respectively, for the years ended December 31, 2019 and 2018. 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 Moleculin LLC and MD Anderson (the “Moleculin Agreement”) have been assigned MBI. Therefore, MBI has obtained a royalty-bearing, worldwide, exclusive license to intellectual property rights, including patent rights, related to its WP1066 drug product candidate. In consideration, the Company 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 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.

HPI

MBI entered into an out-licensing agreement with Houston Pharmaceuticals, Inc. (“HPI”), pursuant to which it 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 the Company was required to 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 the Company's obligation to make the foregoing payments, the HPI Out-Licensing Agreement did 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 ("HPI Option Repurchase Payment") MBI regained 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. The option repurchase payment was paid on April 30, 2019 for $1.0 million and, accordingly, the HPI Out-Licensing Agreement was terminated. The $1.0 million payment was accrued and expensed under research and development in 2018. Total expenses related to HPI were $0.1 million and $1.3 million, for the years ended December 31, 2019 and 2018, respectively. 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, called WP1732, a part of the WP1066 Portfolio. On March 16, 2020, the Company entered into two agreements with HPI. The first agreement, which has a term of two years, continues a prior consulting arrangement with HPI on the Company's licensed molecules and requires payments for $0.04 million per quarter to HPI. The second agreement, which can be cancelled with sixty days notice by either party, allows the Company's employees access to laboratory equipment owned by HPI and this requires a payment of $0.02 million per quarter to HPI.

Sponsored Research Agreements with MD Anderson

In January 2017, MBI amended its Sponsored Laboratory Study Agreement with MD Anderson where it was extended to the end of October 2018. In December 2017, MBI extended this Agreement until the end of October 2019 for total payment amount of $0.3 million spread over that period of time. In September 2018, the Company extended this Agreement until the end of October 2020 for total payment amount of $0.4 million spread over that period of time. In June 2019, the Company amended the Agreement to support the continuation of the project for total payment amount of $0.4 million. In October 2019, the Company amended the agreement until the end of October 2021 for a total additional payment amount of $0.4 million. The expenses recognized under the MD Anderson agreement with regards to the Sponsored Laboratory Study were $0.5 million and $0.4 million, respectively for the years ended December 31, 2019 and 2018.

Other Licenses

Dermin

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. In July 2019, Dermin assigned its rights under the foregoing license agreements to an affiliated entity, Exploration Invest Pte Ltd. (“Exploration”). On July 30, 2019, the Company and Exploration entered into a License Modification Agreement pursuant to which the Company agreed to issue Exploration shares of Company common stock valued at $0.5 million (based on the greater of the closing price of the common stock on the date of the agreement or the 10-day average closing price prior to the date of

the agreement) in exchange for the modifying the license agreements to: (i) limit the licensed territory solely to Poland; and (ii) limit the patent rights and technology rights licensed to Exploration to the patent rights and technology rights that existed on the date the original license agreements were entered into with Dermin. In August 2019, the Company issued 429,978 shares of Company common stock to Exploration to satisfy this commitment.

WPD Pharmaceuticals

In February 2019, the Company sublicensed certain intellectual property rights, including rights to Annamycin, its WP1122 portfolio, and its WP1066 portfolio to WPD Pharmaceuticals sp. z o.o. ("WPD") (the "WPD Agreement"). WPD is affiliated with Dr. Waldemar Priebe, one of the Company's founders and largest shareholder. Under the WPD Agreement, the Company 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 the Company has the right to buyback Germany from the licensed territories by making a payment $0.5 million. On July 30, 2019, the Company entered into the aforementioned July 30, 2019 agreement with Dermin that satisfied the foregoing buyback right, and as such, Germany is no longer considered part of the licensed territories.

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) $2.5 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. This license is subject to the terms in the prior agreements entered into by the Company with Dermin and MDA. WPD is actively seeking Polish government grants for research involving licensed drug candidates. Prior to approval of the WPD Agreement, the Company's board of directors received a fairness opinion from Roth Capital Partners, LLC that stated that it was their opinion that the consideration the Company will receive from WPD pursuant to the WPD Agreement is fair, from a financial point of view, to the Company.

