Table of Contents

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, 2020**
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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 USC. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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 $52 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 11, 2021 was 28,444,425.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of this registrant's definitive proxy statement for its 2021 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.

Moleculin Biotech, Inc.
Table of Contents

Moleculin Biotech, Inc.
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 continue our operations including our clinical trials, clinical drug candidate supplies, preclinical activities and our ability to raise future financing;
- our ability to continue our relationship with MD Anderson, including, but not limited to, our ability to maintain current licenses and license future intellectual property resulting from our sponsored research agreements with MD Anderson;
- 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 or beginning as planned;
- the success or the lack of thereof, 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, and in countries deemed necessary for future trials;
- our ability to complete our clinical trials in a timely fashion and within our expected budget and resources;
- compliance with obligations under intellectual property licenses with third parties;
- any delays in regulatory review and approval of drug candidates in clinical development;
- potential efficacy of our drug candidates;
- 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 and viruses. We have three core technologies, based substantially on discoveries made at MD Anderson Cancer Center (MD Anderson or MDA). We have four drug candidates, three of which have now shown human activity in clinical trials.

During 2020, three of those drug candidates accounted for five clinical trials in the US and Europe. Two of those trials are ongoing externally funded studies of WP1066 in brain tumors. Two of our internally funded Phase 1 clinical trials have essentially concluded. The trial for Annamycin in acute myeloid leukemia (AML) successfully met its safety endpoint, and the trial for WP1220 in cutaneous T-cell lymphoma (CTCL) demonstrated an objective response rate of 45% and a clinical benefit rate of 100%. An additional Phase 1/2 clinical trial of Annamycin in AML is also internally funded and is currently ongoing. In 2021, we anticipate the initiation of five new clinical trials in addition to the three trials continuing from 2020.

In late 2020, we received U.S. Food and Drug Administration (FDA) clearance to proceed with an additional Phase 1b/2 clinical trial of Annamycin for the treatment of sarcoma lung metastases and we are preparing to begin this trial in the US. We also plan to seek approval to begin a Phase 1/2 clinical trial of Annamycin in combination with Ara-C for the treatment of AML in Europe. These two new trials will be internally funded. We expect a second Phase 1b/2 clinical trial of Annamycin in sarcoma lung metastases to be primarily investigator-funded in Europe and we plan to seek a collaborative partner to support a Phase 2 clinical study of WP1220 in CTCL. Finally, we are working to initiate a clinical trial of WP1122, in either a Phase 1a/1b clinical trial in COVID-19 or a physician-sponsored clinical trial for a cancer indication, or both. The ultimate course of action depends on the outcome of additional regulatory and preclinical work. These trials may be internally or externally funded, depending on the timing and nature of the studies. In summary, we had five clinical trials underway or concluded in 2020 and we now expect up to eight clinical trials to be underway or approved in 2021, including physician-sponsored trials related to our drug candidates for which we are not actively involved.

By "internally funded" we mean that the primary costs of the preclinical activity and clinical trials are funded by us. "Externally funded" drug candidates include those for which preclinical work is performed by external collaborators and for which clinical trials are physician-sponsored. For externally funded research, any grant funds that support such preclinical work or clinical trials and most of the associated expenses do not flow through our financial statements. We do provide drug product and other minor supporting activities for externally funded preclinical activities and clinical trials.

We recently announced collaborations with third parties to assist us in developing potential treatments for certain viral diseases, including, potentially, COVID-19. During 2020, we announced that in vitro testing corroborated the antiviral potential of WP1122, including for the SARS-CoV-2 virus responsible for COVID-19. Subsequently, we had written discussions with the FDA regarding the clinical development of WP1122 for the treatment of COVID-19. Based on guidance from the FDA, we believe that we need to demonstrate efficacy in a COVID-19 animal model in order to proceed with an IND for COVID-19 clinical trials in the US. Therefore, the timing of any such clinical trial activity in the US is subject to the limited access we have to validated in vivo efficacy testing. For this reason, we are also evaluating opportunities to pursue COVID-19 clinical development outside the US. The IND-enabling preclinical work already completed for WP1122 is mostly similar to the preclinical work we originally planned as part of developing WP1122 for cancer indications. Accordingly, we intend to apply for an IND or its foreign equivalent for WP1122 in either an antiviral or cancer indication, or both, during 2021.

Based on the results of our clinical activity thus far, we have further narrowed our internal development focus to our nearest term opportunities, especially where human activity has been shown in clinical trials. This focus is primarily on preclinical and clinical activities with Annamycin, preclinical activities associated with an intravenous formulation of WP1066 and IND-enabling studies of WP1122. We intend to rely on external funding, to the extent available. Due to the COVID-19 pandemic, we have internally accelerated development of the WP1122 portfolio with a combined effort of internally and externally funded preclinical work to support an IND application with the FDA or an international regulatory body for the treatment of COVID-19 or a cancer indication or both.

Of our three clinical stage drug candidates, Annamycin is currently in a Phase 1/2 clinical trial for the treatment of acute myeloid leukemia (AML) in Poland. We recently received clearance from the FDA to proceed with a Phase 1b/2 clinical trial of Annamycin as a potential treatment for soft tissue sarcomas (STS) metastasized to the lungs. WP1066, an Immune/Transcription Modulator (p-STAT3 inhibitor or, simply, STAT3 inhibitor) is intended to target a wide range of tumors, including brain tumors such as glioblastoma (GBM) and pediatric brain tumors (like diffuse intrinsic pontine glioma, or DIPG, and medulloblastoma), as well as pancreatic cancer. It is currently in two physician-sponsored Phase 1 clinical trials, one for adult GBM and another for pediatric brain tumors (including DIPG and medulloblastoma). We began and completed a "proof-of-concept" Phase 1 clinical trial in 2019 in Poland for a third drug, WP1220 (a molecule in the WP1066 portfolio), for the topical treatment of cutaneous T-cell lymphoma (CTCL). We are actively seeking collaboration with a strategic partner in the near term for external funding for the continued development of WP1220 in a Phase 2 clinical trial as a topical therapy for CTCL. If we are not successful in this outreach, we may choose to use internal funds to generate additional human data to facilitate such outreach efforts. We are also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as antimetabolites, targeting glycolysis and glycosylation.

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 (the efficacy of all currently approved anthracyclines is limited by both multidrug resistance and cardiotoxicity). We have received an independent expert cardiology assessment confirming the absence of cardiotoxicity in the first 19 patients treated with Annamycin in both our US and European Phase 1 clinical trials. Annamycin is currently in one Phase 1/2 clinical trial in Europe, and the Phase 1 portion of another Phase 1/2 AML trial in the US has been concluded, subject to final database lock and closure. The FDA requested that we demonstrate that Annamycin could be safely administered to patients up to the lifetime maximum allowable level of anthracycline (LTMAD) established by the FDA and the trial met this primary endpoint. The FDA established the LTMAD because of concerns about cardiotoxicity associated with currently approved anthracyclines when administered above the LTMAD. Of the first 19 patients in our trials, 11 have been treated above the LTMAD (one patient received more than double the LTMAD) and none have shown evidence of any cardiotoxicity. As a result of discussions with the FDA, we will focus on establishing a recommended Phase 2 dose (RP2D) in our trial in Europe, and, as requested by the FDA, we will generate additional safety and efficacy data.

The trial in Poland is in its fifth cohort, where patients are being treated at 240 mg/m2. Patient 2 in this cohort experienced a dose limiting toxicity (DLT), related to liver function, secondarily related to concomitant medication not being withheld. Although that DLT resolved, in accordance with the trial protocol, the cohort was expanded and has now enrolled a total of five patients. In March 2021, patient 4 in this cohort experienced a similar DLT and, accordingly, no additional patients will be enrolled at this dose level beyond the five patients enrolled to date. The DLT for Patient 4 is being monitored and, per protocol, other patients in this cohort are permitted to continue to receive the full dose of Annamycin, at the discretion of their physicians and with the patients being notified of the reported DLTs.

We are planning to amend the protocol for this trial to allow exploration of an intermediate dose level between the 210 mg/m2 dose in the fourth cohort and the current 240 mg/m2 dose level, in order to establish the maximum tolerated dosage (MTD) and Recommended Phase 2 dose (RP2D), which may be the same. While this will establish an MTD for Annamycin in AML and inform the starting dose in our planned trials in soft tissue sarcoma (STS) lung metastases, we do not believe it will limit the dose escalation in our STS trials. Because of the different indication and differences in dosing regimen, we expect to determine a separate MTD in the Phase 1 portion of the STS trials. Once the MTD in the single agent AML trial is established, we currently plan to begin the expansion Phase 2 portion of this trial with relapsed patients at the RP2D, in order to determine the potential efficacy of Annamycin as a second line, single agent treatment for relapsed AML. Following on our preclinical research, we also intend to begin the Phase 1 portion of an AML trial using Annamycin in combination with Ara-C, a drug commonly used as a single agent and in combination chemotherapy for AML.

A preliminary review of the data in the completed cohorts in both trials, which is subject to update, indicates that patients received an average of 3+ and a maximum of 9 prior regimens. Thus far in the completed cohorts of our US and European single agent AML trials, there are 13 relapsed patients who were enrolled after one or more relapses from the prior regimens. Of these, 38% had either a CRi, PR or Bridge to Transplant. We view this as encouraging, because recruitment in the expansion Phase 2 will be limited to patients with no more than a single relapse. This is in contrast to the Phase 1 portion of the trial, where, in order to accelerate recruitment, we included a majority of patients who were primarily refractory or who had two or more relapses from alternate therapy. We believe this is significant because patients who are either refractory or have had two or more relapses are considered to be less likely to respond to therapy and especially to a single agent therapy. As a result and considering that all patients in Phase 2 will be treated at the RP2D, we believe the overall response in the expansion Phase 2 may be better than the overall response in the Phase 1 portion of the trial, although we cannot be certain that actual results will reflect this.

Our preclinical work on Annamycin demonstrated activity against certain cancers metastasized to the lungs. In December 2020, we disclosed that the FDA allowed our IND to go into effect to study Annamycin for the treatment of soft tissue sarcoma lung metastases. This allows us to begin a Phase 1b/2 clinical trial in the U.S. for patients with soft tissue sarcoma that has metastasized to the lungs after first-line therapy for their disease. We expect this trial to begin in the first half of 2021. Later in December 2020, we disclosed that the FDA had granted Orphan Drug Designation (ODD) to Annamycin for the treatment of soft tissue sarcomas, in addition to the existing ODD for Annamycin in relapsed or refractory AML. On February 2, 2021, we announced that a preclinical study in animals has confirmed a significant therapeutic benefit of Annamycin against metastatic osteosarcoma. As of day 130 of the study, the survival rate for animals treated with Annamycin was 100%, compared with only 10% for untreated animals. Computerized tomography scans demonstrated that animals treated with Annamycin exhibited suppression of tumor growth and not a single death was observed in the treated animals, whereas observed tumor burden was believed to have contributed to the rapid death of 90% of untreated animals. We believe this data is a promising indication of the possibility of Annamycin's impact on other cancers metastasized to the lungs. We caution that this is preclinical animal data and we can provide no assurance that we will see similar results in our planned clinical trials.

WP1066 is one of several Immune/Transcription Modulators designed to stimulate the immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs) while also inhibiting key oncogenic transcription factors, including p-STAT3 (phosphorylated signal transducer and activator of transcription 3), c-Myc (a celluar signal transducer named after a homologous avian virus called Myelocytomatosis) and HIF-1α (hypoxia inducible factor 1a). These transcription factors are widely sought targets that are believed to contribute to an increase in cell survival and proliferation, and the angiogenesis (coopting vasculature for blood supply), invasion, metastasis and inflammation associated with tumors. They may also play a role in the inability of immune checkpoint inhibitors to affect more resistant tumors. WP1066 is currently in two US physician-sponsored Phase 1 trials, one at MD Anderson for the treatment of glioblastoma (GBM) in adults and another at Emory University for the treatment of pediatric brain tumors.

The trial at MD Anderson is in the fourth and final cohort in the dose escalation phase. In the first quarter of 2021, we were notified that the physician sponsoring this trial is leaving MDA. We cannot be assured that this trial will continue at MDA after her departure. Several additional institutions have expressed an interest in sponsoring similar research on WP1066 in brain tumors, so to help ensure the potential continuation of this important research, regardless of the sponsoring institution, we have requested the IND for this trial to be transferred into our name with the FDA, although we can provide no assurance as to when, or if, this transfer will be completed. While we are making arrangements to continue this research in additional physician-sponsored trials, we expect that continued research on WP1066 in adult GBM will be temporarily delayed in 2021.

The Emory trial for pediatric brain tumors has now treated three patients in the first cohort. The third and last patient in the second cohort has begun treatment at the dose level of 6mg/kg. In that trial, one of the patients in the first cohort with DIPG showed an apparent response to the treatment with both clinical improvement and radiologic reduction of tumor size. We caution that this is preliminary data, and no conclusions should be drawn from this single event. Another physician-sponsored Phase 1 trial is being considered for the treatment of GBM with WP1066 in combination with radiation, although no assurances can be given that such trial will begin.

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.

As the COVID-19 pandemic unfolded, several independent research teams identified that 2-DG may have the potential to treat COVID-19, as well as other diseases caused by coronaviruses. Similar to the dependence of many tumors on glucose, viruses like SARS-CoV-2 are highly dependent on both glycolysis and glycosylation (and, therefore, glucose) in order to successfully invade host cells and proliferate. It is on this basis that we have established an antiviral drug development program focused on WP1122 and its analogs. We are in the process of identifying the best possible pathway to begin a clinical trial in either COVID-19 or cancer patients or both in the first half of 2021.

The spread of COVID-19 has caused significant volatility in US and international markets, including Poland, where we conduct some of our clinical trials, and Italy, where our drug supply is produced. There has been limited interruption of our drug supply, and most Polish clinics where we are conducting trials are limiting access for monitoring activities, which could delay our ability to collect data and authorize new patient recruitment. Additionally, we believe COVID-19 has materially slowed the ability of approved sites to recruit patients for our trials. This could worsen or be alleviated 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, we are unable to determine if it will have a material impact to our operations. Recently, we have experienced a limited increase in activity with regard to recruitment of new patients in Poland. Additionally, we believe that the potential for impact to our supply chain due to COVID-19 will be reduced as vaccine production normalizes throughout the industry. In light of current US trends with respect to COVID-19, we cannot determine whether COVID-19 will materially impact recruitment for current or future US based trials.

We do not have manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, we do not have a sales organization. Our overall strategy is to seek potential outlicensing opportunities with larger pharmaceutical companies who are better suited for the marketing, sales and distribution of our drugs once approved.

Mission and Strategy Overview

Moleculin is focused on developing treatments for highly resistant cancers and viruses. For cancers, these include AML, GBM, CTCL, STS metastasized to the lungs, pancreatic cancer, other vital organ metastases, and others. With regard to viruses, our current focus is the possible treatment of COVID-19, while additional pre-clinical work has demonstrated possible activity against HIV, Zika, and Dengue fever. 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. Many of these traits are also common to certain viruses and 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. As detailed within, although we have conducted much preclinical and early-stage clinical work that we consider very promising, there is no guarantee that any future study will be conducted or will be successful, or that our product candidates will ultimately be successfully commercialized.

We believe our technologies provide an opportunity to help the many patients in need of alternative therapies, both as single agents and 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 and viruses may lead to accelerated approval pathways, potentially reducing the time and capital required to ultimately realize success.

In February 2019, we announced our outlicensing agreement to WPD Pharmaceuticals, an entity associated with one of our co-founders, Dr. Waldemar Priebe, which was amended in March 2021. This agreement provides WPD with territorial rights to certain smaller countries in mainly Eastern Europe and Western Asia in exchange for their agreeing to provide $6.5 million or more of funding, either directly or through the guarantees of grants, to our development efforts over the eight-year period commencing with our initial execution of the agreement in February 2019. WPD recently announced their facilitation of a grant equivalent to $1.5 million USD to the Maria Sklodowska-Curie National Research Institute to fund a Phase 1b/2 clinical trial of Annamycin for the treatment of STS lung metastases. The grant-funded clinical trial will be led by Prof. Piotr Rutkowski, MD, PhD, Head of Department of Soft Tissue/Bone Sarcoma and Melanoma at the Maria Sklodowska-Curie National Research Institute of Oncology in Warsaw, Poland. As we continue to generate additional human data, we intend to pursue additional strategic collaborations on a regional basis for each of our drug candidates.

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, WP1066 and WP1220. We have now seen human activity in these three drug candidates that we think is capable of supporting an accelerated approval pathway with continued positive developments in the respective clinical trials. We are also committed to spending on the WP1122 program to potentially enable a cancer and/or a COVID-19 related IND.

Intellectual Property

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 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 in the United States. A drug that is approved for an orphan-designated indication may receive market exclusivity of 7 years from the date of approval of the New Drug Application (NDA). During that period the FDA generally could not approve another product containing the same active moiety for the same orphan-designated indication. Orphan Drug Exclusivity (ODE) will not bar approval of a product with a different active moiety for the same indication or a product with the same moiety for a different indication. Additionally, ODE will not preclude FDA approval of another product with the same moiety for the same orphan-designated indication under certain circumstances, including if the subsequent product 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. ODD and ODE are also available from the European Union (EU). ODD in the EU is generally available for drug products intended 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. If the orphan-designated product continues to meet the criteria for orphan designation at approval, the approval for an orphan-designated indication conveys a 10-year exclusivity period, during which the competent authorities in the EU may not accept another marketing authorization application and may not grant another marketing authorization for a similar medicinal product (i.e., a medicinal product with an identical active substance, or an active substance with the same principal molecular structural features and acts via the same mechanisms) for the same therapeutic indication. 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. In the EU, ODE does not preclude granting a marketing authorization for a similar medicinal product for the same therapeutic indication, if that medicinal product is demonstrated to be safer, more effective or otherwise clinically superior, or if the company with orphan drug exclusivity is unable to supply sufficient quantities of the product.

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 we believe our drug candidates will be considered to be), which would for a period of time preclude submission of any Abbreviated New Drug Application (ANDA) for a generic version of the product or any 505(b)(2) NDA for a product with the same active moiety that seeks to rely on its similarity to our product for an abbreviated approval pathway, as well as delay approval of such applications. There can be no assurance that such exclusivity will be granted, nor does the exclusivity, if granted, block approval of a “full” NDA (i.e., an NDA that does not rely on similarity to our product) for a competing product. 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, which is intended to expedite drug development and approval, is granted to drugs intended to treat serious conditions, where data demonstrate the potential to address an unmet medical need.

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 derived from the Patent Cooperation Treaty or PCT for synthetic processes for lyophilized Annamycin and for reconstitution of our Annamycin drug product candidate. If the non-provisional patent applications and subsequent PCT applications are approved, for which we can provide no assurance, this would potentially provide patent protection for Annamycin through June 2040.

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 and funded by us, according to the license agreements. Additional patents pending, including licenses being negotiated in the ordinary course of business and currently licensed from MD Anderson, may provide additional potential protection to our drug portfolio, however we can provide no assurance that such patents or additional licenses will be granted or with regard to the extent of protection they might provide.