Animal Life Sciences

In February 2019, the Company sublicensed certain intellectual property rights, including rights to Annamycin, its WP1122 portfolio, and its WP1066 portfolio in the field of non-human animals to ALI (the "ALI Agreement"). ALI is affiliated with Dr. Waldemar Priebe, one of its founders and its largest shareholder. Under the ALI Agreement, the Company 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. This license is subject to the terms in the prior agreements entered into by the Company and MDA. Under the ALI Agreement, the Company has the right to name an observer to ALI's board of directors. In August 2019, the Company named its Chairman and CEO Walter V. Klemp to that position. Since ALI and WPD are beginning the process to develop and commercialize products using the sublicensed intellectual property rights, the Company is currently unable to predict whether ALI and WPD will be successful in developing such products or when the Company may recognize royalty revenues related to such products.

Employment Agreements

The Company has agreements with certain executive and other employees to provide benefits in the event of termination. The base salary and certain other benefits would aggregate approximately $0.9 million using the rate of compensation in effect at December 31, 2019.

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, 2019.

Offering

In February 2020, the Company entered into subscription agreements with certain institutional investors for the sale by the Company of up to7,500,000 shares of common stock and warrants to purchase 5,625,000 shares of common stock at $0.80 per share and related warrant. The warrants will be exercisablesix months from the date of issuance at a price of $1.05 per

share and will expire five years from the date they are first exercisable. The shares of common stock are being offered together with the warrants, but the securities will be issued separately and will be separately transferable. Total proceeds of the offering were approximately $6.0 million, prior to deducting the placement agent fees and other estimated offering expenses.

Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel Coronavirus (COVID-19) as a pandemic, which continues to spread throughout the United States. The spread of COVID-19 has caused significant volatility in U.S. and international markets, including Poland, where the Company conducts some of its clinical trials and Italy, where its drug supply is produced. There has been no interruption of its drug supply, and some Polish clinics where the Company is conducting trials have limited access on monitoring activities, which for now has not slowed the progress of its trials. This could change at any time. Furthermore, there is significant uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the US and international economies and, as such, the Company is unable to determine if it will have a material impact to its operations.

Exhibit 10.24

CONSULTING AGREEMENT

This CONSULTING AGREEMENT is made effective as of the date set forth below by and between Houston Pharmaceuticals, Inc. ("**HPI**") (referred to as **"Consultant**") and Moleculin Biotech, Inc. (the **"Company"**).

Recitals

A. Consultant has certain expertise related to the Company's operations.

B. The Company desires to obtain the consulting services of the Consultant and the Consultant desires to provide such services in accordance with the terms hereof.

Agreement

NOW, THEREFORE, in consideration of the premises and the mutual covenants set forth herein, the parties hereby agree as follows:

1. Engagement. The Company hereby retains the Consultant to provide the Company with the consulting services set forth on Schedule A (the **"Services**"), and the Consultant hereby agrees to perform the Services, on the terms and conditions hereinafter set forth herein, including in Schedule A. The Consultant shall perform the Services in a timely and professional manner consistent with industry standards.

2. Fees and Expenses.

(a) This Agreement shall begin on the date hereof, and shall terminate on the earlier of 1) the date either party terminates this Agreement upon 10 days' notice or 2) on the 2nd anniversary of the date hereof (the "**Term**"), with the following payments to the Consultant: a) $43,500 payable within 45 days after each calendar quarter during the Term beginning for the first calendar quarter in 2020 and b) upon execution of this agreement $50,000 for a nonrefundable retainer. The Consultant shall maintain records of all time devoted to providing the Services and shall make such records available to the Company upon request.

(b) The Company shall reimburse the Consultant for all reasonable and necessary out-of-pocket expenses incurred by the Consultant in connection with providing the Services, including, without limitation, travel, telephone, facsimile, mail, and printing expenses; provided that the Company's prior written consent shall be required for any expenses in excess of $500. All such expenses shall be reasonably documented in accordance with the Company's expense reimbursement policies and in no event shall the Company be required to reimburse the Consultant with respect to general, administrative or other overhead expenses.

3. Ownership of Intellectual Property.

(a) The Consultant acknowledges that no license, right, or other indicia of ownership relating to any proprietary rights of the Company shall be granted or transferred by the Company to the Consultant by virtue of any provision of this Agreement or the performance of the Services as contemplated hereunder. The Consultant further acknowledges that all services and work performed by the Consultant (or any employees, consultants or agents of Consultant) under this Agreement are works produced for hire and constitute the sole and exclusive property of the Company and do not constitute any work or work product, in any way, covered by the Rules and Regulations contained in Section 18 below. In furtherance thereof, the Consultant hereby assigns to the Company all proprietary rights, including, without limitation, to all patents (and applications therefor), copyrights, trade secrets and trademarks the Consultant might otherwise have, by operation of law or otherwise, in all inventions, discoveries, creations, properties, works, ideas, information, laboratory notebooks, knowledge and data developed, reduced to practice or otherwise identified in connection with or related to the Consultant's access to Confidential Information (as defined below) or performance of the Services as contemplated hereunder or the performance of any prior services to the Company. The Consultant further agrees to execute and deliver any additional documents, instruments, applications, oaths or other writings necessary or desirable to further evidence the assignment described in this Section 3 ("**Supporting Documents**"). If the Consultant fails or refuses to execute or deliver any Supporting Documents, the Consultant hereby agrees, for itself, and for its employees, consultants, agents, successors, assigns, donees, executors, administrators, transferees and personal representatives, to the fullest extent permitted by law, that the Chief Executive Officer of the Company shall be appointed, and the same is hereby irrevocably appointed, such Consultant's attorney-in-fact with full authority to execute Supporting Documents and perform all other acts necessary to further evidence such assignment. The Consultant represents that it has the authority to assign the foregoing rights to the Company and that such an assignment does not violate any guidelines, policies, or other requirements imposed on such Consultant by any entity, if applicable.

(b) The Consultant shall not perform any Services during the time that the Consultant is required to devote to any third party. The Consultant shall not use the funding, resources or facilities of any third party to perform the Services and shall not perform any Services in any manner that would give any third-party rights to the product of such work.

4. Confidential Information.

(a) The Consultant shall not disclose to any third party or use for any purposes other than the performance of the Services any Confidential Information (as defined below), without Company's prior written consent. The Consultant shall treat the Confidential Information as it would treat its own most proprietary and confidential information, but in no event shall it use less than a reasonable degree of care. The Consultant shall be responsible for entering into similar confidentiality arrangements or agreements with its managers, officers, employees, agents and advisors (collectively, "**Representatives**") who need to know such Confidential Information, and who agree to use such information solely) for the purpose of providing the Services. Consultant shall be responsible for any breach of this agreement by any of its Representatives. ***The Company acknowledges that Consultant provides services to other***

companies and that for the purpose of this Agreement the term Confidential Information shall only include Moleculin's Confidential Information and not any information belonging to any other companies. The obligation of non-disclosure and non-use shall not apply to the following:

(i) information, which at the time of disclosure hereunder, is generally available to the public;

(ii) information, which after disclosure hereunder, becomes generally available to the public, except through the Consultant's breach of this Agreement;

(iii) information that becomes available to the Consultant from a third party that is not legally prohibited from disclosing such information, provided such information was not acquired directly or indirectly from the Company; and

(iv) information, to the extent that it is required to be disclosed by lawful subpoena, court order or written demand of a federal or state governmental agency, of which the Consultant will immediately notify the Company giving Company an opportunity to object and/or seek confidential treatment.