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 using the drug for AML. We recently concluded the Phase 1 portion of the US clinical trial and a similar Phase 1/2 trial in Europe continues and is in its fifth cohort. We are planning a potential pivotal Phase 2 AML trial once sufficient clinical data is established in this European trial. Based on new research findings resulting from our sponsored research at MD Anderson, we are also preparing to begin an AML clinical trial in Europe for the combination of Annamycin and Ara-C, as well as clinical trials in both the US and EU (with the EU trial being physician-sponsored) for the treatment of soft tissue sarcoma lung metastases with Annamycin as a single agent.

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.

The Importance of No Cardiotoxicity

We have received an independent expert cardiology assessment confirming the absence of cardiotoxicity in the first 19 patients treated with Annamycin in both our US and European Phase 1 clinical trials. 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 (by creating iron-mediated free oxygen radicals, damaging the DNA and cell membranes, and inhibiting topoisomerase II) 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.

Annamycin as a Single Agent in AML

The prior development history of Annamycin in acute leukemia suggests that a possible accelerated approval pathway exists by positioning Annamycin as a single agent for the treatment of relapsed or refractory AML. Notwithstanding the recent approval of multiple drugs for this indication, most of these drugs are targeted therapies that are helpful to only a small percentage of the overall AML patient population. A significant unmet need still exists for those patients that are refractory to or relapse from the traditional first-line induction therapy (known as "7+3") designed to induce remission of AML and, in some cases, prepare patients for a curative bone marrow transplant. Unfortunately, the majority of AML patients do not respond adequately to the current first line therapies. In addition, approximately 40% of AML patients are deemed "unfit" for 7+3 due to the intensity of this chemotherapy. We estimate that a significant portion of those patients are deemed unfit because of the potential for cardiotoxicity inherent in the anthracyclines currently used in 7+3. Given its lack of cardiotoxicity, single agent Annamycin may also provide a viable treatment alternative for such patients.

Annamycin in Combination with Ara-C in AML

As a part of our ongoing sponsored research at MD Anderson, animal testing has indicated that the combination of Annamycin with Ara-C provides a synergistic effect that is more effective in AML mouse models than either drug alone. The data was presented at the 62nd Annual Meeting & Exposition of the American Society for Hematology (ASH) under the title: "High Efficacy of Liposomal Annamycin (L-ANN) in Combination with Cytarabine in Syngeneic p53-null AML Mouse Model."

This study was conducted in a highly aggressive AML mouse model where median survival is approximately 13 days. For animals treated with the combination of Annamycin and Ara-C, median survival ranged from 56 to 76 days, thus expanding median survival by 585%, with some animals being completely cured. We believe these experiments support initiation of clinical development of the combination of Annamycin and Ara-C in AML patients.

Although Annamycin has already shown human activity as a single agent in its two Phase 1 AML clinical trials, including one complete response, and has shown no signs of cardiotoxicity, unlike other anthracyclines, it now appears, based on the observed synergy in vitro and confirmatory in vivo data, that the combination of Annamycin and Ara-C could be more effective in a clinical setting than Annamycin as a single agent. This would be consistent with current practice to use Ara-C in combination with an anthracycline like Annamycin. The current first-line therapy for AML patients is the combination of an anthracycline and Ara-C in a regimen referred to as "7+3" where Ara-C is administered daily for 7 days in parallel with 3 daily doses of an anthracycline. Simply substituting the currently used anthracycline in a similar 7+3 regimen with Annamycin would represent a familiar and well-practiced treatment modality. Beyond that, we believe it would have the added advantages that Annamycin has been shown in published research to be active against tumor cells resistant to doxorubicin and, importantly, has the potential to remove the concern for cardiotoxicity, a significant toxic side effect of currently used anthracyclines.

Annamycin as a Single Agent in STS Lung Metastases

Moleculin recently announced that Annamycin demonstrates consistently high antitumor activity in vivo in all tested animal models of different types of lung-localized cancers, including sarcoma. These promising findings correlate with surprisingly high uptake of Annamycin to the lungs in animal models. We found in our studies that the Annamycin uptake is over 30-fold higher than that of doxorubicin, the primary first-line chemotherapy for soft tissue sarcoma (STS). The limited pulmonary uptake of doxorubicin in animal models may help explain its lack of activity against STS lung metastases in humans. Additionally, our clinical data to date show no cardiotoxicity associated with the use of Annamycin, and the published research demonstrate Annamycin's ability to avoid multidrug resistance mechanisms, both of which are often treatment-limiting effects of anthracyclines (which includes doxorubicin) in this setting. Taken together, these factors suggest that Annamycin could represent an important treatment to help address a significant unmet need in patients with STS lung metastases.

We announced in April 2019 that our ongoing sponsored research 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. 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 activity in animal models of triple negative breast cancer metastasized to the lungs, we are also seeing activity 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.

Furthermore, a poster entitled, "Liposomal annamycin inhibition of lung localized breast cancer," was presented 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.

On February 2, 2021, we announced that a preclinical study in animals has confirmed a significant therapeutic benefit of Annamycin against metastatic osteosarcoma. As of day 130 of the study, the survival rate for animals treated with Annamycin was 100%, compared with only 10% for untreated animals. Computerized tomography scans demonstrated that animals treated with Annamycin exhibited suppression of tumor growth and not a single death was observed in the treated animals, whereas observed tumor burden was believed to have contributed to the rapid death of 90% of untreated animals. We believe this data is a promising indication of the possibility of Annamycin's impact on other cancers metastasized to the lungs. We caution that this is preclinical animal data and we can provide no assurance that we will see similar results in our planned clinical trials.

It is estimated that there are approximately 36,000 new cases of STS in the seven major markets (US, EU5 and Japan) each year. Our clinical advisors estimate that approximately half of all STS patients will eventually develop lung metastases from their primary tumor. Although first-line treatments such as surgical resection, chemotherapy and radiation may provide initial therapeutic benefit for approximately one third of those patients, there are no approved or emerging second-line therapies for the remaining patients who relapse or are refractory. Although the lungs tend to be a major site of relapse, we are aware of only 2 active clinical trials specifically targeting STS lung metastases, indicating that Annamycin currently faces limited competition in this area of development.

Along with the results in STS lung metastases, our animal models have shown activity in other lung metastases, including osteosarcoma, colorectal and triple negative breast cancer, as well as meaningful concentration levels of Annamycin in the liver, spleen and pancreas. Additionally, when tested in a highly aggressive AML mouse model, Annamycin significantly reduced tumor burden in the spleen, lungs and liver, leading to an increase in survival. Based on this promising preclinical data, we believe the ultimate market opportunity for Annamycin could be much larger than just STS lung metastases.

Clinical Trials for Annamycin

In 2021, we expect Annamycin will be studied for the treatment of AML and STS metastasized to the lungs in a total of three separate clinical trials, underway, or planned, including physician-sponsored trials. Additionally, we believe that data supports a fourth clinical trial to begin with Annamycin in combination with Ara-C for the treatment of AML also in 2021.

We filed our IND application for Annamycin for the treatment of AML, 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 was 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 have received an independent expert cardiology assessment confirming the absence of cardiotoxicity in the first 19 patients treated with Annamycin in both our US and European Phase 1 clinical trials. Annamycin is currently in one Phase 1/2 clinical trial in Europe, and the Phase 1 portion of another Phase 1/2 AML trial in the US has been concluded, subject to final database lock and closure. The FDA requested that we demonstrate that Annamycin could be safely administered to patients up to the lifetime maximum allowable level of anthracycline (LTMAD) established by the FDA and the trial met this primary endpoint. The FDA established the LTMAD because of concerns about cardiotoxicity associated with currently approved anthracyclines when administered above the LTMAD. Of the first 19 patients in our trials, 11 have been treated above the LTMAD (one patient received more than double the LTMAD) and none have shown evidence of any cardiotoxicity. As a result of discussions with the FDA, we will focus on establishing a recommended Phase 2 dose (RP2D) in our trial in Europe, and, as requested by the FDA, we will generate additional safety and efficacy data.

The trial in Poland is in its fifth cohort, where patients are being treated at 240 mg/m2. Patient 2 in this cohort experienced a dose limiting toxicity (DLT), related to liver function, secondarily related to concomitant medication not being withheld. Although that DLT resolved, in accordance with the trial protocol, the cohort was expanded and has now enrolled a total of five patients. In March 2021, patient 4 in this cohort experienced a similar DLT and, accordingly, no additional patients will be enrolled at this dose level beyond the five patients enrolled to date. The DLT for Patient 4 is being monitored and, per protocol, other patients in this cohort are permitted to continue to receive the full dose of Annamycin, at the discretion of their physicians and with the patients being notified of the reported DLTs.

Moleculin is planning to amend the protocol for this trial to allow exploration of an intermediate dose level between the 210 mg/m2 dose in the fourth cohort and the current 240 mg/m2 dose level, in order to establish the maximum tolerated dosage (MTD) and Recommended Phase 2 dose (RP2D), which may be the same. While this will establish an MTD for Annamycin in AML and inform the starting dose in our planned trials in soft tissue sarcoma (STS) lung metastases, we do not believe it will limit the dose escalation in our STS trials. Because of the different indication and differences in dosing regimen, we expect to determine a separate MTD in the Phase 1 portion of the STS trials. Once the MTD in the single agent AML trial is established, we currently plan to begin the expansion Phase 2 portion of this trial with relapsed patients at the RP2D, in order to determine the potential efficacy of Annamycin as a second line, single agent treatment for relapsed AML. Following on our preclinical research, we also intend to begin the Phase 1 portion of an AML trial using Annamycin in combination with Ara-C, a drug commonly used as a single agent and in combination chemotherapy for AML.

A preliminary review of the data in the completed cohorts in both trials, which is subject to update, indicates that patients received an average of 3+ and a maximum of 9 prior regimens. Thus far in the completed cohorts of our US and European single agent AML trials, there are 13 relapsed patients who were enrolled after one or more relapses from the prior regimens. Of these, 38% had either a CRi, PR or Bridge to Transplant. We view this as encouraging, because recruitment in the expansion Phase 2 will be limited to patients with no more than a single relapse. This is in contrast to the Phase 1 portion of the trial, where, in order to accelerate recruitment, we included a majority of patients who were primarily refractory or who had two or more relapses from alternate therapy. We believe this is significant because patients who are either refractory or have had two or more relapses are considered to be less likely to respond to therapy and especially to a single agent therapy. As a result and considering that all patients in Phase 2 will be treated at the RP2D, we believe the overall response in the expansion Phase 2 may be better than the overall response in the Phase 1 portion of the trial, although we cannot be certain that actual results will reflect this.

Study Design for AML -

We have been studying Annamycin in both the US and Europe in Phase 1/2 open label, single arm clinical trials to assess the safety and efficacy of Annamycin for the treatment of adults with relapsed or refractory AML. 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 in the Phase 2 portion. The Phase 1 portion of the 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, 3 and 4 in Europe received a dose of 120, 150, 180 and 210 mg/m2, respectively, and the results have permitted moving to Cohort 5 with dosing at 240 mg/m2. Refer to the discussion above for an update on this trial. Cohort 1 in the US started at 100 mg/m2, and the results supported moving to Cohort 2 at 120 mg/m2, which has now been fully recruited, treated, and evaluated. 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. The European trial has benefited from a more aggressive dose escalation scheme than was allowed in the US trial and, as a result, has recruited much more rapidly and to much higher dose levels. Accordingly, we have closed the US trial and will rely on the European trial to establish the RP2D.

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 this study 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 our clinical trials, with each announcement also including an update on any other related trials. 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.

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 (DLTs) at any dose tested until the 240 mg/m2 cohort in Poland. The DLTs in that cohort are discussed above. To date, an independent expert assessment of the absence of cardiotoxicity in the first 19 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 19 patients treated thus far in both of our Annamycin clinical trials and where safety has been assessed, none has shown an increase in troponin levels, again supporting the absence of cardiotoxicity. As previously noted, although these data are, in our view, promising, there remains significant additional clinical investigation to be done, and there can be no guarantee of the future results.

Preliminary Evidence of Potential Effectiveness in AML -

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, 15 AML patients have been evaluated after receiving Annamycin at or above 120 mg/m2 in closed cohorts (below 240 mg/m2). When they entered the study, 10 of the 15 patients were considered relapsed and 5 were considered refractory. Although reduction in bone and/or circulating blasts has been seen in most relapsed and refractory AML patients, each of the 5 patients where efficacy endpoints were met was a relapsed patient. In the 15 patients mentioned, efficacy signals have been demonstrated to date in 50% of the relapsed and 33% of the refractory patients. 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 (from diffuse to a few lesions) 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, unlike what is seen with doxorubicin. Of the 19 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 10 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 for AML -

Upon conclusion of our European AML clinical 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, as measured by echocardiograms and cardiac health biomarkers, principally blood troponin levels, among other things. 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, and, if approved, with an additional confirmatory post-approval Phase 3 study also possibly being required. 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.

Plans for a Phase 1/2 Trial of AnnAraC in AML

Based on the preclinical data discussed above, we are preparing to start a new clinical trial for the treatment of relapsed or refractory AML with the combination of Annamycin with Ara-C, a combination we are calling “AnnAraC.” We expect this clinical trial to begin sometime in the second half of 2021.

We intend for our planned study of AnnAraC in AML to have a similar trial design to the current Phase 1/2 study of Annamycin as a single agent in AML. We believe safety data from our current single agent trial will enable us to begin the combination trial at a higher starting dose of Annamycin in the Phase 1 portion but that will be an issue for the applicable regulatory agency when we approach them on an IND or CTA. We believe that the initial site for a combination trial will most likely be in Europe.

Plans for a Phase 1b/2 Trial of Annamycin in STS Lung Metastases

We have been moving quickly to begin a clinical trial in the US to study Annamycin for STS lung metastases, and in light of the importance of producing human clinical data to facilitate outlicensing opportunities, we included this upcoming trial as part of our internally funded clinical development program. In December 2020, we announced that the FDA allowed our IND application to study Annamycin for the treatment of STS lung metastases to go into effect. This allows us to begin a Phase 1b/2 clinical trial in the US for patients with soft tissue sarcoma that has metastasized to the lungs after first-line therapy for their disease.

We are also collaborating with WPD and physicians in Poland who have shown a high level of interest in testing Annamycin in STS lung metastases and are currently pursuing a physician-sponsored clinical trial in Europe. WPD recently announced their facilitation of a grant equivalent to $1.5 million USD to the Maria Sklodowska-Curie National Research Institute to fund a Phase 1b/2 clinical trial of Annamycin for the treatment of STS lung metastases. The grant-funded clinical trial will be led by Prof. Piotr Rutkowski, MD, PhD, Head of Department of Soft Tissue/Bone Sarcoma and Melanoma at the Maria Sklodowska-Curie National Research Institute of Oncology in Warsaw, Poland, and it will be operated independently of our study in the US.

It is our goal to have to have our US clinical trial begin by mid-2021, with the possibility of the European-funded clinical trial to begin later in 2021.

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 using the drug to treat glioblastoma.

Our WP1066 Portfolio (including lead drug candidates WP1066 and WP1220) 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. During 2020, we have been working on developing an appropriate IV formulation for the portfolio of WP1066. As a result of these studies, we believe that the lead molecule WP1066 may be our best candidate for intravenous administration and studies of an IV formulation candidate are currently underway. Additionally, we determined that the stability of WP1732, another molecule in the WP1066 Portfolio was less than satisfactory and, as such, in March 2021 we terminated our license for WP1732 with MDA.

The high level of anticancer activity demonstrated in multiple tumors in animal models by WP1066 is potentially related to its ability to also inhibit such important key oncogenic transcription factors such as 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 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. We intend to pursue additional study to build on this preclinical evidence and preliminary animal model data.

Recently published research papers have presented several findings that may point to 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 co-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 the STAT3 inhibitor WP1066. In vitro efficacy of this inhibitor was assessed using proliferation and apoptosis induction assays in a panel of patient-derived and commercially available Pancreatic Ductal Adenocarcinoma (PDAC) cell lines. WP1066 was shown to be potent and 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. Importantly, WP1066 shows in-vivo efficacy in preliminary experiments when tested alone or in combination with T cell immune checkpoint inhibitors.

Clinical Activity WP1066 -

Two trials are underway with WP1066. The first trial is a physician-sponsored Phase 1 trial of WP1066 in patients with recurrent malignant glioma and brain metastasis from melanoma which the FDA allowed to proceed in December 2017. In July 2018, this trial opened for recruitment in the US. This dose-escalation Phase 1 brain tumor clinical trial via a physician-sponsored 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 have begun the fourth and final cohort in the dose escalation phase.

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.

In the first quarter of 2021, we were notified that the physician sponsoring this trial is leaving MDA. Although we cannot be assured that this trial will continue at MDA after her departure, several additional institutions have expressed an interest in sponsoring similar research on WP1066 in brain tumors, so to help ensure the potential continuation of this important research, regardless of the sponsoring institution, we have requested the IND for this trial to be transferred into our name with the FDA, although there is no assurance that we will be successful in completing such transfer. While we are making arrangements to continue this research in additional physician-sponsored trials, we expect that continued research on WP1066 in adult GBM will be delayed.

At the 2009 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 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 is being conducted at the Aflac Cancer & Blood Disorders Center at Children's Healthcare of Atlanta. This trial has now successfully completed treatment of three patients in the first cohort and two patients in the second cohort, with the third and last patient in the second cohort having begun treatment at the dose level of 6mg/kg. In that trial, one of the patients with DIPG showed an apparent response to the treatment with both clinical improvement and radiologic reduction of tumor size. We caution that this is preliminary data and no conclusions should be drawn from this single event.

In July 2020 we announced that a peer-reviewed article published in Clinical Cancer Research (Clin Cancer Res June 30 2020 DOI:10.1158/1078-0432.CCR-19-4092) reported findings that WP1066, used in combination with traditional whole brain radiation therapy (WBRT) resulted in long-term survivors and enhanced median survival time relative to monotherapy in mice with implanted human brain tumors. The paper can be accessed at: https://clincancerres.aacrjournals.org/content/early/2020/06/30/1078-0432.CCR-19-4092.full-text.pdf

The study was performed by lead author Martina Ott, Ph.D., Instructor of Neurosurgery, senior author Amy Heimberger, M.D., professor of Neurosurgery, and a team of researchers at The University of Texas MD Anderson Cancer Center. Dr. Heimberger was also the Principal Investigator of the current physician-sponsored clinical trial of WP1066 for brain tumors. In the current study, C57BL/6 mice underwent intracerebral implantation of GL261 glioma cells, WBRT, and treatment with WP1066, a blood-brain barrier penetrant inhibitor of the STAT3 pathway, or the two in combination. The role of the immune system was evaluated using tumor rechallenge strategies, immune incompetent backgrounds, immunofluorescence, immune phenotyping of tumor-infiltrating immune cells (via flow cytometry), and nanostring gene expression analysis of 770 immune-related genes from immune cells, including those directly isolated from the tumor microenvironment.

The combination of WP1066 and WBRT resulted in long-term survivors and enhanced median survival time relative to monotherapy in the GL261 glioma model (combination vs. control $p<0.0001$). Immunological memory appeared to be induced, because mice were protected during subsequent tumor rechallenge. The therapeutic effect of the combination was completely lost in immune incompetent animals. Nanostring analysis and immunofluorescence revealed immunological reprogramming in the brain tumor microenvironment specifically affecting dendritic-cell antigen presentation and T cell effector functions. The study indicates that the combination of STAT3 inhibition and WBRT enhances the therapeutic effect against gliomas in the CNS by inducing dendritic-cell and T cell interactions in the brain tumor, which seems to be a requirement for a fully functional immune response

This study is consistent with preliminary data we announced last year. Importantly, the study indicated the potential that the combination of STAT3 inhibition with whole brain radiotherapy had the capacity to enhance the therapeutic effect against established tumors as well as developing immune memory that appears to prevent recurrence.