(b) All Confidential Information, however, and wherever produced, including, without limitation, Confidential Information stored in computer databases or by other electronic means, shall be and remain the sole property of the Company. At any time upon the request of the Company, or without such request upon termination of the Consultant's role as a consultant to the Company for whatever reason, such Consultant shall deliver to the Company (without retaining any electronic or physical copies, extracts, or other reproductions) or destroy immediately upon the Company's request all documents and electronic storage devices that contain Confidential Information and that are in such Consultant's possession or subject to his or its control, including, without limitation, any and all records, drawings, notebooks, memoranda, and computer diskettes. In addition, the Consultant shall return to the Company any equipment, tools, or other devices owned by the Company and in such Consultant's possession.

(c) **"Confidential Information"** means any and all oral, written, tangible and/or intangible technical, scientific, financial, business and/or other information and/or trade secrets of the Company (including any information developed by the Consultant, which is the property of the Company under Section 3 in connection with this Agreement) that is confidential, proprietary and/or not generally available outside of the Company including, without limitation, (i) confidential and proprietary information supplied by the Company to the Consultant (whether or not marked "Confidential" or the equivalent thereof), (ii) the Company's marketing and customer support strategies, financial information (including sales, costs, profits and pricing methods), internal organization, employee information and customer lists and other data and information relating to the business of the Company, (iii) the Company's technology, including without limitation discoveries, inventions, research and development efforts, data, physical and chemical formulations, formulation techniques, compound characteristics, product specifications, manufacturing processes and operations, compositions, analytical methodology, safety and efficacy data, and testing data, patents, patent applications, trademarks, trade secrets, processes, programs, formulas, methods, products, know-how and show-how, (iv) all derivatives,

improvements, additions, modifications and enhancements to any of the above, (v) information of third parties as to which the Company has an obligation of confidentiality or a duty to use such information only for certain limited purposes, and (vi) the terms of this Agreement.

(d) During the term of this Agreement, the Consultant agrees to properly protect any proprietary information or trade secrets of such Consultant's former or concurrent consultees, employers or companies (or those of its respective employees or principals), if any, and agrees not to bring onto the premises of the Company any unpublished documents or any property belonging to such persons or companies unless consented to in writing (which consent shall be provided to the Company in advance) by those persons or companies. The Consultant further recognizes that the Company has received and, in the future, will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and, in some cases, to use it only for certain limited purposes. The Consultant agrees, both during the term of the Consultant's engagement and thereafter, to hold all such confidential or proprietary information in the strictest confidence and not to disclose it to any person, firm or corporation (except in a manner that is consistent with the Company's agreement with the third party) or use it for the benefit of anyone other than the Company or such third party (consistent with the Company's agreement with the third party).

5. Company Policies. If, at any time, the Consultant is required to work at any of the Company's premises or use any of its equipment, the Consultant will comply with all relevant health, safety and security regulations and related instructions issued by the Company. By executing this Agreement, the Consultant acknowledges that it has received and reviewed the Company's Code of Business Conduct and Ethics and the Company's Anti-Bribery Compliance Policy, and that it agrees to comply with the provisions and restrictions set forth therein.

6. Term and Termination.

(a) This Agreement shall be effective as of the date stated above and shall continue until the end of the Term.

(b) Promptly after the termination or expiration of this Agreement, the Consultant shall return to the Company all whole and partial copies and derivatives of Confidential Information and other materials belonging to the Company that are in such Consultant's possession or under such Consultant's direct or indirect control.

(c) The provisions of Sections 3, 4, and 6 shall survive the expiration or earlier termination of this Agreement.

7. Conflicts of Interest. The Consultant hereby represents and warrants that he or it is not a party to any existing agreement that will be breached by such Consultant's performance of the Services or that conflict with the terms of this Agreement. During the Term, if the Consultant intends to enter into any activity, employment, or business arrangement that is in conflict with the Company's interests in the cancer drug area or such Consultant's obligations under this Agreement, then such Consultant agrees to notify the Company thereof prior to implementation and the Company shall have the right either (a) to approve such Consultant's

plans thereby waiving any conflict or (b) to terminate this Agreement immediately upon written notice to such Consultant.