With this preclinical data, we believe that another physician-sponsored Phase 1 trial should be considered for the treatment of GBM with WP1066 in combination with radiation, although no assurances can be given that such trial will begin.

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 previously received 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.

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 an improvement in the Composite Assessment of Index Lesion Severity (CAILS) score.

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, 11 lesions were assessed according to the CAILS scoring system. The only related adverse event (AE) was mild contact dermatitis in one subject that the Investigator deemed was not related to the drug. 4 of the 5 subjects improved in CAILS scores on index lesions, with one exhibiting stable disease, with a median reduction of 56% (range 25-94%). Improvement was noted within 7 days of treatment initiation and maintained 1 month after discontinuation. Of the 11 lesions, 45% exhibited a CR or a 50% or more reduction in CAILS and 55% exhibited stable disease with 100% showing a clinical benefit. Independent dermatologic review based on photographic documentation was conducted and corroborated these findings.

Although this was a small proof-of-concept clinical trial, WP1220, topically applied, had no safety issues and appeared to be effective in MF. We believe this is the first demonstration in humans suggesting that inhibition of p-STAT3 with topical therapy has efficacy in CTCL. As a result of this, we are actively seeking third-party collaborations to begin a Phase 2a/2b trial with approximately 60 patients. If a suitable collaborator is not identified, we will consider internally funding a Phase 2a clinical trial to gather further human efficacy data.

IV Formulation for the WP1066 Portfolio

The topical application WP1220 does not appear to result in systemic exposure to the drug, which is desirable in case of a topical drug targeting a dermatologic condition, however, WP1066 is currently administered orally with the intent of systemic uptake. Although preliminary data from physician-sponsored brain tumor trials indicates that the oral administration of WP1066 does result in detectable levels of WP1066 in plasma, we believe our opportunity for successful development of a p-STAT3 inhibitor would be expanded if we were able to develop a compound capable of intravenous (IV) administration. In 2020, we began developing IV formulation methods for WP1066 that might address its lack of solubility. As a backup, however, we also invested in research to identify molecular analogs that may be more soluble and, therefore, easier to develop for IV administration. 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, that was soluble in water. After continuing research on WP1732, we have more recently identified challenges with the stability of the compound that could limit its development as a drug. In light of these challenges, we terminated the license with MD Anderson related to WP1732. Although we intend to continue our work toward a viable IV formulation of WP1066, there can be no assurance that this effort will be successful.

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. These new compounds are 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 we believe 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.

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 24,530 new cases of brain and other nervous system cancers will occur in the United States in 2021, resulting in 18,600 deaths. Despite the severity and poor prognosis of these tumors, there are few FDA-approved drugs on the market.

Additionally, based on independent preclinical data, we believe that this technology has the potential to impact hard to treat viruses that also rely heavily on glycolysis and glycosylation. Due to the COVID-19 pandemic, we initiated development of the WP1122 portfolio with a combined effort of internally and externally funded preclinical work on WP1122 for the treatment of COVID-19. We recently announced collaborations with third parties to assist us in developing potential treatments for certain viral diseases, including, potentially, COVID-19. During 2020, we announced that in vitro testing corroborated the antiviral potential of WP1122, including for the SARS-CoV-2 virus responsible for COVID-19. Subsequently, we had written discussions with the FDA regarding the clinical development of WP1122 for the treatment of COVID-19. Based on guidance from the FDA, we believe that we need to demonstrate efficacy in a COVID-19 animal model in order to proceed with an IND for COVID-19 clinical trials in the US. Therefore, the timing of any such clinical trial activity in the US is subject to the limited access we have to validated in vivo efficacy testing. For this reason, we are also evaluating opportunities to pursue COVID-19 clinical development outside the US. The IND-enabling preclinical work already completed for WP1122 is mostly similar to the preclinical work we originally planned as part of developing WP1122 for cancer indications.

The timing of an IND in the US or an equivalent in certain other countries is mainly dependent on gaining access to validated in vivo testing that is currently in very high demand and therefore limited availability. There are very few validated in vivo testing models for COVID-19 and the wait time for such testing is extremely long. We are focusing our efforts on jurisdictions that may not require testing in a COVID-19 animal model prior to initiating clinical trials. As an example, the CDSCO (the Indian equivalent of the FDA) recently approved human clinical trials for 2-DG (the active moiety of WP1122) in COVID-19 patients. Furthermore, according to information published by the CDSCO, the resulting Phase 2 trial in 40 COVID-19 patients demonstrated efficacy of 2-DG. Given that WP1122 is prodrug of 2-DG designed to improve its circulation time and tissue/organ uptake, we consider this human data regarding 2-DG to be potentially more relevant to the potential for WP1122 to be useful in treating COVID-19 than any available animal testing model.

Accordingly, we believe the preclinical work under way for WP1122 will support an IND application or its foreign equivalent for either cancer-related or virus-related clinical trials (or both) in the first half of 2021. Regardless, there can be no assurance that we will be able to move forward in a timely manner with research on using WP1122 to treat COVID-19, or that WP1122 will be effective in COVID-19 patients.

Additionally, we will rely on external collaborations for testing other molecules in the WP1122 portfolio against other hard to treat viruses such as HIV, Dengue fever, and Zika.

Overview of The Market for Our Oncology Drugs

Cancer is the second leading cause of death in the United States behind heart disease. In 2019, an estimated 16.9 million people in the United States were living with a past or current diagnosis of cancer, and, the American Cancer Society further estimates that in 2021, nearly 1.9 million new cases will be diagnosed and over 600,000 Americans will die from cancer. Importantly, these estimates are based on reported cancer incidence and mortality through 2017 and 2018, respectively, and do not account for the unknown impact of COVID-19 on cancer diagnoses and deaths.

The Orphan Drug Act and other legislative initiatives, such as "Rare Pediatric Disease" designation, 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 have obtained and continue to consider obtaining Orphan Drug exclusivity and have pursued and continue to consider pursuing accelerated approval to be important parts 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

Digestive, reproductive, breast and respiratory cancers comprise most of expected cancer diagnoses in 2021, 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 25,930 of the estimated 61,090 new cases expected in the United States in 2021. The National Cancer Institute estimates that cancer-related direct medical costs in the US were $183 billion in 2015 and are projected to increase to $246 billion by 2030, a 34% increase based only on population growth and aging. However, the projection is likely an underestimate because of the growing cost of prescription medicines, with the list price for many now more than $100,000 annually.

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 $770 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 – estimated to rise to $1.6 billion by 2025. Of this worldwide amount, The US market is estimated to comprise the largest share.

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, in the majority of these patients there remains no effective therapy for inducing remission 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.

Soft tissue sarcoma is a broad term for cancers that start in soft tissues (muscle, tendons, fat, lymph and blood vessels, and nerves). These cancers can develop anywhere in the body but are found mostly in the arms, legs, chest, and abdomen. A research paper by a recognized source of information in the industry provided market estimates to us in late 2020 and the following estimates are based on that paper.

The lungs are the most frequent site of metastasis from soft-tissue sarcomas. From several studies, it has been estimated that around 50-60% of the STS cases develop lung metastases. Effective systemic therapies for metastatic STS are currently limited; when possible, surgical removal of the lung metastases (known as pulmonary metastasectomy, PM) is the preferred treatment. Metastasectomy and/or chemotherapy are the most common treatments offered to patients with metastatic sarcoma. Pulmonary metastasectomy, either video-assisted or through a formal thoracotomy, has been shown to increase overall survival in select populations of both osseous and soft tissue sarcoma patients. The market is expected to grow as a result of factors like an increase in the patient pool.

The market size of STS with lung metastases in the seven major markets is expected to rise from $177 million in 2017 to reach $198 million by 2030. The total incident population of STS with lung metastases in the seven major markets is anticipated to rise from 7,871 in 2017 to 8,698 by 2030. According to the estimates, the highest market size of STS with lung metastases was estimated in the United States, followed by Germany. The market of STS with lung metastases is categorized into first-line and second-line+ therapies. The therapies in the first line of treatment involve surgery, off-label treatment, and stereotactic radiation therapy (SBRT). It has been estimated that around 60-65% of patients taking the first-line treatment due to relapse of the disease progress on to second-line treatment. Since there are no approved or emerging therapies for treatment of relapsed/refractory patients, first-line therapies are often used again in second-line management. Given this backdrop, we believe the best initial pathway for Annamycin is to pursue the second-line treatment of STS lung metastasis.

Market for Our WP1066 Portfolio

Our two other active development projects, WP1066 and WP1122, have potential 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.

WP1066 is our most published asset (over 50 peer reviewed articles), and we believe it is one of very few drug candidates in the market focused on the inhibition of p-STAT3, and that its mechanism of action is unique. Clinical research on WP1066 is currently focused on the treatment of adult GBM and childhood brain tumors, including DIPG. An industry recognized data source in late 2020 estimated that the incidence rate of primary malignant brain and central nervous system tumors in the U.S. is 7.4 cases per 100,000 person-years. This translates to an incidence of approximately 20,000 cases of malignant brain cancer per year. It is estimated that more than 81,000 people were living with a diagnosis of primary malignant brain and central nervous system tumor in the United States in 2000. In Europe in 2002, 33,000 people were diagnosed with primary brain/CNS cancers, and of which 85-90% are brain tumors. Incidence in Asians is significantly lower and based on the results of several large epidemiological studies, we estimate a Japanese incidence of close to 3,000 a year. Gliomas (mainly glioblastoma and astrocytomas) account for 78% of malignant tumors.

Diffuse Intrinsic Pontine Glioma (DIPG) - also called: Pontine Glioma or Brainstem Glioma – is a type of pediatric (6-9 years old) tumor that starts in the brain stem. These tumors are called gliomas because they grow from glial cells, a type of supportive cell in the brain. DIPG falls into the Glioma staging system, so they can be classified according to the four stages below based on how the cells look under the microscope. The grades are from the least severe to the most severe: Low Grade: Grade I or II means that the tumor cells are the closest to normal; and High Grade: Grade III or IV means that these are the most aggressive tumors. The main issue with DIPG is that most of these tumors are not classified by grade because biopsy or removal of the tumor is not safe because of the location of the tumor, so they are diagnosed by their appearance on MRI. Symptoms usually develop rapidly in the majority of patients because of the fast growth of these tumors. The most common symptoms are issues related to balance and walking; eyes, chewing and swallowing, nausea and vomiting, headaches and facial weakness or drooping (usually one side). 10-20% of all pediatric gliomas are DIPG. DIPG impacts an estimated 200 to 400 children per year in the US alone. After diagnosis, median survival is usually nine months. Only 10% live for more than two years. When compared to pediatric glioblastoma, the prognosis for DIPG is the worst with less overall survival. There are no effective treatments for DIPG.

We believe there is a significant unmet need for an effective treatment for DIPG. While chemotherapy trials of over 200 drugs have not shown any impact on the disease, a DIPG patient in the first cohort of the Emory University study of WP1066 responded to treatment with both a radiologic reduction in tumor size and a clinical improvement in symptoms. While this is only an “n” of one, we believe the response this is important and encouraging, especially since we believe this was a subtherapeutic dose level. In December 2020, we announced that the FDA had approved our request for a "Rare Pediatric Disease" designation for our drug candidate WP1066. The designation may entitle us to receive a transferrable Priority Review Voucher (PRV) upon approval of an NDA for one of three indications, including DIPG, medulloblastoma and atypical teratoid rhabdoid tumor. We believe that the early activity we are seeing in WP1066 is both surprising and encouraging. The approval of these three Rare Pediatric Disease designations is a reminder of just how important our efforts are to potentially help children with brain tumors. These vouchers are issued upon drug approval of the rare disease indication from the FDA and once issued, can be transferred to other drug developers. PRVs have historically had significant value and have recently been sold for up to $100 million or more.

Additionally, WP1220 which is in the WP1066 Portfolio, has shown activity in a clinical trial for the treatment of CTCL. CTCL is a neoplastic transformation of T-lymphocytes and most often occurs between the ages of 40 and 60. Unlike other forms of non- Hodgkin lymphoma, CTCL is initially manifested as skin lesions (mycosis fungoides "MF"), but later stages involve lymph nodes, circulating tumor cells in the blood, as well as viscera. We use an industry respected database Informa Pharma Intelligence to form the following estimates. MF is considered a low-grade cutaneous lymphoma accounting for more than half of primary CTCLs. Early-stage MF (Stages I and II; ~70% of patients) is generally treated with skin-directed treatments (topical therapy) using systemic drugs that do not have significant side effects as secondary treatments. Advanced-stage MF requires more aggressive (systemic) therapies due to more extensive involvement of tissues and organs. Treatment is based mainly on a recently published European Organization for Research and Treatment of Cancer (EORTC) guideline. A consensus guideline for clinical endpoints and response criteria to be incorporated into clinical trials was published. However due to the rarity of this disease, it has been difficult to perform randomized studies. There is currently no cure for this disease

The incidence of CTCL is approximately 16,000 worldwide in 2020 (US + EU 48%) and estimated to be growing to 18,000 by 2026. Asia has the highest incidence (38%). Prevalence is estimated to be 42,000 in US & EU growing to 45,000 with prevalence in Japan growing to a total of 49,000 by 2026. Since this is a chronic disease, we believe introduction of a new topical therapy that is more effective and less toxic than currently available topical drugs (if that is what is shown) would be important to this market. The US market was estimated to represent $40 million in annual sales in 2020, yet consists of technologies that are as much as 40 years old. Our WP1220 Proof of Concept (PoC) Trial for the treatment of CTCL was conducted in 5 patients, including the treatment of a total of 11 lesions and concluded with an objective response rate (ORR) of 45%, no adverse events and 55% stable disease, resulting in 100% clinical benefit. We believe that a significant unmet need remains for early stage (Stages IA through IIA) CTCL, and therefore, we believe a meaningful opportunity exists for WP1220.

Market for Our WP1122 Portfolio

Certain cancers depend heavily on glycolysis and glycosylation for growth and survival. Additionally, viruses depend on glycolysis and glycosylation for infectivity and replication. Glycolysis and glycosylation can be disrupted by using a glucose decoy known as 2-DG. While 2-DG has been shown to be effective in vitro and may have some activity in humans, its lack of drug-like properties limits its efficacy. Based on our preclinical testing in vitro (against cancers and viruses) and in vivo (against certain cancers only), WP1122 appears to improve the drug-like properties of 2-DG by creating a prodrug of 2-DG that reaches much higher tissue/organ concentrations than 2-DG alone. We believe WP1122 should be well suited as a treatment for highly glycolytic cancers such as GBM and pancreatic cancers.

In addition to the market for GBM described above, pancreatic cancer is a rare and difficult to treat form of cancer. Cancers of the exocrine pancreas are a very serious health issue in the United States where approximately 27,000 patients are diagnosed annually with pancreatic cancer while about the same number die annually from this disease. Due to difficulties in diagnosis, the intrinsic aggressive nature of pancreatic cancers, and the sparse systemic treatment options available, only approximately 4% of patients diagnosed with pancreatic adenocarcinoma will be alive five years after diagnosis. Pancreatic cancer is the fifth leading cause of cancer deaths following breast cancer; lung cancer, colon cancer, and prostate cancer.

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, 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 $0.3 million and $0.2 million for the year ended December 31, 2020 and 2019, 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 $0.6 million and $0.5 million for the year ended December 31, 2020 and 2019, respectively. In February 2021, we extended this Agreement until December 31, 2022 for total payment of $1.0 million spread over that period of time.

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. As discussed above, we determined that the stability of WP1732 was less than satisfactory and, as such, in March 2021 we terminated our license for WP1732 with MD Anderson.

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. This agreement was amended in May 2020 to provide for extension of a certain milestone requirement and allowed for us to extend such milestone upon our request and extension payment. The initial milestone required us to file an IND with the FDA for a Phase I study by February 20, 2021. We extended the deadline for this milestone by six months by making the required extension payment, and we have the right to receive two additional six-month extensions in the future by making additional extension payments.

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), which sublicense was amended on March 22, 2021 (the "WPD Agreement"). WPD is affiliated with Dr. Waldemar Priebe, our founder. 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 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").

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, either directly or through the guarantees of grants, by or on behalf of WPD or any of its affiliates of at least: (i) $2.5 million during the first four years of the agreement on the research, development and commercialization of products in the licensed territories; and (ii) $1.0 million annually for the four years thereafter on the research and development of products in the licensed territories.

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 $7.5 million in Commercially Reasonable Development Efforts, the override royalty percentage will decrease to 0.75% of net sales; or (ii) more than $9.5 million in Commercially Reasonable Development Efforts, 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%; 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 $6.5 million; and (B) the denominator of which is $6.5 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. Prior to approval of the March 2021 amendment to the WPD Agreement, our board of directors received a fairness opinion from Maxim Group, LLC stating their opinion that the consideration we will receive from WPD pursuant to the amended 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. 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 71,663 shares of common stock (taking into account the reverse stock split completed January 29, 2021) 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 and clinical development and reduce the overall cost of our continued drug development efforts.

On January 29, 2021, we completed a one-for-six reverse stock split of our shares of common stock and proportionate reduction in the number of authorized shares of common stock from approximately 72,000,000 shares to approximately 12,000,000. The reverse stock split was effected in accordance with the authorization adopted by our stockholders at our 2020 annual meeting of stockholders.

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.

Competition for other indications targeted for each of our drug candidates is described above.

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

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 restoration 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 date 14 years after 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. We cannot be certain that any of our products will qualify for patent term restoration or, if so, for how long the patent term will be extended.

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, 2020 we had ten 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

Summary of Risk Factors:

Below is a summary of the principal factors that make an investment in our company speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below, after this summary, and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making an investment decision in our securities.

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.
- We are conducting important clinical trials in Poland, 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.
- 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 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.
- 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.
- 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.
- A portion of our clinical development plan relies on physician-sponsored trials, which we do not control and which may encounter delays for reasons outside of our control.
- 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.
- 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.
- 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 received Orphan Drug designation for Annamycin and WP1066, but it may not effectively prevent approval of a competing product.
- 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.
- 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.
- Interim or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We may not be able to conduct, or contract others to conduct, animal testing in the future, which could harm our research and development activities.

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.
- The intellectual property rights we have licensed from MD Anderson are subject to the rights of the US government.
- We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.
- 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.
- If we breach any of the agreements under which we license patent rights or if we fail to meet certain development deadlines, pay certain fees including extension fees or exercise certain rights to technology, we could lose or fail to obtain license rights that are important to our business.

Risks Relating to Our Business and Financial Condition

- We will require 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.
- 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.
- 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 have in the past completed related party transactions that were not conducted on an arm's length basis.
- 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 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.
- Our financial condition would be adversely impacted if our intangible assets become impaired.
- 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 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.
- We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.
- We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.
- We do not expect that our insurance policies will cover all of our business exposures thus leaving us exposed to significant uninsured liabilities.
- We may incur penalties if we fail to comply with healthcare regulations.
- We may not be able to recover from any catastrophic event affecting our suppliers.
- 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.
- The COVID-19 outbreak has delayed recruitment in our clinical trials and may continue or worsen, may affect the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to our planned clinical trials and ultimately of reviews and approvals of our product candidates.
- 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 depend on our information technology and infrastructure so compromises could materially harm our ability to conduct business or delay our financial reporting.