8. Waiver. A party's failure to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy, does not constitute a waiver of such provision, right or remedy, or prevent such party thereafter from enforcing any or all provisions and exercising any or all other rights and remedies. The exercise of any right or remedy does not constitute an election or prevent the exercise of any or all rights or remedies, all rights and remedies being cumulative.

9. Notice. Any and all notices referred to herein shall be sufficient if furnished in writing and delivered by hand, by overnight delivery service maintaining records of receipt, to the respective parties at the following addresses:

If to the Company:

Moleculin Biotech, Inc.
5300 Memorial Drive, suite 950
Houston, Texas 77007
Attn: CFO
Phone: 713-300-5160

If to the Consultant: To the address set forth on the signature page hereto.

or to such other address or addresses as either party may from time to time designate by notice given as aforesaid. Notices shall be effective when delivered.

10. Assignment. The Consultant shall not assign or transfer its interest or obligations under this Agreement, in whole or in part, without the prior written consent of the Company and any such assignment contrary to the terms hereof shall be null and void and of no effect. The Company may assign all its rights and liabilities under this Agreement to any of its affiliates or to a successor to all or a substantial part of its business or assets without the consent of the Consultant. The Consultant shall not subcontract any portion of the Services without the Company's prior written consent.

11. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Texas, without regard to the choice of law provisions thereof. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in Houston, Texas, for the adjudication of any dispute pursuant to this Agreement.

12. Entire Agreement. This Agreement constitutes, on and as of the date hereof, the entire agreement of the parties with respect to the subject matter hereof, and all prior or contemporaneous understandings or agreements, whether written or oral, between the parties with respect to such subject matter are hereby superseded in their entireties. This Agreement

shall not be amended in any respect whatsoever except by a further agreement, in writing, fully executed by each of the parties.

13. Independent Contractors. The Consultant is engaged as an independent contractor and not as an employee of the Company. The Consultant is providing the Services solely at its own direction and under its own supervision. Nothing herein shall be construed as creating an employer/employee relationship between Company and the Consultant or placing the parties in a partnership or joint venture relationship. The Consultant shall have absolutely no authority to bind, commit or otherwise obligate the Company in any way whatsoever nor shall it represent to any person that it has any such right or authority. Nothing in this Agreement shall be construed as establishing an agency, partnership, employer/employee or joint venture relationship between the parties hereto.

14. Taxes. The Consultant shall pay and report all applicable local, state and federal taxes and insurance in connection with the Consultant' receipt of payments under this Agreement. The Consultant further agrees to maintain workers' compensation insurance in the amount required by the laws of the state in which the Consultant's employees performing the Services are located. The Consultant shall provide the Company with a completed IRS Form W-9, including his or her United States Tax Identification Number (TIN) upon execution of this Agreement. The Company shall provide the Consultant with an Internal Revenue Service (IRS) Form 1099 in connection with the performance of the Services.

15. No Debarment. The Consultant represents and agrees that neither the Consultant nor any of the Consultant's employees, consultants or agents, if applicable, has been debarred by the FDA and that no FDA debarred person will, in the future, be employed or engaged by the Consultant in connection with the Services. The Consultant further agrees that the Consultant will notify Company immediately in the event of any debarment or threat of debarment occurring during the period in which the Consultant is performing Services or thereafter.

16. No Violation. The Consultant shall perform the Services in compliance with applicable federal, state, and local laws and regulations. The Consultant represents to the Company that its execution and performance of this Agreement does not violate any agreement, or other ethical policies, rules, or regulations to which the Consultant is subject or represents a conflict of interest.

17. Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one agreement binding on the parties hereto. Copies of original signature pages sent by facsimile and/or PDF shall have the same effect as signature pages containing original signatures.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement effective as of the date first set forth above.

Houston Pharmaceuticals, Inc.

By: /s/ Teresa Szwarocka-Priebe, Ph. D

Name: Teresa Szwarocka-Priebe

Date: March 16, 2020

Moleculin Biotech, Inc.

By: /s/ Jonathan P. Foster

Name: Jonathan P. Foster

Title: EVP & Chief Financial Officer

Date: March 16, 2020

Schedule A

Services

Research as directed by our Chief Science Officer on the Company's licensed molecules.

Exhibit 10.25

Moleculin Biotech, Inc.
5300 Memorial Drive
Suite 950
Houston, TX 77007

March 16, 2020

Houston Pharmaceuticals, Inc.
2575 West Bellfort Street
Houston, Texas 77054

Dear Sir/Madam:

Houston Pharmaceuticals, Inc. ("HPI") is currently utilizing certain lab space leased by Moleculin Biotech, Inc. ("Moleculin") located at 2575 West Bellfort Street, Houston, Texas (the "Lab"). HPI hereby agrees that Moleculin shall be permitted to utilize the lab equipment owned or leased by HPI that is located in the Lab in exchange for paying $15,000 to HPI on or before 30 days after each calendar quarter ends and beginning on April 30, 2020. Additionally, Moleculin agrees to pay HPI an upfront nonrefundable retainer of $20,000. HPI agrees that it will not terminate this letter agreement for as long as it utilizes any of the leased space. Such termination must be given with a 60 days' notice to become effective. Additionally, HPI agrees that Moleculin can offset any monies due HPI to Moleculin to such payments described above.

Very truly yours,

Moleculin Biotech, Inc.

By: /s/ Jonathan P. Foster, EVP & CFO
Jonathan P. Foster, EVP & CFO

Agreed and Accepted:

Houston Pharmaceuticals, Inc.

By: /s/ Teresa Szwarocka-Priebe, Ph. D
Title: President

Exhibit 10.26

SCIENTIFIC ADVISORY BOARD AGREEMENT

This Scientific Advisory Board Agreement (the "Agreement") is entered into as of the 28th day of February, 2020, by and between Moleculin Biotech, Inc. (the "Company") and Waldemar Priebe, PhD (the "Science Advisor").

RECITALS

WHEREAS, the Science Advisor has been serving at the request of the Company as the chair and a member of the Company's Scientific Advisory Board (the "SAB") since its public inception; and

WHEREAS, in that capacity, will provide the Company with advice and assistance regarding its drug development programs; and

WHEREAS, the Company wishes to provide the Science Advisor with compensation for his time, going forward, incurred in providing services hereunder.

NOW THEREFORE, in consideration of the premises and the mutual covenants and agreements set forth herein and other good and valuable consideration, the receipt and sufficiency are hereby acknowledged, the parties hereto hereby agree as follows:

AGREEMENT

1) **SAB Membership.** The Company agrees to engage the Science Advisor, and the Science Advisor agrees to participate as a member of the Company's SAB. As SAB member and its Chair, the Science Advisor will consult with the Company on its drug development efforts during the term of this Agreement. The Science Advisor's position as an SAB member will include attending meetings of the SAB at the offices of the Company or elsewhere, consulting individually with the Company's officers and employees, as reasonably requested, and occasionally, participating in other meetings, including telephonic meetings, or conducting other activities, as reasonably requested by the Company, subject to Science Advisor's availability. Subject to Section 2, the term of this Agreement shall be for an initial period (the **"Initial Term")** commencing on the date hereof (the **"Effective Date")** and ending on the first anniversary of the Effective Date. The Agreement shall continue for successive one-year renewal periods (the **"Renewal Periods")** unless terminated by either the Science Advisor or the Company in accordance with Section 2.

a) **Scope of Engagement.** The Science Advisor is expected to advise the Company with regard to the development of the Company's drug pipeline.

b) **Estimate of Time Required.** The Company estimates that the time required for this engagement will be several times per week.

c) **Employee of The University of Texas MD Anderson Cancer Center.** Notwithstanding any of the other terms of this Agreement, and in exception thereto, the parties to this Agreement acknowledge and agree that the Science Advisor is an employee of The University of Texas MD Anderson Cancer Center (UMDACC) and therefore the Science