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.
- We are an early clinical stage biotechnology company and have incurred significant losses since our inception and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability, which could have an impact on finding additional financing.
- 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 a biotechnology company, we are at increased risk of securities class action litigation.
- 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.
- Failure to maintain our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.
- We cannot predict the effect that our reverse stock split will have on the market price for shares of our common stock.

General Risks

- Your ownership may be diluted if additional capital stock is issued to raise capital, to finance acquisitions or in connection with strategic transactions.
- Negative research about our business published by analysts or journalists could cause our stock price to decline. A lack of regularly published research about our business could cause trading volume or our stock price to decline.
- Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.
- We have no intention of declaring dividends in the foreseeable future.
- Certain provisions in our organizational documents could enable our board of directors to prevent or delay a change of control.
- 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.

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 drug candidates, 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, 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 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.

A portion of our clinical development plan relies on physician-sponsored trials, which we do not control and which may encounter delays for reasons outside of our control.

Our drug product candidate, WP1066, is currently in two physician-sponsored Phase 1 clinical trials, one for adult GBM and another for pediatric brain tumors. In 2021, we expect our drug product candidate, Annamycin, to be in a physician-sponsored Phase 1b/2 clinical trial in Poland for the treatment of STS lung metastases. These physician-sponsored trials are an important part of our clinical development plan. Although we provide drug product and other minor supporting activities for these clinical trials, we are not otherwise directly involved in these physician-sponsored trials. As such, we are dependent on the institutions conducting the trials to proceed with such trials on a timely basis, and we have encountered unforeseen delays in our physician-sponsored trials. For example, in the first quarter of 2021, we were notified that the physician sponsoring our WP1066 trial in adult GBM was leaving MD Anderson. Although we cannot be assured that this trial will continue at MD Anderson after her departure, several additional institutions have expressed an interest in sponsoring similar research on WP1066 in brain tumors, so to help ensure the potential continuation of this important research, regardless of the sponsoring institution, we have requested the IND for this trial to be transferred into our name with the FDA, although there is no assurance we will be successful in completing such transfer. While we are making arrangements to continue this research in additional physician-sponsored trials, we expect that continued research on WP1066 in adult GBM will be delayed. We can provide no assurance that we will not encounter future delays with our physician-sponsored trials.

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 and in 2020 we received notice that the FDA granted ODD for Annamycin for the treatment of soft tissue sarcomas. In February 2019, we received notice that the FDA granted ODD for WP1066 for the treatment of glioblastoma.

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 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. 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 soft tissue sarcomas, 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.

Interim or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

We have in the past, and intend in the future, to publicly disclose preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of preliminary or interim data by us could result in volatility in the price of our common stock.

In addition, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the approvability of the particular drug candidate and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug candidate or our business. If the interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our current or any our future drug candidate, our business, operating results, prospects or financial condition may be materially harmed.

We may not be able to conduct, or contract others to conduct, animal testing in the future, which could harm our research and development activities.

Certain laws and regulations relating to drug development require us to test our product candidates on animals before initiating clinical studies involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

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.

If we breach any of the agreements under which we license patent rights or if we fail to meet certain development deadlines, pay certain fees including extension fees or exercise certain rights to technology, we could lose or fail to obtain license rights that are important to our business.

We license all of our technology from MD Anderson, and we must meet various payment and other obligations under our license agreements with MD Anderson. Our license agreements generally require that we meet various milestones by certain dates, each of which generally requires the payment of additional fees, including extension fees. To date, we have been able meet such milestones, pay certain fees or have been able to enter into extensions with MD Anderson related to such milestones. However, our failure to meet any financial or other obligations under our license agreements in a timely manner could result in the loss of our rights to our core technologies.

We are a party to a number of license agreements with MD Anderson under which we are granted rights to intellectual property that are critical to our business and we expect that we will need to enter into additional license agreements in the future with MD Anderson based on development work we are pursuing under a sponsored research agreement. With respect to inventions arising from our sponsored research agreement, MD Anderson has provided us with an option to negotiate a royalty-bearing, exclusive license to any invention or discovery that is conceived or reduced to practice. However, regardless of such option to negotiate, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue a program based on that technology.

Risks Relating to Our Business and Our Financial Condition

We will require 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. 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 future.

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

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

We have 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 conducting Phase 1 clinical trials. We have only recently completed our initial 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 averse 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 co-founder, 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. (which was amended in March 2021) and Animal Lifesciences, LLC. Dr. Priebe is affiliated with both WPD Pharmaceuticals, Inc. and Animal Lifesciences, LLC.

For the sublicense agreement (and subsequent amendment) with WPD Pharmaceuticals, Inc., since Dr. Priebe was affiliated with the entity, our board of directors received fairness opinions as to the adequacy of the consideration we received in the sublicense agreement (and subsequent amendment). 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, 2020, we incurred a net loss of $17.4 million. We had an accumulated deficit of $56.9 million as of December 31, 2020.

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 it in 2019 for $0.2 million. No similar activity occurred in 2020 and in March 2021 we terminated our license agreement related to WP1732. Management believes that maintaining the subsidiary allows for the possibility of future preclinical and clinical activities to be performed in Australia.

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, 2020. 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, 2020, we had ten 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.

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 COVID-19 outbreak has delayed recruitment in our clinical trials and may continue or worsen, may affect the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to our planned clinical trials and ultimately of reviews and approvals of our product candidates.

The COVID-19 outbreak has delayed recruitment in clinical trials and may continue or worsen. Additionally, it may delay the approvals of our product candidates due to its effect on the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to planned clinical trials. The spread of COVID-19 may also slow potential enrollment of clinical trials and reduce the number of eligible patients for our clinical trials. The COVID-19 outbreak and mitigation measures also have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 outbreak impacts our business and operations will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact. We have relationships with contract research organizations to conduct certain pre-clinical programs and testing and other services in Europe and those business operations are subject to potential business interruptions arising from protective measures that may be taken by the governmental or other agencies or governing bodies. In addition, certain of our collaborative relationships with research facilities and academic research institutions in the United States, Europe and in Australia may be materially and adversely impacted by protective measures taken by those institutions or federal and state agencies and governing bodies to restrict access to, or suspend operations at, such facilities. Such protective measures, including quarantines, travel restrictions and business shutdowns, may also have a material negative affect on our core operations.

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 EU Data Protection Directive entered into force on May 24, 2016 and applied from May 25, 2018. The EU Data Protection Regulation introduced new data protection requirements in the E.U. and substantial fines for breaches of the data protection rules. The EU Data Protection Regulation increased 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 those 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 so compromises could materially harm our ability to conduct business or delay our financial reporting.

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 $57.48 to a low of $1.94 (taking into account the one-for-six reverse stock split completed January 29, 2021), 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.

We are an early clinical stage biotechnology company and have incurred significant losses since our inception and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability, which could have an impact on finding additional financing.

Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We have incurred significant operating losses since inception. We expect to continue to incur significant operating losses for the foreseeable future. To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. We may never succeed in these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability. Our ability to continue our operations depends on our ability to complete equity or debt financings or generate profitable operations in the future and beyond the near term. Such financings may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that could result from the outcome of this uncertainty. If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern

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, 2020, we had a material number of outstanding options and warrants to purchase shares of common stock. As of December 31, 2020, we had warrants and options outstanding to purchase an aggregate of 3,746,771 shares of common stock at an average exercise price of $10.11 per share (taking into account the reverse stock split completed January 29, 2021). 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.

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 $57.48 to a low of $1.94 (taking into account the one-for-six reverse stock split completed January 29, 2021). 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.

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.

We have in the past, and we may again in the future, 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 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.

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.” 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.

We cannot predict the effect that our reverse stock split will have on the market price for shares of our common stock.

On January 29, 2021, we completed a one-for-six reverse stock split of our shares of common stock and proportionate reduction in the number of authorized shares of common stock from approximately 72,000,000 shares to approximately 12,000,000. The reverse stock split was effected in accordance with the authorization adopted by our stockholders at our 2020 annual meeting of stockholders.

We cannot predict the effect that the reverse stock split will have on the market price for shares of our common stock, and the history of similar reverse stock splits for companies in like circumstances has varied. Some investors may have a negative view of a reverse stock split. Even if the reverse stock split has a positive effect on the market price for shares of our common stock, performance of our business and financial results, general economic conditions and the market perception of our business, and other adverse factors which may not be in our control could lead to a decrease in the price of our common stock following the reverse stock split.

Even if the reverse stock split does result in an increased market price per share of our common stock, the market price per share following the reverse stock split may not increase in proportion to the reduction of the number of shares of our common stock outstanding before the implementation of the reverse stock split. Accordingly, even with an increased market price per share, the total market capitalization of shares of our common stock after the reverse stock split could be lower than the total market capitalization before the reverse stock split. Also, even if there is an initial increase in the market price per share of our common stock after the reverse stock split, the market price may not remain at that level.

If the market price of shares of our common stock declines following the reverse stock split, the percentage decline as an absolute number and as a percentage of our overall market capitalization may be greater than would occur in the absence of the reverse stock split due to decreased liquidity in the market for our common stock. Accordingly, the total market capitalization of our common stock following the reverse stock split could be lower than the total market capitalization before the reverse stock split.

General Risks

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.

Negative research about our business published by analysts or journalists could cause our stock price to decline. A lack of regularly published research about our business could cause trading volume or our stock price to decline.

The trading market for our common stock depends in part on the research and reports that analysts and journalists publish about us or our business. If analysts or journalists publish inaccurate or unfavorable research about our business, our stock price would likely decline. If we fail to meet the expectations of analysts for our operating results, or if the analysts who covers us downgrade our stock, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our certificate of incorporation and bylaws contain provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, or DGCL, the personal liability of our directors and executive officers for monetary damages for breach of their fiduciary duties as a director or officer. Our certificate of incorporation and bylaws also provide that we will indemnify our directors and executive officers and may indemnify our employees and other agents to the fullest extent permitted by the DGCL. Any claims for indemnification made by our directors or officers could impact our cash resources and our ability to fund the 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.

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 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") for 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 the 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".

Holders

As of March 11, 2021, there were approximately 146 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 2020 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, 2020.

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

We are a clinical stage pharmaceutical company focused on the treatment of highly resistant cancers and viruses. We have three core technologies, based substantially on discoveries made at MD Anderson Cancer Center (MD Anderson or MDA). We have four drug candidates, three of which have now shown human activity in clinical trials.

During 2020, three of those drug candidates accounted for five clinical trials in the US and Europe. Two of those trials are ongoing externally funded studies of WP1066 in brain tumors. Two of our internally funded Phase 1 clinical trials have essentially concluded. The trial for Annamycin in acute myeloid leukemia (AML) successfully met its safety endpoint, and the trial for WP1220 in cutaneous T-cell lymphoma (CTCL) demonstrated an objective response rate of 45% and a clinical benefit rate of 100%. An additional Phase 1/2 clinical trial of Annamycin in AML is also internally funded and is currently ongoing. In 2021, we anticipate the initiation of five new clinical trials in addition to the three trials continuing from 2020.

In late 2020, we received U.S. Food and Drug Administration (FDA) clearance to proceed with an additional Phase 1b/2 clinical trial of Annamycin for the treatment of sarcoma lung metastases and we are preparing to begin this trial in the US. We also plan to seek approval to begin a Phase 1/2 clinical trial of Annamycin in combination with Ara-C for the treatment of AML in Europe. These two new trials will be internally funded. We expect a second Phase 1b/2 clinical trial of Annamycin in sarcoma lung metastases to be primarily investigator-funded in Europe and we plan to seek a collaborative partner to support a Phase 2 clinical study of WP1220 in CTCL. Finally, we are working to initiate a clinical trial of WP1122, in either a Phase 1a/1b clinical trial in COVID-19 or a physician-sponsored clinical trial for a cancer indication, or both. The ultimate course of action depends on the outcome of additional regulatory and preclinical work. These trials may be internally or externally funded, depending on the timing and nature of the studies. In summary, we had five clinical trials underway or concluded in 2020 and we now expect up to eight clinical trials to be underway or approved in 2021, including physician-sponsored trials related to our drug candidates for which we are not actively involved.

By "internally funded" we mean that the primary costs of the preclinical activity and clinical trials are funded by us. "Externally funded" drug candidates include those for which preclinical work is funded and performed by external collaborators and for which clinical trials are physician-sponsored. For externally funded research, any grant funds that support such preclinical work or clinical trials and most of the associated expenses are not reflected in our financial statements. However, the costs of drug product and other minor supporting activities that we provide for externally funded preclinical activities and clinical trials are included in our financial statements.

We recently announced collaborations with third parties to assist us in developing potential treatments for certain viral diseases, including potentially COVID-19. The preclinical work to evaluate molecules within the WP1122 portfolio of antimetabolites (which include molecules capable of inhibiting glycolysis and altering glycosylation) for viral indications is mostly similar to the preclinical work we originally planned as part of developing WP1122 for cancer indications. Accordingly, we believe the preclinical work under way for WP1122 will support an Investigational New Drug (IND) application or its equivalent in other countries for either cancer-related or virus-related clinical trials (or both) in the first half of 2021. Conducting any such clinical trials for viral diseases is subject to the limited access we have to validated in vivo efficacy testing and our ability to obtain approval from a regulatory body to proceed without in vivo efficacy studies. Additionally, we primarily rely on such collaborations for testing other molecules in the WP1122 portfolio against other hard to treat viruses.

Based on the results of our clinical activity thus far, we have further narrowed our internal development focus to our nearest term opportunities, especially where human activity has been shown in clinical trials. This focus is primarily on preclinical and clinical activities with Annamycin, preclinical activities associated with an intravenous version of WP1066 and IND-enabling studies of WP1122. We intend to rely on external funding, to the extent available. Due to the COVID-19 pandemic, we have internally accelerated development of the WP1122 portfolio with a combined effort of internally and externally funded preclinical work to support an IND application with the FDA or an international regulatory body for the treatment of COVID-19 or a cancer indication or both.

Of our three clinical stage drug candidates, Annamycin is currently in a Phase 1/2 clinical trial for the treatment of acute myeloid leukemia (AML) in Poland. We recently received clearance from the FDA to proceed with a Phase 1b/2 clinical trial of Annamycin as a potential treatment for soft tissue sarcomas (STS) metastasized to the lungs. WP1066, an Immune/Transcription Modulator (p-STAT3 inhibitor or, simply, STAT3 inhibitor) is intended to target a wide range of tumors, including brain tumors such as glioblastoma (GBM) and pediatric brain tumors (like diffuse intrinsic pontine glioma, or DIPG, and medulloblastoma), as well as pancreatic cancer. It is currently in two physician-sponsored Phase 1 clinical trials, one for adult GBM and another for pediatric brain tumors (including DIPG and medulloblastoma). We began and completed a "proof-of-concept" Phase 1 clinical trial in 2019 in Poland for a third drug, WP1220 (a molecule in the WP1066 portfolio), for the topical treatment of cutaneous T-cell lymphoma (CTCL). We are actively seeking collaboration with a strategic partner in the near term for external funding for the continued development of WP1220 in a Phase 2 clinical trial as a topical therapy for CTCL. If we are not successful in this outreach, we may choose to use internal funds to generate additional human data to facilitate such outreach efforts. We are also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as antimetabolites, targeting glycolysis and glycosylation.

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 (the efficacy of all currently approved anthracyclines is limited by both multidrug resistance and cardiotoxicity). We have received an independent expert cardiology assessment confirming the absence of cardiotoxicity in the first 19 patients treated with Annamycin in both our US and European Phase 1 clinical trials. Annamycin is currently in one Phase 1/2 clinical trial in Europe, and the Phase 1 portion of another Phase 1/2 AML trial in the US has been concluded, subject to final database lock and closure. The FDA requested that we demonstrate that Annamycin could be safely administered to patients up to the lifetime maximum allowable level of anthracycline (LTMAD) established by the FDA and the trial met this primary endpoint. The FDA established the LTMAD because of concerns about cardiotoxicity associated with currently approved anthracyclines when administered above the LTMAD. Of the first 19 patients in our trials, 11 have been treated above the LTMAD (one patient received more than double the LTMAD) and none have shown evidence of any cardiotoxicity. As a result of discussions with the FDA, we will focus on establishing a recommended Phase 2 dose (RP2D) in our trial in Europe, and, as requested by the FDA, we will generate additional safety and efficacy data.

The trial in Poland is in its fifth cohort, where patients are being treated at 240 mg/m2. Patient 2 in this cohort experienced a dose limiting toxicity (DLT), related to liver function, secondarily related to concomitant medication not being withheld. Although that DLT resolved, in accordance with the trial protocol, the cohort was expanded and has now enrolled a total of five patients. In March 2021, patient 4 in this cohort experienced a similar DLT and, accordingly, no additional patients will be enrolled at this dose level beyond the five patients enrolled to date. The DLT for Patient 4 is being monitored and, per protocol, other patients in this cohort are permitted to continue to receive the full dose of Annamycin, at the discretion of their physicians and with the patients being notified of the reported DLTs.

We are planning to amend the protocol for this trial to allow exploration of an intermediate dose level between the 210 mg/m2 dose in the fourth cohort and the current 240 mg/m2 dose level, in order to establish the maximum tolerated dosage (MTD) and Recommended Phase 2 dose (RP2D), which may be the same. While this will establish an MTD for Annamycin in AML and inform the starting dose in our planned trials in soft tissue sarcoma (STS) lung metastases, we do not believe it will limit the dose escalation in our STS trials. Because of the different indication and differences in dosing regimen, we expect to determine a separate MTD in the Phase 1 portion of the STS trials. Once the MTD in the single agent AML trial is established, we currently plan to begin the expansion Phase 2 portion of this trial with relapsed patients at the RP2D, in order to determine the potential efficacy of Annamycin as a second line, single agent treatment for relapsed AML. Following on our preclinical research, we also intend to begin the Phase 1 portion of an AML trial using Annamycin in combination with Ara-C, a drug commonly used as a single agent and in combination chemotherapy for AML.

A preliminary review of the data in the completed cohorts in both trials, which is subject to update, indicates that patients received an average of 3+ and a maximum of 9 prior regimens. Thus far in the completed cohorts of our US and European single agent AML trials, there are 13 relapsed patients who were enrolled after one or more relapses from the prior regimens. Of these, 38% had either a CRi, PR or Bridge to Transplant. We view this as encouraging, because recruitment in the expansion Phase 2 will be limited to patients with no more than a single relapse. This is in contrast to the Phase 1 portion of the trial, where, in order to accelerate recruitment, we included a majority of patients who were primarily refractory or who had two or more relapses from alternate therapy. We believe this is significant because patients who are either refractory or have had two or more relapses are considered to be less likely to respond to therapy and especially to a single agent therapy. As a result and considering that all patients in Phase 2 will be treated at the RP2D, we believe the overall response in the expansion Phase 2 may be better than the overall response in the Phase 1 portion of the trial, although we cannot be certain that actual results will reflect this.