Advisor executes this Agreement subject to the Rules and Regulations of The Board of Regents of The University of Texas System and all terms and conditions therein that apply to the Science Advisor. The Science Advisor has no right, power or authority to assign or enter into any other agreement with respect to intellectual property, confidential or other proprietary information owned by the Board of Regents that is inconsistent with these Rules and Regulations. A complete copy of the Rules and Regulations of The Board of Regents of The University of Texas System may be found at www.utsystem.edu/bor.rules/. This agreement is subject to the approval by the appropriate authorities at UMDACC. The Science Advisor will notify the Company in writing of such approval.

2) **Termination of SAB Membership.** The Science Advisor's membership on the SAB may be terminated at any time by the Science Advisor or the Company at any time and for any reason.

a) **Notice of Termination.** Any termination by the Company or by the Science Advisor shall be communicated by Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" means a written notice which (i) sets forth the fact of termination of the Science Advisor's membership on the SAB and (ii) if the Date of Termination (as defined below) is other than the date of receipt of such notice, specifies the termination date (which date shall not be more than 30 days after the giving of such notice).

b) **Date of Termination. "Date of Termination"** means (i) if the Science Advisor's membership on the SAB is terminated by reason of death or disability, the date of death of the Science Advisor or the disability Effective Date, as the case may be, and (ii) if the Science Advisor is terminated by the Company within 30 days of the expiration of the Initial Term or a Renewal Period, the date of expiration of the Initial Term or Renewal Period as the case may be, and (iii) if the Science Advisor's membership on the SAB is terminated for any other reason, on the date of receipt of the Notice of Termination or any later date specified therein.

3) **Compensation.**

a) Cash. In consideration of the services to be provided by Science Advisor under this Agreement, the Company shall pay the Science Advisor an annual amount of $68,500 until the Date of Termination (or, if the Date of Termination occurs prior to the Initial Term or the expiration of a Renewal Period, a pro rata portion of the annual amount shall be paid to the Science Advisor). The Company will pay this in quarterly installments prior to the 30th day after each calendar quarter end with the first payment due for the first calendar quarter of 2020 beginning on April 30, 2020.

4) **Expense Reimbursement.** During the term of this Agreement, the Science Advisor shall be entitled to receive prompt reimbursement for all reasonable out-of-pocket expenses incurred by the Science Advisor in the performance of his duties as a SAB member in accordance with the policies, practices and procedures of the Company.

5) **Confidentiality.** The Science Advisor acknowledges that in the course of his activities for the Company, he will have access to certain proprietary technology of the Company, including but not limited to technology, inventions, processes, methods, products and other trade secrets (collectively referred to hereinafter as the "Proprietary Technology") and to certain confidential information relating to the Proprietary Technology and to the Company's plans and strategies, including plans and

strategies for research, development, production, collaboration or expansion, and other information about the business of the Company, which the Company desires to protect and preserve in confidence (collectively referred to as "Confidential Information"). This section is superseded by any obligations related to the Science Advisor's duties under Section 1.c. above. The Company acknowledges that Science Advisor provides services to other companies and that for the purpose of this Agreement the term Confidential Information shall only include exclusively Moleculin's Confidential Information and not any information belonging to any other companies. The Science Advisor agrees to the following obligations with respect to the Proprietary Technology and Confidential Information:

(a) **Obligations of Confidence.**

(i) The Science Advisor shall keep the Proprietary Technology and Confidential Information in confidence, and shall not disclose or otherwise make available, or facilitate the availability, of the same or any part thereof to any person, firm, corporation, or other entity, except as expressly permitted by the Company.

(ii) The Science Advisor shall not make, disclose or distribute, directly or indirectly, documents or copies of documents containing disclosures of such Proprietary Technology and Confidential Information, except as necessary to carry out the purposes of this Agreement.