Our preclinical work on Annamycin demonstrated activity against certain cancers metastasized to the lungs. In December 2020, we disclosed that the FDA allowed our IND to go into effect to study Annamycin for the treatment of soft tissue sarcoma lung metastases. This allows us to begin a Phase 1b/2 clinical trial in the U.S. for patients with soft tissue sarcoma that has metastasized to the lungs after first-line therapy for their disease. We expect this trial to begin in the first half of 2021. Later in December 2020, we disclosed that the FDA had granted Orphan Drug Designation (ODD) to Annamycin for the treatment of soft tissue sarcomas, in addition to the existing ODD for Annamycin in relapsed or refractory AML. On February 2, 2021, we announced that a preclinical study in animals has confirmed a significant therapeutic benefit of Annamycin against metastatic osteosarcoma. As of day 130 of the study, the survival rate for animals treated with Annamycin was 100%, compared with only 10% for untreated animals. Computerized tomography scans demonstrated that animals treated with Annamycin exhibited suppression of tumor growth and not a single death was observed in the treated animals, whereas observed tumor burden was believed to have contributed to the rapid death of 90% of untreated animals. We believe this data is a promising indication of the possibility of Annamycin’s impact on other cancers metastasized to the lungs. We caution that this is preclinical animal data and we can provide no assurance that we will see similar results in our planned clinical trials.

WP1066 is one of several Immune/Transcription Modulators designed to stimulate the immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs) while also inhibiting key oncogenic transcription factors, including p-STAT3 (phosphorylated signal transducer and activator of transcription 3), c-Myc (a celluar signal transducer named after a homologous avian virus called Myelocytomatosis) and HIF-1α (hypoxia inducible factor 1α). These transcription factors are widely sought targets that are believed to contribute to an increase in cell survival and proliferation, and the angiogenesis (coopting vasculature for blood supply), invasion, metastasis and inflammation associated with tumors. They may also play a role in the inability of immune checkpoint inhibitors to affect more resistant tumors. WP1066 is currently in two US physician-sponsored Phase 1 trials, one at MD Anderson for the treatment of glioblastoma (GBM) in adults and another at Emory University for the treatment of pediatric brain tumors.

The trial at MD Anderson is in the fourth and final cohort in the dose escalation phase. In the first quarter of 2021, we were notified that the physician sponsoring this trial is leaving MDA. We cannot be assured that this trial will continue at MDA after her departure. Several additional institutions have expressed an interest in sponsoring similar research on WP1066 in brain tumors, so to help ensure the potential continuation of this important research, regardless of the sponsoring institution, we have requested the IND for this trial to be transferred into our name with the FDA, although we can provide no assurance as to when, or if, this transfer will be completed. While we are making arrangements to continue this research in additional physician-sponsored trials, we expect that continued research on WP1066 in adult GBM will be temporarily delayed in 2021.

The Emory trial for pediatric brain tumors has now treated three patients in the first cohort. The third and last patient in the second cohort has begun treatment at the dose level of 6mg/kg. In that trial, one of the patients in the first cohort with DIPG showed an apparent response to the treatment with both clinical improvement and radiologic reduction of tumor size. We caution that this is preliminary data, and no conclusions should be drawn from this single event. Another physician-sponsored Phase 1 trial is being considered for the treatment of GBM with WP1066 in combination with radiation, although no assurances can be given that such trial will begin.

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.

As the COVID-19 pandemic unfolded, several independent research teams identified that 2-DG may have the potential to treat COVID-19, as well as other diseases caused by coronaviruses. Similar to the dependence of many tumors on glucose, viruses like SARS-CoV-2 are highly dependent on both glycolysis and glycosylation (and, therefore, glucose) in order to successfully invade host cells and proliferate. It is on this basis that we have established an antiviral drug development program focused on WP1122 and its analogs. We are in the process of identifying the best possible pathway to begin a clinical trial in either COVID-19 or cancer patients or both in the first half of 2021.

The spread of COVID-19 has caused significant volatility in US and international markets, including Poland, where we conduct some of our clinical trials, and Italy, where our drug supply is produced. There has been limited interruption of our drug supply, and most Polish clinics where we are conducting trials are limiting access for monitoring activities, which could delay our ability to collect data and authorize new patient recruitment. Additionally, we believe COVID-19 has materially slowed the ability of approved sites to recruit patients for our trials. This could worsen or be alleviated 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, we are unable to determine if it will have a material impact to our operations. Recently, we have experienced a limited increase in activity with regard to recruitment of new patients in Poland. Additionally, we believe that the potential for impact to our supply chain due to COVID-19 will be reduced as vaccine production normalizes throughout the industry. In light of current US trends with respect to COVID-19, we cannot determine whether COVID-19 will materially impact recruitment for current or future US based trials.

We do not have manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, we do not have and do not intend to have a sales organization. Our overall strategy is to seek potential outlicensing opportunities with larger pharmaceutical companies who are better suited for the marketing, sales and distribution of our drugs once approved.

Recent Developments

Equity Offerings

Subsequent to December 31, 2020, we issued equity and received gross proceeds of $80.9 million. During January 2021 we issued approximately 469,000 shares for gross proceeds of $2.9 million using our At The Market Agreement with Oppenheimer & Co., Inc. Additionally, on February 3, 2021, we announced the pricing of an underwritten public offering of an aggregate of 14,273,684 shares of common stock at a public offering price of $4.75 per share. We granted the underwriters a 30-day option to purchase up to an additional 2,141,052 shares of common stock offered in the public offering. The offering closed on February 5, 2021 and gross proceeds of the offering were approximately $67.8 million, prior to deducting the underwriting discount and other estimated offering expenses. On February 10, 2021, the underwriters of the public offering exercised in full their option to purchase an additional 2,141,052 shares of common stock at the public offering price of $4.75 per share, bringing total gross proceeds to approximately $78.0 million before underwriting discount.

Engagement of a Clinical Research Organization for the STS Lung Metastasis Clinical Trial

On February 1, 2021, we entered into an agreement with Catalyst Clinical Research (Catalyst), a contract research organization, to manage our US clinical trial to study the ability of Annamycin to treat soft tissue sarcoma (STS) that has metastasized to the lungs.

Moleculin Biotech, Inc.
Results of Operations for the Year Ended December 31, 2020 as Compared to the Year Ended December 31, 2019

The following table is data derived from the Consolidated Statement of Operations (in thousands) and the discussions that follow are in approximate amounts:

	Year ended December 31,	
	2020	**2019**
Revenue	$ —	$ —
Operating expenses:		
Research and development	12,757	11,013
General and administrative	6,785	6,312
Depreciation and amortization	200	199
Total operating expense	19,742	17,524
Loss from operations	(19,742)	(17,524)
Other income:		
Gain from change in fair value of warrant liability	2,346	4,062
Other income, net	28	15
Interest income, net	13	13
Net loss before taxes	(17,355)	(13,434)
Income tax benefit	-	229
Net loss	$ (17,355)	$ (13,205)

Research and Development Expense

Research and development (R&D) expense was $12.8 million and $11.0 million for the years ended December 31, 2020 and 2019, respectively. The increase in R&D of $1.8 million mainly relates to: increased clinical trial activity (3 drugs in 4 clinical trials in 2019, versus 3 drugs in 5 clinical trials in 2020), increased costs related to sponsored research agreements, costs related to manufacturing of additional drug product and two additional employees in R&D headcount.

General and Administrative Expense

General and administrative (G&A) expense was $6.8 million and $6.3 million for the years ended December 31, 2020 and 2019, respectively. The increase in G&A of $0.5 million was mainly attributable to increased payroll related costs for an additional finance staff, increased stock-based compensation expense, and increased costs for directors and officer's liability insurance being partially offset by reduced travel expenses due to the COVID-19 pandemic.

Gain from Change in Fair Value of Warrant Liability

We recorded a gain of $2.3 million during the year ended December 31, 2020 as compared to a gain of $4.1 million, during the year ended December 31, 2019, 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. Generally, 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, 2020 was $17.4 million, which included non-cash gains of $2.3 million on warrants in 2020 as compared to $4.1 million in the prior year and approximately $1.7 million of stock-based compensation expense in 2020 as compared to $1.5 million in 2019.

Liquidity and Capital Resources

As of December 31, 2020, we had cash and cash equivalents of $15.2 million and prepaid expenses and other expenses of $2.0 million. We also had $1.1 million of accounts payable and $1.8 million of accrued expenses and other current liabilities. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our preclinical activities and our clinical trials. For the years ended December 31, 2020 and 2019, we used approximately $17.8 million and $17.2 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 2020 reflects the increase in preclinical and clinical activity over 2019. For the year ended December 31, 2020, net proceeds from financing activities were $22.5 million, predominately from the sale of our common stock and warrants. In 2019, approximately $20.9 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, 2020 was approximately $0.4 million primarily related to mass spectrometer equipment purchased for the lab in 2020. The equipment will be used to analyze uptake, metabolism, and tissue organ distribution of anti-cancer and anti-viral agents, which is critical for determination of pharmacokinetic and pharmacodynamic parameters of the drug.

Subsequent to December 31, 2020, we issued equity and received gross proceeds of $80.9 million. During January 2021 we issued approximately 469,000 shares for gross proceeds of $2.9 million using our At The Market Agreement with Oppenheimer & Co., Inc., discussed below. Additionally, on February 3, 2021, we announced the pricing of an underwritten public offering of an aggregate of 14,273,684 shares of common stock at a public offering price of $4.75 per share. We granted the underwriters a 30-day option to purchase up to an additional 2,141,052 shares of common stock offered in the public offering. The offering closed on February 5, 2021 and gross proceeds of the offering were approximately $67.8 million, prior to deducting the underwriting discount and other estimated offering expenses. On February 10, 2021, the underwriters of the public offering exercised in full their option to purchase an additional 2,141,052 shares of common stock at the public offering price of $4.75 per share, bringing total gross proceeds to approximately $78.0 million before underwriting discount.

We believe that our cash resources as of December 31, 2020, along with the additional funding received subsequent to year-end, will be sufficient to meet our projected operating requirements, which include a potential increase over our current R&D rate of expenditures, through at least the year 2023. Such projections are subject to changes in our internally funded preclinical and clinical activities, including unplanned preclinical and clinical activity. We anticipate incurring operating losses for the next several years as we support the preclinical and clinical activities necessary to prepare our drug candidates for successful out licensing, including our efforts to expand our technologies. These factors raise uncertainties about our ability to fund operations in future years. If we need to raise additional capital in order to continue to execute our business plan, there is no assurance that additional financing will be available when needed or that we will be able to obtain financing on terms acceptable to us. A failure to raise sufficient capital could adversely impact our ability to achieve our intended business objectives and meet our financial obligations as they become due and payable.

February 2020 Stock Offering

In February 2020 we entered into subscription agreements with certain institutional investors for the sale of up to 1,250,000 shares of our common stock (taking into account the one-for-six reverse stock split completed January 29, 2021) and warrants to purchase 937,501 shares of common stock (taking into account the one-for-six reverse stock split completed January 29, 2021) at a combined public offering price of $4.80 per share and related warrant. The warrants were exercisable commencing six months from the date of issuance at a price of $6.30 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.

Lincoln Park Equity Line

In November 2020, we entered into a purchase agreement (the 2020 Purchase Agreement) with Lincoln Park Capital Fund, LLC (Lincoln Park). Pursuant to the terms of the 2020 Purchase Agreement, Lincoln Park agreed to purchase from us up to $22.0 million of the Company's common stock (subject to certain limitations) from time to time during the term of the 2020 Purchase Agreement. Pursuant to the terms of the 2020 Purchase Agreement, at the time we signed the 2020 Purchase Agreement, we issued 126,699 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2020 Purchase Agreement. During the year ended December 31, 2020, pursuant to the 2020 Purchase Agreement, we sold Lincoln Park 638,203 shares of common stock, and issued a total of 133,017 commitment shares, at an average price of $4.30 per share, resulting in gross proceeds of $2.7 million. We terminated the 2020 Purchase Agreement on February 2, 2021.

ATM Agreements

In July 2020, we entered into a new At Market Issuance Sales Agreement with Oppenheimer & Co. Inc. (the 2020 ATM Agreement). Pursuant to the terms of the 2020 ATM Agreement, the Company was able to sell from time to time through Oppenheimer shares of the Company's common stock with an aggregate sales price of up to $15.0 million. During the year ended December 31, 2020, pursuant to the 2020 ATM Agreement, the Company issued 471,405 shares of common stock at an average price of $6.11 per share, resulting in net proceeds of $2.8 million.

In addition, at December 31, 2020, we had 26,966 shares of our common stock subscribed in ATM transactions under the 2020 ATM Agreement for net proceeds, after deducting commissions and other transaction costs, of approximately $0.1 million at an average selling price of $4.96 per share. Accordingly, we have recorded a subscription receivable of $0.1 million as a reduction of stockholders' equity in our consolidated balance sheet as of December 31, 2020. We terminated the 2020 ATM Agreement on February 2, 2021.

In July 2019, we entered into an at-the-market equity agreement (the 2019 ATM Agreement) with Oppenheimer & Co. Inc. During the year ended December 31, 2020, pursuant to the 2019 ATM Agreement, we issued 1,412,017 shares of common stock at an average price of $8.68 per share, resulting in net proceeds of $11.9 million. We paid a commission to Oppenheimer equal to 3.0% of the gross proceeds from the sale of our common stock under the 2019 ATM Agreement. In the third quarter of 2020, the 2019 ATM Agreement expired and was terminated.

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

	For the Year Ended December 31,	
	2020	2019
Net cash used in operating activities	$ (17,771)	$ (17,198)
Net cash used in investing activities	(374)	(51)
Net cash provided by financing activities	22,549	20,854
Effect of exchange rate changes on cash and cash equivalents	34	(4)
Net change in cash and cash equivalents	$ 4,438	$ 3,601

Cash used in operating activities

Net cash used in operating activities was $17.8 million for the year ended December 31, 2020 compared to $17.2 million for the year ended December 31, 2019. 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; 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 $0.4 million for the year ended December 31, 2020 compared to $0.05 million for the year ended December 31, 2019. The increase relates to mass spectrometer equipment purchased for the lab in 2020. The equipment will be used to analyze uptake, metabolism, and tissue organ distribution of anti-cancer and anti-viral agents, which is critical for determination of pharmacokinetic and pharmacodynamic parameters of the drug.

Cash provided by financing activities

Net cash provided by financing activities was $22.5 million for the year ended December 31, 2020 compared to the prior period of $20.9 million. Net cash provided by financing in 2020 consisted primarily of net proceeds from issuance of common stock. The prior period financing activities consisted primarily of $19.3 million net proceeds from issuance of common stock, and $1.6 million net proceeds from the exercise of warrants.

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 (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, 2019, and 2020. 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, 2019, and 2020 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, April 2019, and February 2020 Offerings (Offerings) are included in long-term liabilities on the accompanying financial statements as of December 31, 2020 and 2019 respectively.

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 was 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 was 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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are 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 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. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits 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.

Management concluded that our disclosure controls and procedures were effective as of December 31, 2020.

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.

Remediation of a Prior Material Weakness

We previously identified and disclosed in our 10-K filed with the SEC on March 19, 2020, as well as in our quarterly reports for March 31, 2020, June 30, 2020, and September 30, 2020, a material weakness related to a lack of segregation of duties associated with the design of our internal controls.

With input and oversight from the Audit Committee, we implemented a remediation plan to ensure that control deficiencies contributing to the material weakness were remediated such that these controls will operate effectively. We took the following remediation actions which have facilitated the proper segregation of duties in the initiation of transactions, the recording of transactions, and the custody of assets:

- Implemented new information technology systems and policies and procedures;
- Management added additional accounting and IT personnel, including the use of qualified contractors;
- Developed formalized accounting procedures and clearly defined authorities;
- Engaged third party specialists to assess and document the design of our internal controls over financial reporting including the evaluation of proper segregation of duties, and to identify and evaluate any weaknesses in our information systems;
- Reported regularly to the audit committee on the progress and results of the remediation plan, including the identification, status and resolution of internal control deficiencies.

These actions resulted in an improved internal control environment with enhanced segregation of duties that were in place for a period of time to allow for our management to conclude, based on evidence obtained in validating the design and implementation of these controls, that we have fully remediated this material weakness as of December 31, 2020.

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 Rule 13a-15(f). Management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2020. 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 effective as of December 31, 2020.

Changes in Internal Control Over Financial Reporting

Except for those remedial actions described above, there was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Annual Report on Form 10-K 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 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2020 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 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2020 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 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2020 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 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2020 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 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2020 and is incorporated into this Annual Report on Form 10-K by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

a. Documents filed as part of this Report

1. Financial Statements

The financial statements and notes thereto which are attached hereto have been included by reference into Item 8 of this part of the annual report on Form 10-K. See the Index to Financial Statements on page 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	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 January 29, 2021)
3.4	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)
4.10*	Description of Registrant's Securities
10.1 **	Moleculin Biotech, Inc. Amended and Restated 2015 Stock Plan (incorporated by reference to Annex B to the preliminary proxy statement filed March 27, 2020)
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	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)
10.16	Lease Agreement for 5300 Memorial (incorporated by reference to Exhibit 10.1 of the Form 10-Q filed May 14, 2018)
10.17 †	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)
10.18	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)
10.19	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)
10.20	Consulting Agreement, dated March 16, 2020, entered into between the Company and Houston Pharmaceuticals, Inc. (HPI) (incorporated by reference to Exhibit 10.24 of the Form 10-K filed March 19, 2020)
10.21	Equipment Lab Letter, dated March 16, 2020, entered into between the Company and Houston Pharmaceuticals, Inc. (HPI) (incorporated by reference to Exhibit 10.25 of the Form 10-K filed March 19, 2020)
10.22	Scientific Advisory Board Agreement, dated February 28, 2020, entered into between the Company and Waldemar Priebe, PhD (incorporated by reference to Exhibit 10.26 of the Form 10-K filed March 19, 2020)
10.23*	Amended and Restated Sublicense Agreement entered into between the Company and WPD Pharmaceuticals dated March 22, 2021

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 *	Inline XBRL Instance Document
101.SCH *	Inline XBRL Taxonomy Extension Schema Document
101.CAL *	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF *	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB *	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE *	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* 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 24, 2021

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 24, 2021
/s/ Jonathan P. Foster Jonathan P. Foster	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 24, 2021
/s/ Robert George Robert George	Director	March 24, 2021
/s/ Michael Cannon Michael Cannon	Director	March 24, 2021
/s/ John Climaco John Climaco	Director	March 24, 2021
/s/ Elizabeth Cermak Elizabeth Cermak	Director	March 24, 2021

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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

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 24, 2021

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

	December 31,	
	2020	**2019**
Assets		
Current Assets:		
Cash and cash equivalents	$ 15,173	$ 10,735
Prepaid expenses and other current assets	2,025	2,749
Total current assets	17,198	13,484
Furniture and equipment, net of accumulated depreciation of $474 and $284, respectively	483	316
Intangible assets	11,148	11,148
Operating lease right-of-use asset	202	287
Total Assets	$ 29,031	$ 25,235
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,129	$ 2,153
Accrued expenses and other current liabilities	1,791	1,417
Total current liabilities	2,920	3,570
Operating lease liability - long-term, net of current portion	159	276
Warrant liability - long-term	8,192	5,818
Total Liabilities	11,271	9,664
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 authorized as of December 31, 2020 and December 31, 2019, 11,536,720 and 7,621,338 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	69	46
Additional paid-in capital	74,671	55,055
Subscription receivable	(129)	—
Accumulated other comprehensive income	65	31
Accumulated deficit	(56,916)	(39,561)
Total stockholders' equity	17,760	15,571
Total liabilities and stockholders' equity	$ 29,031	$ 25,235

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,	
	2020	**2019**
Revenue	$ —	$ —
Operating expenses:		
Research and development	12,757	11,013
General and administrative	6,785	6,312
Depreciation and amortization	200	199
Total operating expenses	19,742	17,524
Loss from operations	(19,742)	(17,524)
Other income:		
Gain from change in fair value of warrant liability	2,346	4,062
Other income, net	28	15
Interest income, net	13	13
Net loss before taxes	(17,355)	(13,434)
Income tax benefit	—	229
Net loss	$ (17,355)	$ (13,205)
Net loss per common share - basic and diluted	$ (1.76)	$ (1.95)
Weighted average common shares outstanding, basic and diluted	9,845,685	6,786,901
Comprehensive loss:		
Net loss	$ (17,355)	$ (13,205)
Other comprehensive income (loss):		
Foreign currency translation	34	(4)
Comprehensive loss	$ (17,321)	$ (13,209)

See accompanying notes to these consolidated financial statements.