(i) The Science Advisor shall not advise anyone that such Proprietary Technology and Confidential Information is known or used by the Company or others associated with the Company, except as expressly permitted by the Company.

(b) **Non-Use and Related Obligations; Duty of Notification.** Nothing herein contained confers on the Science Advisor any right or license under any of the Company's intellectual property rights.

(c) **Non-Confidential Information.** The Company acknowledges that the Science Advisor's obligations of confidence do not apply to that which is already known to the Science Advisor as demonstrated by written record, or which is now publicly available or which becomes publicly available in the future other than by breach of this Agreement by the Science Advisor, or which is disclosed to the Science Advisor by third parties under no obligation of confidence to the Company.

(d) **Indemnification and Hold Harmless.** The Science Advisor shall not be liable for any acts, errors or omissions in performing its duties, except if such performance is conducted in bad faith or with gross negligence that results in material harm to the Company. The Company will indemnify, hold harmless and pay all expenses, costs, liabilities of the Science Advisor incurred in defense of legal actions brought against the Science Advisor, except actions or omissions of the Science Advisor that constitute fraud, gross negligence or willful misconduct.

6) **Miscellaneous.**

a) This Agreement shall be governed by and construed in accordance with the laws of the State of Texas, without reference to principles of conflict of laws. The captions of this Agreement are not part of the provisions hereof and shall have no force or effect. This Agreement

may not be amended or modified otherwise than by a written agreement executed by the parties hereto or their respective successors and legal representatives.

b) Any notice required by this Agreement must be given by email or facsimile transmission confirmed by personal delivery (including delivery by reputable messenger services such as Federal Express) or by prepaid, first class, certified mail, return receipt requested, addressed as follows:

If to the Science Advisor: Waldemar Priebe
2575 West Bellfort
Suite 333
Houston, TX 77054

If to the Company: Walter V. Klemp
Chairman & CEO
Moleculin Biotech, Inc.
5300 Memorial, Suite 90
Houston, TX 77007
For payment purposes: ap@moleculin.com
Office Phone: (713) 305-5041

or to such other address as either party shall have furnished to the other in writing in accordance herewith. Notice and communications shall be effective when actually received by the addressee.

c) If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the term of this Agreement, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

d) The Science Advisor's or the Company's failure to insist upon strict compliance with any provision of this Agreement or the failure to assert any right the Science Advisor or the Company may have hereunder shall not be deemed to be a waiver of such provision or right or any other provision or right of this Agreement.

e) The provisions of this Agreement constitute the complete understanding and agreement among the parties with respect to the subject matter hereof

f) This Agreement may be executed in two or more counterparts.

IN WITNESS WHEREOF, the Science Advisor has hereunto set the Science Advisor's hand and, pursuant to the authorization from its Board, the Company has caused this Agreement to be executed in its name on its behalf, as of the date first written above.

SCIENCE ADVISOR

/s/ Waldemar Priebe, PhD
Waldemar Priebe, PhD

Moleculin Biotech, Inc.
/s/ Walter V. Klemp, Chairman & CEO
Walter V. Klemp, Chairman & CEO

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 19, 2020, with respect to the consolidated financial statements included in the Annual Report of Moleculin Biotech, Inc. on Form10-K for the year ended December 31, 2019. We consent to the incorporation by reference of said reports in the Registration Statements of Moleculin Biotech, Inc. on Forms S-1 (File No. 333-214898, File No. 333-215974, File No. 333-224243, File No. 333-226146 and File No. 333-227845), Form S-3 (File No. 333-219434) and on Forms S-8 (File No. 333-212619 and File No. 333-225867).

/s/ GRANT THORNTON LLP

Houston, Texas

March 19, 2020

Exhibit 31.1

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

I, Walter Klemp, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 19, 2020

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

Exhibit 31.2

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

I, Jonathan Foster, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 19, 2020

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K for the fiscal year ended December 31, 2019 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Walter Klemp, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: March 19, 2020

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

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K for the fiscal year ended December 31, 2019 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan Foster, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: March 19, 2020

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

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