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

	December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (17,355)	$ (13,205)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	200	199
Stock-based compensation	1,680	1,537
License rights expense settled in stock	—	490
Loss (gain) from sale of fixed assets	6	(1)
Change in fair value of warrant liability	(2,346)	(4,062)
Operating lease, net of sublease receipts	85	(14)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	724	(1,909)
Accounts payable	(1,024)	907
Accrued expenses and other current liabilities	259	(1,140)
Net cash used in operating activities	(17,771)	(17,198)
Cash flows from investing activities:		
Purchase of fixed assets	(376)	(52)
Proceeds from sale of fixed assets	2	1
Net cash used in investing activities	(374)	(51)
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	5
Proceeds from exercise of warrants	5	1,557
Payment of tax liability for vested restricted stock units	(17)	—
Proceeds from sale of common stock, net of issuance costs	22,561	19,292
Net cash provided by financing activities	22,549	20,854
Effect of exchange rate changes on cash and cash equivalents	34	(4)
Net change in cash and cash equivalents	4,438	3,601
Cash and cash equivalents, at beginning of year	10,735	7,134
Cash and cash equivalents, at end of year	$ 15,173	$ 10,735
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ —	$ 1
Cash paid for taxes	$ 24	$ 19
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued liabilities	$ —	$ 22
Subscription receivable	$ 129	$ —
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		Common Stock Subscribed						
	Shares	Par Value Amount	Shares	Par Value Amount	Additional Paid-In-Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Subscription Receivable	Stockholders' Equity
Balance at December 31, 2018	4,754,829	$ 29	—	$ —	$ 40,564	$ (26,356)	$ 35	$ —	$ 14,272
Issued for cash - sale of common stock in March 2019, net of issuance costs of $617	875,000	5	—	—	3,221	—	—	—	3,226
Issued to Lincoln Park - sale of common stock, net of $59 issuance costs	117,674	—	—	—	935	—	—	—	935
Issued for cash - sale of common stock in April 2019, net of issuance costs of $1,300	1,562,500	9	—	—	3,575	—	—	—	3,584
Common stock issued for license rights	71,663	1	—	—	489	—	—	—	490
Warrants exercised	235,505	2	—	—	4,729	—	—	—	4,731
Stock options exercised	4,167	—	—	—	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	7,621,338	$ 46	—	$ —	$ 55,055	$ (39,561)	$ 31	$ —	$ 15,571
Issued for cash - sale of common stock in February 2020, net of issuance costs of $709	1,250,000	7	—	—	559	—	—	—	566
Issued for cash - sale of common stock pursuant to the 2019 ATM Agreement, net of issuance costs of $471	1,412,017	8	—	—	11,778	—	—	—	11,786
Issued for cash - sale of common stock pursuant to the 2020 ATM Agreement, net of issuance costs of $108	471,405	3	—	—	2,770	—	—	—	2,773
Issued for cash - sale of common stock to Lincoln Park, net of issuance costs of $575	771,220	5	—	—	2,708	—	—	—	2,713
Subscription of common stock in connection with the 2020 ATM Agreement, net of commissions	—	—	26,966	—	129			(129)	—
Warrants exercised	750	—	—	—	9	—	—	—	9
Common stock issued upon vesting of restricted stock units (net of shares withheld for payment of tax liability)	9,990	—	—	—	(17)	—	—	—	(17)
Stock based compensation	—	—	—	—	1,680	—	—	—	1,680
Consolidated net loss	—	—	—	—	—	(17,355)	—	—	(17,355)
Cumulative translation adjustment	—	—	—	—	—		34	—	34
Balance at December 31, 2020	11,536,720	$ 69	26,966	$ —	$ 74,671	$ (56,916)	$ 65	$ (129)	$ 17,760

See accompanying notes to these consolidated financial statements.

Moleculin Biotech, Inc.
Notes to the Consolidated Financial Statements

1. Nature of Business

The terms “MBI” or “the Company”, “we”, “our” and “us” are used herein to refer to Moleculin Biotech, Inc. MBI is a clinical-stage pharmaceutical company, organized as a Delaware corporation in July 2015, with its focus on the treatment of highly resistant cancers and viruses through the development of its drug candidates, based substantially on discoveries licensed from 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 perform certain preclinical development in Australia. This has enabled the Company to realize 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.

The Company has three core technologies: 1) Annamycin which the Company believes is a "next generation" anthracycline; 2) Immune/Transcription Modulators, of which WP1066 is a member; and 3) Metabolism/Glycosylation Inhibitors, of which WP1122 is a member. The Company has four drug candidates, representing all three core technologies, and three of which have shown human activity in clinical trials. As of the end of 2020, those three drug candidates accounted for five clinical trials in the US and Europe. Two of those trials are ongoing externally funded studies of WP1066 in brain tumors. Two internally funded Phase 1 clinical trials, Annamycin in acute myeloid leukemia (AML), and WP1220 in cutaneous T-cell lymphoma (CTCL), were successfully concluded. An additional Phase 1/2 clinical trial of Annamycin in AML is also internally funded and is currently ongoing. In 2021, we anticipate the initiation of five new clinical trials in addition to the three trials continuing from 2020.

In late 2020, MBI received U.S. Food and Drug Administration (FDA) clearance to proceed with an additional Phase 1b/2 clinical trial of Annamycin for the treatment of sarcoma lung metastases and the Company is preparing to begin this trial in the US. MBI also plans to seek approval to begin a Phase 1/2 clinical trial of Annamycin in combination with Ara-C for the treatment of AML in Europe. MBI expects a second Phase 1b/2 clinical trial of Annamycin in sarcoma lung metastases to be primarily investigator-funded in Europe and the Company plans to begin a Phase 2 clinical study of WP1220 in CTCL. The Company is also working to initiate a clinical trial of WP1122, in either a Phase 1a/1b clinical trial in COVID-19 or a physician-sponsored clinical trial for a cancer indication, or both. The ultimate course of action depends on the outcome of additional regulatory and preclinical work. These trials may be internally or externally funded, depending on the timing and nature of the studies. In summary, we had five clinical trials underway or concluded in 2020 and we now expect up to eight clinical trials to be underway or approved in 2021.

The Company does not have manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, the Company does not have and does not intend to have a sales organization. The Company’s overall strategy is to seek potential outlicensing opportunities with larger pharmaceutical companies who are better suited for the marketing, sales and distribution of our drugs once approved.

COVID-19 - 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 world. The spread of COVID-19 has caused significant volatility in US and international markets, including Poland, where MBI conducts some of its clinical trials and Italy, where its drug supply is produced. There has been limited interruption of its drug supply, and most Polish clinics where the Company is conducting trials are limiting access for monitoring activities. Additionally, MBI believes COVID- 19 has materially slowed the recruitment of patients for its trials. This could worsen or be alleviated 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. Additionally, the Company believes that the potential for impact to its supply chain due to COVID-19 will be reduced as vaccine production normalizes throughout the industry. In light of current US trends with respect to COVID-19, MBI does not expect COVID-19 to materially impact recruitment for current or future US based trials as COVID-19 hospitalizations have recently decreased. However, the Company cannot be certain that these trends will continue and there is the possibility they may reverse.

2. Basis of presentation, principles of consolidation and significant accounting policies

Reverse Stock Split - On January 29, 2021, pursuant to authority granted by our stockholders, our board of directors approved a one-for-six reverse stock split of our common stock and the filing of an amendment to our amended and restated certificate of incorporation to effectuate the reverse stock split. The amendment was filed with the Secretary of State of the State of Delaware and the reverse stock split became effective in accordance with the terms of the amendment at 5:00 p.m. Eastern Time on January 29, 2021 (the “Effective Time”). The amendment provides that, at the Effective Time, every six shares of our issued and outstanding common stock will automatically be combined into one issued and outstanding share of common stock, without any change in par value per share, which will remain $0.001. The accompanying consolidated financial statements and notes to the consolidated financial statements gives retroactive effect to the reverse stock split for all periods presented. Certain amounts in the financial statements, the notes thereto, and elsewhere in the Form 10-K may be slightly different than previously reported due to rounding up of fractional shares as a result of the Reverse Stock Split.

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 as one segment. As a result, the financial information disclosed herein represents all of the material financial information related to our principal operating segment.

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

Liquidity and Financial Condition - The Company is an early stage and emerging growth company (EGC) and has not generated any revenues to date. As such, the Company is subject to all of the risks associated with early stage and emerging growth companies. Since inception, the Company has incurred losses and negative cash flows from operating activities.

For the years ended December 31, 2020 and 2019, the Company incurred net losses of $17.4 million and $13.2 million, respectively, and had net cash flows used in operating activities of $17.8 million and $17.2 million, respectively. At December 31, 2020, the Company had an accumulated deficit of $56.9 million and cash of $15.2 million. Subsequent to December 31, 2020, we issued equity and received gross proceeds of $80.9 million, described more fully below. The Company expects its cash on hand as of December 31, 2020 plus the cash received subsequent to year-end will be sufficient to fund the Company's operations beyond the near term. Such projections are subject to changes in the Company's internally funded preclinical and clinical activities, including unplanned preclinical and clinical activity. The Company does not expect to experience positive cash flows from operating activities in the near future and anticipates incurring operating losses for the next few years as it supports the development of its core technologies to the point of generating revenue, most likely via outlicensing, and continues to invest in research and development for additional applications of the Company's core technologies and potentially increase its pipeline of drug candidates. The Company anticipates incurring operating losses for the next several years. If we need to raise additional capital in order to continue to execute our business plan, there is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us. A failure to raise sufficient capital could adversely impact our ability to achieve our intended business objectives and meet our financial obligations as they become due and payable.

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,	
	2020	**2019**
Vendor prepayments and deposits	$ 1,281	$ 1,857
Prepaid insurance	579	352
Other current assets	164	529
Related party receivables	—	10
Non-trade receivables	1	1
Total prepaid expenses and other current assets	$ 2,025	$ 2,749

Vendor prepayments at December 31, 2020 and 2019 includes approximately $1.1 million and $1.5 million, respectively, for the expansion of Annamycin production commitments on a commercial scale currently expected to be delivered in the first half of 2021 for use 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:

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

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

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

The Company’s financial assets and liabilities recorded at fair value on a recurring basis include the fair value of our warrant liability discussed in Note 6.

The following table provides the financial assets and liabilities reported at fair value and measured on a recurring basis at December 31, 2020 and 2019 (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, 2020	$ 8,192	$ —	$ —	$ 8,192
December 31, 2019	$ 5,818	$ —	$ —	$ 5,818

The following table provides a summary of changes in fair value associated with the Level 3 liabilities for the years ended December 31, 2020 and 2019 (in thousands):

	Warrant Liability Current	Warrant Liability Long-Term	Warrant Liability Total
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
Exercise of warrants	—	(4)	(4)
Issuances of warrants	—	4,724	4,724
Change in fair value - net	—	(2,346)	(2,346)
December 31, 2020	$ —	$ 8,192	$ 8,192

The above table of Level 3 liabilities begins with the valuation as of December 31, 2018 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, modifications to existing stock options, and equity classified warrants 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 (or if the date of grant is not a business day, on the business day prior to the date of the 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, net of forfeitures which are recognized as they occur. In 2019, compensation expense related to awards to non-employees with service-based vesting conditions was 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. In 2020, compensation expense related to awards to non-employees with performance-based vesting conditions is recognized based on the grant date fair value. Effective January 1, 2020, the Company began using the volatility of its own stock since it now has sufficient historic data in its stock price.

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, 2020, and 2019, approximately 3.6 million and approximately 2.0 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.

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 and elsewhere in other notes to the financial statements.

Recent Accounting Pronouncements

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, 2020 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 afterDecember 15, 2020. Early adoption is permitted upon issuance of this ASU. The Company adoption of this pronouncement effective December 15, 2020 did not have a material impact on the Company's consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40) (ASU 2020-06). ASU 2020-06 amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. The Board observed that the application of the derivatives scope exception guidance results in accounting for some contracts as derivatives while accounting for economically similar contracts as equity. The Board also decided to improve and amend the related EPS guidance. The amendments in this Update are effective for public business entities that meet the definition of a Securities and Exchange Commission (SEC) filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning afterDecember 15, 2020, including interim periods within those fiscal years. 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 butnot 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, 2020 and 2019, respectively.

4. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities at December 31, 2020 and 2019 consist of the following components (in thousands):

	December 31,	
	2020	2019
Accrued chemistry manufacturing and control costs	$ 460	$ 49
Accrued payroll and bonuses	426	436
Accrued clinical activities	281	93
Accrued legal, regulatory, and professional	178	272
Accrued license fees and sponsored research agreements	166	201
Operating lease liability - current	118	103
Accrued other	84	164
Related party payable	78	99
Total accrued expenses and other current liabilities	$ 1,791	$ 1,417

Additionally, Accounts payable includes $48,000 and zero as of December 31, 2020 and 2019, respectively, for a related party payable to HPI.

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, 2020 and 2019, the Company has the following warrants outstanding:

	Number of Shares Under Outstanding Warrants at December 31, 2020	Number of Shares Under Outstanding Warrants at December 31, 2019	Weighted Average Exercise Price at December 31, 2020	Remaining Contractual Life at December 31, 2020 (Years)
Liability Classified Warrants (1)				
Issued February 2017	67,349	67,349	$ 8.42	1.1
Issued February 2018	378,951	378,951	16.80	2.6
Issued June 2018 (2)	123,836	123,836	12.20	2.9
Issued March 2019	263,507	264,257	6.60	3.2
Issued April 2019	875,001	875,001	10.50	3.3
Issued February 2020	1,025,001	—	6.30	4.6
	2,733,645	1,709,394	$ 9.45	
Equity Classified Warrants				
Issued May 2016 - Bonwick	17,970	17,970	$ 45.00	0.3
Issued July 2017 - Consulting (3)	25,001	25,001	15.64	1.6
Issued April 2018 - Consulting	16,667	16,667	18.00	0.2
Issued August 2019 - Consulting	25,000	25,000	9.84	1.6
Issued April 2020 - Consulting	16,667	—	6.84	4.3
Issued December 2020 - Consulting	8,334	—	4.72	5.0
	109,639	84,638	$ 17.32	
Balance outstanding	2,843,284	1,794,032	$ 9.75	

(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 118,372 shares at an exercise price of $12.12, expiring December 22, 2023, and warrants to purchase 5,464 shares at an exercise price of $13.92, expiring June 21, 2023.

(3) Includes warrants to purchase 16,667 shares at an exercise price of $14.46 and warrants to purchase 8,334 shares at an exercise price of $18.00.

Liability Classified Warrants

The Company uses the Black-Scholes option pricing model (BSM) 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 onzero 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. Beginning in 2020, only the volatility of the Company's own stock is used in the BSM as it now has sufficient historic data in its stock price. In 2019, the Company used the volatility of its own stock blended with the volatility of peer entities due to the lack of sufficient historical data of its stock price.

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

	Year Ended December 31,	
	2020	2019
Risk-free interest rate	0.1% to 0.3%	1.6% to 1.7%
Volatility	113.7% to 127.4%	97.5% to 107.5%
Expected life (years)	1.1 to 4.6	2.1 to 4.3
Dividend yield	— %	— %

A summary of the Company's liability classified warrant activity during the year ended December 31, 2020 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, 2019	1,709,394	6.600 to 16.8080	$ 11.33	4.0
Granted	1,025,001	6.300 to 6.3030	$ 6.30	4.6
Exercised	(750)	6.600 to 6.6060	$ 6.60	—
Expired	—	—	$ —	—
Outstanding at December 31, 2020	2,733,645	6.300 to 16.8080	$ 9.45	3.6
Vested and Exercisable at December 31, 2020	2,733,645	6.300 to 16.8080	$ 9.45	3.6

In connection with the Company's stock offering that closed in February 2020, the Company issued warrants to purchase 937,501 shares of its common stock, that are exercisable six months from the date of issuance, at a price of $6.30 per share, subject to adjustment in certain circumstances, and expire five years from the date they are first exercisable, and issued Oppenheimer & Co. Inc. a warrant (Underwriter Warrant) to purchase up to 87,500 shares of its common stock with an exercise price of $6.30 per share, subject to adjustment in certain circumstances, which expires in February 2025.

For a summary of the changes in fair value associated with our warrant liability for the years ended December 31, 2020 and 2019, see Note 2. Basis of presentation, principles of consolidation and significant accounting policies – Fair Value of Financial Instruments.

Equity Classified Warrants

In December 2020, equity warrants to purchase up to 8,334 shares of common stock were issued to a consultant, with vesting contingent on certain conditions focused on executing licensing arrangements.

In April 2020, equity warrants to purchase up to 16,667 shares of common stock were issued to a consultant, with vesting contingent on certain conditions focused on generating up to $10.0 million of approved research and development expenditures on the Company's drug portfolio.

At December 31, 2020 the Company had 109,639 equity classified warrants outstanding and 85,472 warrants were exercisable. At December 31, 2019, the Company had 84,638 equity classified warrants outstanding and all were exercisable.

The Company recorded stock compensation expense for the non-employee consulting agreements of $5,000 and $94,000 for the years ended December 31, 2020 and 2019, respectively. At December 31, 2020, there was $124,000 of unrecognized stock compensation expense related to the Company's equity-classified warrants.

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 inone 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, 2020, the Company has not issued any preferred stock.

Common Stock

February 2020 Stock Offering

In February 2020, the Company entered into subscription agreements with certain institutional investors for the sale by the Company of1,250,000 shares of its common stock and warrants to purchase 937,501 shares of common stock at a combined public offering price of $4.80 per share and related warrant. The Company received total proceeds of $6.0 million, net of $0.7 million in transaction expenses. See Note 5 - Warrants for equity classified warrants granted during the year ended December 31, 2020.

Lincoln Park Transaction

In October 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 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 40,503 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement and agreed to issue an additional 20,252 commitment shares pro-rata when and if Lincoln Park purchased (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 2019, the Company issued 117,674 shares to Lincoln Park which included 1,007 commitment shares for $1.0 million. In November 2020, the Company terminated its purchase agreement dated October 2018 with Lincoln Park.

In November 2020, the Company entered into a purchase agreement (the "2020 Purchase Agreement") and a registration rights agreement (the "2020 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC (Lincoln Park). Pursuant to the terms of the 2020 Purchase Agreement, Lincoln Park agreed to purchase from the Company up to $22.0 million of the Company's common stock (subject to certain limitations) from time to time during the term of the 2020 Purchase Agreement. Pursuant to the terms of the 2020 Registration Rights Agreement, the Company filed with the SEC a registration statement to register the shares that have been or may be issued to Lincoln Park under the 2020 Purchase Agreement. Pursuant to the terms of the 2020 Purchase Agreement, at the time the Company signed the 2020 Purchase Agreement and the 2020 Registration Rights Agreement, the Company issued 126,699 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2020 Purchase Agreement and agreed to issue an additional 50,680 shares pro-rata when and if Lincoln Park purchases (at the Company's discretion) the $22.0 million aggregate commitment. The commitment shares were valued at $0.5 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, 2020, the Company issued 771,220 shares, which included 133,017 commitment shares for net proceeds of $2.2 million. The Company terminated the 2020 Purchase Agreement on February 2, 2021.

At Market Issuance Sales Agreements (ATM)

In July 2019, the Company entered into an At Market Issuance Sales Agreement (the "2019 ATM Agreement") with Oppenheimer & Co. Inc. (the "Agent"). Pursuant to the terms of the 2019 ATM Agreement, the Company was able to 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"). The Company agreed to 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 also provided the Agent with customary indemnification rights. During the year ended December 31, 2020, pursuant to the 2019 ATM Agreement, the Company issued 1,412,017 shares of common stock at an average price of $8.68 per share, resulting in net proceeds of $11.9 million. In the third quarter of 2020, the 2019 ATM Agreement expired and was terminated.

In July 2020, we entered into a new At Market Issuance Sales Agreement with Oppenheimer & Co. Inc. (the "2020 ATM Agreement"). Pursuant to the terms of the 2020 ATM Agreement, the Company was able to sell from time to time through Oppenheimer shares of the Company's common stock with an aggregate sales price of up to $15.0 million. During the year ended December 31, 2020, pursuant to the 2020 ATM Agreement, the Company issued 471,405 shares of common stock at an average price of $6.11 per share, resulting in net proceeds of $2.8 million.

In addition, at December 31, 2020, we had 26,966 shares of our common stock subscribed in ATM transactions under the 2020 ATM Agreement for net proceeds, after deducting commissions and other transaction costs, of approximately $0.1 million at an average selling price of $4.96 per share. Accordingly, we have recorded a subscription receivable of $0.1 million as a reduction of stockholders' equity in our consolidated balance sheet as of December 31, 2020. The Company terminated the 2020 ATM Agreement on February 2, 2021.

Adoption of 2015 Stock Plan

In December 2015, the Board of Directors of the Company approved the Company's 2015 Stock Plan, which was amended in April 2016, April 2018, and June 2020. 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 currently 1,750,001 shares, including the amendments. 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 15, 2020, 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 1,000,000 shares.

Stock-based Compensation and Outstanding Awards

Under the terms of the Company's 2015 Stock Plan, as amended, and approved by its stockholders in June 2020, 1,750,001 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, 2020, there were 726,493 shares remaining to be issued under the 2015 Stock Plan.

Stock-based compensation expense for the years ended December 31, 2020 and 2019 is as follows (in thousands):

	Year Ended December 31,	
	2020	2019
General and administrative	$ 1,347	$ 1,324
Research and development	333	213
Total Stock-Based Compensation	$ 1,680	$ 1,537

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. Beginning in2020, the Company used the volatility of its own stock in the BSM as it now has sufficient historic data in its stock price. Prior to 2020, the volatility was determined by referring to the average historical volatility of a peer group of public companies combined with its own 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,	
	2020	2019
Risk-free interest rate	0.2% to 0.6%	1.6% to 2.2%
Volatility	122.5% to 128.0%	85% to 110%
Expected life (years)	3.7 to 6.3	5.3 to 6.3
Expected dividend yield	— %	— %

Stock option activity for the year ended December 31, 2020 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding, December 31, 2019	639,353	$ 9.53	$ 13.55	8.3	$ —
Granted	267,468	$ 4.96	$ 5.66		
Exercised	—	$ —	$ —		
Forfeited	(3,334)	$ 5.34	$ 6.36		
Outstanding, December 31, 2020	903,487	$ 8.19	$ 11.24	7.9	$ —
Exercisable, December 31, 2020	364,852	$ 11.23	$ 16.39	6.9	$ —

Options granted during 2020 have an aggregated fair value of $1.3 million that was calculated using the Black-Scholes option-pricing model. At December 31, 2020, total compensation cost not yet recognized was $2.6 million and the weighted average period over which this amount is expected to be recognized is2.5 years. The aggregate fair value of options vesting in the years ended December 31, 2020 and 2019 was $1.5 million and $1.3 million, respectively. In July 2020, the Company granted 224,964 employee stock options. In August 2020, the Company issued 16,667 options to Dr. Waldemar Priebe, one of the Company's founders and chair of the Company's Scientific Advisory Board. In October 2020, the Company granted 6,667 stock options, with 3-year annual vesting upon appointment of Elizabeth Cermak to the Company's Board of Director's.

Restricted Stock

Restricted stock units are granted with a grant date fair value determined using the closing price of the Company's common stock on the grant date. Restricted stock units vest annually in four equal installments. 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.

Restricted stock unit activity for the year ended December 31, 2020 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (years)
Unvested Shares, December 31, 2019	52,818	$ 7.86	3.5
Granted	58,869	$ 5.57	
Vested	(13,205)	$ 7.86	
Unvested Shares, December 31, 2020	98,482	$ 6.49	3.0

As of December 31, 2020, total compensation cost not yet recognized was $0.5 million and the weighted average period over which this amount is expected to be recognized is 3.0 years.

7. Income Taxes

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

	Year Ended December 31,	
	2020	2019
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,	
	2020	2019
Valuation allowance at beginning of period	$ 9,418	$ 5,855
Income tax benefit	4,449	3,563
Release of valuation allowance	—	—
Valuation allowance at end of period	$ 13,867	$ 9,418

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,			
	2020		2019	
	Amount	Percent	Amount	Percent
Federal tax benefit at statutory rate	$ 3,645	21.0%	$ 2,773	21.0%
State tax benefit net of federal	44	0.3%	(4)	(0.0)%
Foreign rate differential	6	0.0%	11	0.1%
Stock warrant costs	493	2.8%	853	6.5%
Other permanent differences	(63)	(0.4)%	(72)	(0.5)%
Permanent provision to return items	361	2.1%	107	0.8%
Stock compensation change	12	0.1%	(34)	(0.3)%
Research and development tax credits	—	—%	229	1.7%
Uncertain tax provision	(48)	(0.3)%	(33)	(0.3)%
Other	—	—%	(38)	(0.3)%
Increase in valuation allowance	(4,450)	(25.6)%	(3,563)	(27.0)%
Total tax (expense) benefit	$ —	—%	$ 229	1.7%

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

	Year Ended December 31,	
	2020	2019
Deferred tax assets:		
Start-up costs	$ 4,158	$ 2,991
Federal net operating loss carryforwards	7,982	5,376
State tax loss carryforwards	48	19
Foreign net operating loss carryforwards	126	51
Tax credit carryforward	670	405
ROU Liability	58	—
Deferred compensation	880	609
Total deferred tax assets	$ 13,922	$ 9,451
Less valuation allowance	(13,867)	(9,418)
Net deferred tax assets	$ 55	$ 33
Deferred tax liabilities:		
Fixed assets	$ (12)	$ (33)
ROU Asset	(43)	—
Total deferred tax liabilities	$ (55)	$ (33)
Net deferred taxes	$ —	$ —

The Company has incurred net operating losses since inception. As of December 31, 2020, the Company had total U.S. federal operating loss carry forwards of approximately $38 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. However, with the signing of the CARES Act net operating loss carryforwards created in 2018, 2019, and 2020 are able to offset 100% 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, 2020, the Company had state operating losses of approximately $1.2 million which expire commencing in 2032. 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, 2020. 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 $13.9 million and $9.4 million has been established at December 31, 2020 and 2019, respectively. The change in the valuation allowance for the year ended December 31, 2020 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 2020 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, 2020.

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

	Year Ended December 31,	
	2020	2019
Balance, beginning of year	$ 72	$ 38
Additions for tax positions related to the current year	—	—
Additions for tax positions related to prior years	46	34
Reductions due to lapse of statutes of limitations	—	—
Decreases related to settlements with tax authorities	—	—
Balance, end of year	$ 118	$ 72

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, 2020 within the next year.

8. Commitments and Contingencies

In addition to the commitments and contingencies described elsewhere in these notes, see below for a discussion of the Company's commitments and contingencies as of December 31, 2020.

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 additional 5 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 a related party, 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 $42,000 and $14,000 in sublease income from the related party for the year ended December 31, 2020 and December 31, 2019, respectively. Sublease income is recorded as other income on the Company's condensed consolidated statement of operations and comprehensive loss.

During the year ended December 31, 2020, the Company did not enter into any lease arrangements requiring any additional right-of-use assets or liabilities to be recorded.

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 following summarizes quantitative information about the Company's operating leases for the years ended December 31, 2020, and December 31, 2019, respectively (in thousands):

	Year Ended December 31,	
	2020	2019
Lease cost:		
Operating lease cost	$ 116	$ 60
Short-term lease cost	17	43
Variable lease cost	29	27
Total	$ 162	$ 130

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

	Year Ended December 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 134	$ 74
Right-of-use assets obtained in exchange for lease liabilities:		
Operating leases	$ —	$ 321

As of December 31, 2020, 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, 2020
2021	$ 138
2022	105
2023	56
2024	10
2025	—
2026 and thereafter	—
Total lease payments	309
Less: imputed interest	(32)
Present value of operating lease liabilities	$ 277

As of December 31, 2020, the weighted average remaining lease term for operating leases is 2.5 years, 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.

Licenses

MD Anderson

Under agreements associated with Annamycin, the WP1122 Portfolio and the WP1066 Portfolio 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 $255,000 and $240,000, respectively, for the years ended December 31, 2020 and 2019. On June 29, 2017, the Company entered into an agreement with MD Anderson licensing certain technology related to the method of preparing Liposomal Annamycin. On March 22, 2021, after a determination that the Company did not intend to pursue development of WP1732, the Company entered into a termination of the license agreement dated February 12, 2018 with MD Anderson related to WP1732.

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. This agreement was amended in May 2020 to allow for the extension of certain milestones. The initial milestone required the Company to file an IND with the FDA for a Phase I study by February 20, 2021. The Company extended the deadline for this milestone by six months by making the required extension payment, and the Company has the right to receive two additional six-month extensions in the future by making additional extension payments.

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 outlicensing agreement with 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 in2018. Total expenses related to HPI were $284,000 and $75,000, for the years ended December 31, 2020 and 2019, respectively. 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 $43,500 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 $15,000 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 $347,000 spread over that period of time. InSeptember 2018, the Company extended this Agreement until the end of October 2020 for total payment amount of $395,000 spread over that period of time. InJune 2019, the Company amended the Agreement to support the continuation of the project for total payment amount of $438,000. In October 2019, the Company amended the agreement until the end of October 2021 for a total additional payment amount of $395,000. In February 2021, the Company amended the agreement until the end of December 2022 for a total additional payment amount of $1.0 million. The expenses recognized under the MD Anderson agreement with regards to the Sponsored Laboratory Study were $629,000 and $544,000, respectively for the years ended December 31, 2020 and 2019.

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). OnJuly 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 the10-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 71,663 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), which sublicense was amended on March 22, 2021 (such agreement as amended, 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 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").

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, either directly or through the guarantees of grants, by or on behalf of WPD or any of its affiliates of at least: (i) $2.5 million during the first four years of the agreement on the research, development and commercialization of products in the licensed territories; and (ii) $1.0 million annually for the four 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 original 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. Prior to approval of the amendment to the WPD Agreement, the Company's board of directors received a fairness opinion from Maxim Group LLC that stated that it was their opinion that the consideration the Company will receive from WPD pursuant to the amended 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, 2020.

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, 2020.

Reverse Stock Split

On January 29, 2021, pursuant to authority granted by our stockholders, the Company's board of directors approved a one-for-six reverse stock split of our common stock and the filing of an amendment to the Company's amended and restated certificate of incorporation to effectuate the reverse stock split. The amendment was filed with the Secretary of State of the State of Delaware and the reverse stock split became effective in accordance with the terms of the amendment at 5:00 p.m. Eastern Time on January 29, 2021 (the "Effective Time"). The amendment provides that, at the Effective Time, every six shares of the Company's issued and outstanding common stock will automatically be combined into one issued and outstanding share of common stock, without any change in par value per share, which will remain $0.001. The accompanying consolidated financial statements and notes to the consolidated financial statements gives retroactive effect to the reverse stock split for all periods presented. Certain amounts in the financial statements, the notes thereto, and elsewhere in the Form 10-K may be slightly different than previously reported due to rounding of fractional shares as a result of the Reverse Stock Split.

Issuances of Equity and Warrant Exercises

Subsequent to December 31, 2020, the Company issued equity and received gross proceeds of $80.9 million. During January 2021 it issued approximately 469,000 shares for gross proceeds of $2.9 million using its At The Market Agreement with Oppenheimer & Co., Inc., discussed above. Additionally, on February 3, 2021, MBI announced the pricing of an underwritten public offering of an aggregate of 14,273,684 shares of common stock at a public offering price of $4.75 per share. The Company granted the underwriters a 30-day option to purchase up to an additional 2,141,052 shares of common stock offered in the public offering. The offering closed on February 5, 2021 and gross proceeds of the offering were approximately $67.8 million, prior to deducting the underwriting discount and other estimated offering expenses. On February 10, 2021, the underwriters of the public offering exercised in full their option to purchase an additional 2,141,052 shares of common stock at the public offering price of $4.75 per share, bringing total gross proceeds to approximately $78.0 million before underwriting discount. Subsequent to December 31, 2020 and through the date of filing of these financial statements, 10,000 shares were issued due to the exercise of various warrants related to past public offerings. Gross proceeds due to these exercises approximated $63,000.

EXHIBIT 4.10

DESCRIPTION OF THE COMPANY'S SECURITIES

The following summary is a description of the material terms of our capital stock. This summary is not complete, and is qualified by reference to our amended and restated certificate of incorporation, as amended, and our amended and restated bylaws, which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our amended and restated certificate of incorporation, as amended, our amended and restated bylaws and the applicable provisions of the Delaware General Corporation Law for additional information.

Our amended and restated certificate of incorporation authorizes us to issue up to 100,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, $0.001 par value per share.

Common Stock

Shares of our common stock have the following rights, preferences and privileges:

Voting

Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Any action at a meeting at which a quorum is present will be decided by a majority of the voting power present in person or represented by proxy, except in the case of any election of directors, which will be decided by a plurality of votes cast. There is no cumulative voting.

Dividends

Holders of our common stock are entitled to receive dividends when, as and if declared by the our board of directors out of funds legally available for payment, subject to the rights of holders, if any, of any class of stock having preference over the common stock. Any decision to pay dividends on our common stock will be at the discretion of our board of directors. Our board of directors may or may not determine to declare dividends in the future. The board's determination to issue dividends will depend upon our profitability and financial condition any contractual restrictions, restrictions imposed by applicable law and the SEC, and other factors that our board of directors deems relevant.

Liquidation Rights

In the event of a voluntary or involuntary liquidation, dissolution or winding up of the company, the holders of our common stock will be entitled to share ratably on the basis of the number of shares held in any of the assets available for distribution after we have paid in full, or provided for payment of, all of our debts and after the holders of all outstanding series of any class of stock have preference over the common stock, if any, have received their liquidation preferences in full.

Other

Our issued and outstanding shares of common stock are fully paid and nonassessable. Holders of shares of our common stock are not entitled to preemptive rights. Shares of our common stock are not convertible into shares of any other class of capital stock, nor are they subject to any redemption or sinking fund provisions.

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock. Our certificate of incorporation authorizes the board to issue these shares in one or more series, to determine the designations and the powers, preferences and relative, participating, optional or other special rights and the qualifications, limitations and restrictions thereof, including the dividend rights, conversion or exchange rights, voting rights (including the number of votes per share), redemption rights and terms, liquidation preferences, sinking fund provisions and the number of shares constituting the series. Our board of directors could, without stockholder approval, issue preferred stock with voting and other rights that could adversely affect the voting power and other rights of the holders of common stock and which could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, a majority of our outstanding voting stock.

Limitations on Liability and Indemnification of Officers and Directors

Our certificate of incorporation and bylaws limit the liability of our officers and directors and provide that we will indemnify our officers and directors, in each case, to the fullest extent permitted by the Delaware General Corporation Law.

Certificate of Incorporation and Bylaw Provisions

Our certificate of incorporation and bylaws include a number of anti-takeover provisions that may have the effect of encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include:

Advance Notice Requirements. Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of stockholders. These procedures provide that notice of stockholder proposals must be timely and given in writing to our corporate Secretary. Generally, to be timely, notice must be received at our principal executive offices not fewer than 120 calendar days prior to the first anniversary date on which our notice of meeting and related proxy statement were mailed to stockholders in connection with the previous year's annual meeting of stockholders. The notice must contain the information required by the bylaws, including information regarding the proposal and the proponent.

Special Meetings of Stockholders. Our bylaws provides that special meetings of stockholders may be called at any time by only the Chairman of the Board, the Chief Executive Officer, the President or the board of directors, or in their absence or disability, by any vice president.

No Written Consent of Stockholders. Our certificate of incorporation and bylaws provide that any action required or permitted to be taken by stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by any consent in writing by such stockholders.

Exclusive Forum Provision. 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 (the "DGCL"), 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 condition.

Amendment of Bylaws. Our stockholders may amend any provisions of our bylaws by obtaining the affirmative vote of the holders of a majority of each class of issued and outstanding shares of our voting securities, at a meeting called for the purpose of amending and/or restating our bylaws.

Preferred Stock. Our certificate of incorporation authorizes our board of directors to create and issue rights entitling our stockholders to purchase shares of our stock or other securities. The ability of our board to establish the rights and issue substantial amounts of preferred stock without the need for stockholder approval may delay or deter a change in control of us. See "Preferred Stock" above.

Delaware Takeover Statute

We are subject to Section 203 of the DGCL which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any "business combination" (as defined below) with any interested stockholder for a period of three years following the date that such stockholder became an interested stockholder, unless: (1) prior to such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (2) on consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding those shares owned (x) by persons who are directors and also officers and (y) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to this plan will be tendered in a tender or exchange offer; or (3) on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2⁄3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 of the DGCL defines generally "business combination" to include: (1) any merger or consolidation involving the corporation and the interested stockholder; (2) any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder; (3) subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; (4) any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or (5) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation. In general, Section 203 defines an "interested stockholder" as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol "MBRX".

Transfer Agent

The transfer agent for our common stock is VStock Transfer, LLC.

EXHIBIT 10.23

AMENDED AND RESTATED SUBLICENSE AGREEMENT

This **AMENDED AND RESTATED SUBLICENSE AGREEMENT** (the "Agreement") as originally entered into February 19, 2019 (the "Effective Date") and amended on August 2, 2019, and as further amended on _March 22_, 2021, (the "2nd Amendment Date"), is entered into by and between Moleculin Biotech Inc., ("MBI") having a business address of 5300 Memorial Drive, Suite 950 Houston, TX 77007 and WPD Pharmaceuticals, ("WPD"), a Polish corporation, having a business address of ul. Żwirki i Wigury 101, 02-089 Warszawa. MBI and WPD are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, subject to the MD Anderson License Agreements (defined below), MBI has obtained licenses to research, develop, make, have made, use, offer to sell, sell, export and/or import and commercialize Licensed Products within the Licensed Territory for use within the Licensed Field under Patent Rights;

WHEREAS, WPD wishes to obtain a sublicense from MBI to research and develop, manufacture, have manufactured, use, export/import, offer to sell and/or sell Sublicensed Products under the Sublicensed Subject Matter for use in the Sublicensed Field within the Sublicensed Territories;

WHEREAS, MBI and WPD wish to share Development Data; and

WHEREAS, MBI AND WPD wish to continue the Agreement by amending certain provisions on the 2nd Amendment Date.

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained, the Parties agree as follows:

ARTICLE I.
DEFINITIONS

1.1 "Additional Patents" has the meaning set forth in Section 7.2 of this Agreement.

1.2 "Agreement" means this Sublicense Agreement.

1.3 "Annual Development Plan" has the meaning set forth in section 4.2 of this Agreement.

1.4 "April 2012 Agreement" means the Patent and Technology License Agreement dated April 2, 2012, entered into by and between Intertech Bio Corporation on the one hand and Board on behalf of UTMDACC on the other hand, and any amendments thereto.

1.5 "Board" means the Board of Regents of the System.

1.6. "Buyback Consideration" has the meaning set forth in Section 15.3(b) of this Agreement.

1.7. "Buyback Event" has the meaning set forth in Section 15.3(a) of this Agreement.

1.8. "Buyback Percentage" has the meaning set forth in Section 15.3(c) of this Agreement.

1.9. "Calendar Quarter" means a period of three (3) consecutive calendar months commencing on January 1, April 1, July 1 or October 1; provided, however, that the first Calendar Quarter under this Agreement shall commence upon the Effective Date of this Agreement, and the last Calendar Quarter shall extend from the first day of such Calendar Quarter until the effective date of the termination or expiration of this Agreement.

1.10. "Calendar Year" means any twelve (12) month period commencing on January 1st and expiring on December 31st of the same year; provided, however, that the first Calendar Year under this Agreement shall commence on the Effective Date of this Agreement, and the last day of the last Calendar Year shall be the effective date of the termination or expiration of this Agreement.

1.11. "Claims" has the meaning set forth in Section 12.1 of this Agreement.

1.12. "Commercially Reasonable Development Efforts" has the meaning set forth in Section 4.1 of this Agreement.

1.13. "Confidential Information" includes: (1) all information contained in documents marked "confidential" and disclosed by one Party (the "disclosing party") to the other Party (the "recipient party") pursuant to this Agreement; (2) orally disclosed information which is disclosed by the disclosing party to the recipient party pursuant to this Agreement, summarized in writing, identified as "confidential" and delivered to the recipient party; and (3) all proprietary technical information, business and financial information, and all other information which a reasonable person would treat confidentially that relates to the Sublicensed Subject Matter and disclosed from the disclosing party to the recipient party, whether or not the information is marked as "confidential". Notwithstanding anything to the contrary, MBI shall be permitted to make sure disclosures as MBI determines, in its sole discretion, is required pursuant to the Securities Exchange Act of 1934, as amended, and the rules and regulations thereof.

1.14. "Dermin 2010 Agreement" means the Patent and Technology Development and License Agreement dated October 27, 2010 entered into by and between Dermin LLC and MBI.

1.15. "Dermin 2011 Agreement" means the Patent and Technology Development and License Agreement dated April 15, 2011 entered into by and between Dermin LLC and Intertech Bio Corporation.

1.16. "Dermin 2012 Agreement" means the Patent and Technology Development and License Agreement dated June 28, 2012 entered into by and between Dermin LLC and Annamed Inc.

1.17. "Dermin License Agreements" means the Dermin 2010 Agreement, Dermin 2011 Agreement, and Dermin 2012 Agreement, collectively.

1.18. "Development Data" means any data, information or know-how resulting from or relating to the research and development of the Sublicensed Subject Matter or Sublicensed Products. For the purposes of Section 5.1 of this Agreement, Development Data of WPD includes any data, information or know-how resulting from or relating to the research and development of the Sublicensed Subject Matter or Sublicensed Products in the possession or control of MBI or any of its employees, agents, representatives, or affiliates.

1.19 Reserved.

1.20. "Disagreement" has the meaning set forth in Section 3.6 of this Agreement.

1.21. "Effective Date" is as defined in the Header of this Agreement.

1.22. "Executive(s)" shall have the meaning set forth in Section 3.6 of this Agreement.

1.23 "February 2018 Agreement" means the Patent and Technology License Agreement dated February 12, 2018 entered into by and between MBI on the one hand and the Board on behalf of UTMDACC on the other hand, and any amendments thereto.

1.24. "Force Majeure Event" has the meaning set forth in Section 16.9 of this Agreement.

1.25. "Government" has the meaning set forth in Section 10.2 of this Agreement.

1.26. "Improvements" has the meaning set forth in Section 7.3 of this Agreement.

1.27. "Indemnified Party" has the meaning set forth in Section 12.1 of this Agreement.

1.28 "Indemnifying Party" has the meaning set forth in Section 12.1 of this Agreement.

1.29 "Licensed Field" has the meaning set forth in the MD Anderson License Agreements.

1.30 "Licensed Product(s)" has the meaning set forth in each of the MD Anderson License Agreements, collectively.

1.31. "Licensed Subject Matter" has the meaning set forth in each of the MD Anderson License Agreement, collectively.

1.32. "Licensed Territory" has the meaning set forth in the MD Anderson License Agreements.

1.33. "MBI" has the meaning set forth in the Header of this Agreement.

1.34. "MD Anderson License Agreements" means the June 2010 Agreement, April 2012 Agreement, June 2017 Agreement, and February 2018 Agreement, collectively.

1.35. "Marketing Approval" means the regulatory approval necessary to market and sell a Sublicensed Product in a country.

1.36 Reserved.

1.37. "Minimum Annual Royalty" has the meaning set forth in Section 6.3 of this Agreement.

1.38. "Minimum Buyback Consideration" has the meaning set forth in Section 15.3(d) of this Agreement.

1.39. "Net Sales" has the meaning set forth in the June 2010 Agreement, April 2012 Agreement, June 2017 Agreement, or February 2018 Agreement, as applicable, to calculate payments for pass-through royalties and override royalty percentage pursuant to Sections 6.1 and 6.2 of this Agreement, respectively.

1.40. "November 2015 Assignment" means the Assignment and Assumption Agreement dated November 17, 2015, entered into by and between MBI and Intertech Bio Corporation, pursuant to which Intertech Bio Corporation assigned all of its rights, title and interest under the April 2012 Agreement to MBI.

1.41. "JDC" has the meaning set forth in Section 3.1 of this Agreement.

1.42. "JDC Chair" has the meaning set forth in Section 3.3 of this Agreement.

1.43. "June 2010 Agreement" means the Patent and Technology License Agreement dated June 21, 2010 entered into by and between Moleculin, LLC (which merged into MBI in 2016) on the one hand and the Board on behalf of UTMDACC on the other hand, and any amendments thereto.

1.44. "June 2017 Agreement" means the Patent and Technology License Agreement dated June 29, 2017 entered into by and between MBI on the one hand and the Board on behalf of UTMDACC on the other hand, and any amendments thereto.

1.45. "Party" and "Parties" has the meaning set forth in the Header of this Agreement.

1.46 "Patent Rights" has the meaning set forth in each of the MD Anderson License Agreements, collectively.

1.47. "Phase II Study" means, in respect of a Sublicensed Product, (a) that portion of the FDA submission and approval process which provides for early controlled clinical studies conducted to obtain preliminary data on the effectiveness of a product for a particular indication, as more specifically defined by the rules and regulations of the FDA, including 21 C.F.R. § 312.21(b) or any future revisions or substitutes thereof; or (b) similar clinical study in any national jurisdiction other than the United States.

1.48. "Phase III Study" means, in respect of a Sublicensed Product, (a) that portion of the FDA submission and approval process in which expanded clinical studies are conducted to gather the additional information about effectiveness and safety that is need to evaluate the overall benefit-risk relationship of a product as more specifically defined by the rules and regulations of the FDA, including 21 C.F.R. § 312.21(c) or any future revisions or substitutes thereof; or (b) a similar clinical study in any natural jurisdiction other than the United States.

1.49. "Regulatory Approval" has the meaning set forth in the June 2017 Agreement.

1.50. "Sale" or "Sold" means the transfer or disposition of a Sublicensed Product for value to a party other than WPD for purposes other than research and development.

1.51. "Sublicensed Field" means the field of pharmaceutical drug products for the treatment of any illness, disease, or symptom in h umans.

1.52. "Sublicensed Patent Rights" means MBI's rights, as of the Effective Date of this Agreement, in the information and discoveries described in invention disclosures, or claimed in any patents and/or patent applications in the Sublicensed Territory pursuant to the collective MD Anderson License Agreements.

1.53. "Sublicensed Product(s)" means any product or service sold by WPD or its affiliates comprising, using or made through the use of the Sublicensed Subject Matter pursuant to this Agreement.

1.54. "Sublicensed Subject Matter" means Sublicensed Patent Rights and Sublicensed Technology Rights within the Sublicensed Field.

1.55. "Sublicensed Technology Rights" means MBI's rights and interests, as of the Effective Date of this Agreement, to Technology Rights granted pursuant to the MD Anderson License Agreements, collectively.

1.56. "Sublicensed Territory" means those countries listed in **Exhibit** "**A**" to this Agreement.

1.57. "System" means the University of Texas system.

1.58. "Technology Rights" has the meaning set forth in the MD Anderson License Agreements, collectively.

1.59. "Term" has the meaning set forth in Section 15.1 of this Agreement.

1.60. "Third Party Indemnity Claim" has the meaning set forth in Section 12.2 of this Agreement.

1.61. "UTMDACC" means the University of Texas M.D. Anderson Cancer Center, a component of System.

1.62. "WPD" has the meaning set forth in the Header of this Agreement.

1.63. "WPD Improvements" has the meaning set forth in Section 7.3 of this Agreement.

1.64. "WPD Intellectual Property" has the meaning set forth in Section 7.3 of this Agreement.

1.65. "Grant Guarantees" shall mean any guarantee, promise, contingent liability, assumed debt or the like of existing and possible commitments derived from third party grants related to Commercially Reasonable Development Efforts and approved by MBI.

1.66. "Required Extension Fee" shall mean for the extensions described in Section 4.4, $20,000 for the first extension, $40,000 for the second extension, and $60,000 for the third extension.

1.67. "Initial Hurdle Date" shall be as defined in Section 4.1.

ARTICLE II.
SUBLICENSE

2.1 Subject to the terms and conditions of this Agreement, including without limitation, Sections 2.2 and 2.3 below, MBI hereby grants to WPD an exclusive sublicense even as to MBI under the Sublicensed Subject Matter to research, develop, manufacture, have manufactured, use, import, offer to sell and/or sell Sublicensed Products within the Sublicensed Territories for use within the Sublicensed Field.

2.2 The Parties agree that the scope of the license rights granted pursuant to this Agreement do not exceed the scope of rights conferred to MBI pursuant to the MD Anderson License Agreements and such sublicensed rights are subject to any and all restrictions and limitations set out therein.

2.3 The sublicense granted herein is subject to (i) the timely payment by WPD to MBI of all consideration as provided herein (subject to any cure period, if applicable); (ii) MBI's use of Development Data for any purpose pursuant to Section 5.2 of this Agreement; and (iii) is further subject to the following rights retained by the Board and UTMDACC as per the MD Anderson License Agreements including the right to (A) publish the general scientific findings from research and development related to the Sublicensed Subject Matter, subject to the terms of Article XI of each of the MD Anderson License Agreements and section 13.4 of this Agreement; (B) use Sublicensed Subject Matter solely for research, teaching, patient care and other academic purposes; and (C) transfer Sublicensed Subject Matter to academic or research institutions for non-commercial purposes.

ARTICLE III.
JOINT DEVELOPMENT COMMITTEE

3.1 The Parties agree to establish, for the purposes specified herein, a joint development committee (the "JDC"). The Parties acknowledge and agree that neither the JDC, nor any other committee formed or to be formed under this Agreement has the power to amend any term or condition of this Agreement; and the JDC does not have the power to require WPD to acceceleratе its expenditure deadlines as set out in section 4.1..

3.2 The JDC shall be established by the Parties within forty-five (45) days of the Effective Date of this Agreement and shall oversee the activities of WPD with respect to the research and development of Sublicensed Products and in furtherance of this Agreement for the purposes of exploiting and optimizing the development and ultimate Marketing Approval of Sublicensed Products in the Sublicensed Territory.

3.3 Each Party shall appoint one (1) senior level representative having expertise in research and development within thirty (30) days of the Effective Date to sit on the JDC. A Party may change any of its representatives appointed to the JDC at any time with a new person (with appropriate expertise) by giving written notice of such change to the other Party; provided, however, that, without limiting the foregoing, a key objective with respect to membership in the JDC shall be preserving continuity. The total number of JDC members may be changed by unanimous vote of the JDC from time to time as appropriate; provided, that the JDC shall in all cases be comprised of an equal number of members for each of MBI and WPD. Either Party may invite additional agents or representatives of that Party, which must be under a non-disclosure agreement satisfactory to MBI, to attend any JDC meeting in order to provide the expertise such Party deems reasonably necessary for such meeting, subject to the prior consent of the other Party, such consent not to be unreasonably withheld, delayed or conditioned. A representative appointed by WPD shall serve as Chair of the JDC ("JDC Chair"). The JDC Chair shall: (i) set meeting agendas, provided that the agenda shall include any matter requested by either Party; (ii) call emergency meetings of the JDC upon the request of a JDC member; and (iii) at the request of either Party, present JDC Disagreements (as defined below) that have been unresolved for thirty (30) days to the Executive (as defined below). The JDC Chair shall be responsible for recording, preparing and issuing minutes of the JDC meetings, which meeting minutes shall be prepared and submitted to the other JDC members for approval within thirty (30) days of the JDC meeting.

3.4 The responsibilities of the JDC shall be exercised consistent with this Agreement and shall include:

a. Review and approval of the Annual Development Plan, and any material changes and updates thereto, prepared and submitted to the JDC by WPD in accordance with Section 4.3, provided that WPD shall incorporate into the applicable Annual Development Plan any comments provided by MBI;

b. Reviewing updates from WPD regarding the status of the research and development of the Sublicensed Products in each of the Sublicensed Territories and WPD's progress in the implementation of the Annual Development Plan;

c. Reviewing and approving activities and expenditures in satisfaction of WPD's obligation to use Commercially Reasonable Development Efforts in accordance with Section 4.1 of this Agreement, including Grant Guarantees;

d. Reviewing written reports summarizing the Commercially Reasonable Development Efforts and progress of the research and development and all efforts to develop and/or commercialize a Sublicensed Product in each of the Sublicensed Territories within the Sublicensed Field during the preceding Calendar Year. Such reports shall include, without limitation, a full financial report of the expenditures actually made by WPD relative to its claimed Commercially Reasonable Development Efforts.

e. No more than once (1) per Calendar Year, the JDC or MBI may inspect the books and records of WPD that support Commercially Reasonable Development Efforts claimed by WPD, unless otherwise necessary for MBI to comply with its reporting obligations pursuant to any of the MD Anderson License Agreements.

f. Reviewing Development Data that may have been generated as a result of research and development efforts.

3.5 Meetings of the JDC shall be held at least once each Calendar Quarter unless the Parties agree otherwise. Meetings shall be face-to-face, unless otherwise agreed to by the Parties. Each Party shall provide to the other Party copies of all materials, reports or data that are to be considered or reviewed at any meeting at least five (5) business days prior to the date of such meeting.

3.6 The JDC shall operate by unanimous vote. Each of MBI and WPD will have one vote on the JDC, which vote shall be cast by such Party's designee. If a unanimous vote on any matter within the jurisdiction of the JDC cannot be obtained within thirty (30) days of the date the matter was first presented to the JDC for a vote (a "Disagreement"), then the matter will be determined by the CEO of MBI, or its designate (the "Executive").

ARTICLE IV.
DEVELOPMENT EFFORTS

4.1 WPD hereby agrees that it must use Commercially Reasonable Development Efforts to develop and commercialize Sublicensed Products in the Sublicensed Territory within the Sublicensed Field. For purposes of this Agreement, the term "Commercially Reasonable Development Efforts" or "CRDE" shall mean, subject to Section 5.1 below, the expenditure, including Grant Guarantees, by or on behalf of WPD or any of its affiliates of at least: (i) U.S. $2,500,000 during the first four (4) years (the "Initial Hurdle Date") immediately following the Effective Date of this Agreement on the research, development and commercialization of Sublicensed Products in the Sublicensed Territories; and (ii) U.S. $1,000,000 annually for each of the four (4) years after the Initial Hurdle Date on the research and development of Sublicensed Products in the Sublicensed Territories. The minimum required total CRDE or "CRDE Min" is $6.5 million. WPD receives financial support and in-kind contributions from third parties including grants from governmental and non-governmental agencies, in connection with WPD's research and development efforts. MBI acknowledges and agrees that the value of any grants or other financial support or in-kind contributions expended by WPD or any of its affiliates on the research and development of Sublicensed Products as approved by the JDC shall be considered expenses by or on behalf of WPD or its affiliate as applicable, in calculating the Commercially Reasonable Development Efforts, provided such financial support and in-kind contributions are approved by the JDC as constituting Commercially Reasonable Development Efforts. In the event that WPD fails to use Commercially Reasonable Development Efforts to develop Sublicensed Product, MBI shall have the right to terminate this Agreement pursuant to the terms specified in Section 15.2(c) below.

4.2 WPD shall provide an initial Annual Development Plan for the upcoming Calendar Year within ninety (90) days of the Effective Date of this Agreement. Thereafter, the JDC shall meet to discuss and vote on the proposed Annual Development Plan. The term "Annual Development Plan" means a plan which includes: (a) list of research and development activities in furtherance of the research and development and Marketing Approval of Sublicensed Products for the Sublicensed Field in each Sublicensed Territory; (b) the budget allocated towards each research and development activity; and (c) such other items as the JDC may reasonably determine.

4.3 Reserved.

4.4 WPD may extend by up to three years the Initial Hurdle Date by paying the Required Extension Fee.

ARTICLE V.
INFORMATION

5.1 Reserved.

5.2 WPD hereby grants MBI the right to use Development Data provided by WPD for any purpose in any territory. Development Data shall be also shared with UTMDACC and the Board as may be required pursuant to each of the MD Anderson License Agreements. MBI shall have no obligation to provide support or assistance to WPD in connection with development of Sublicensed Products, except as may be set forth in a separate written agreement executed by the Parties. Notwithstanding the foregoing, upon WPD's written request, MBI may reasonably assist WPD, at WPD's expense, in its efforts to obtain funding required for research, development, and Marketing Approval of Sublicensed Products in the Sublicensed Territories. Such assistance, or lack thereof, cannot be used as a defense by WPD in adhering to this Agreement.

ARTICLE VI.
CONSIDERATION, REIMBURSEMENTS AND PAYMENT

6.1 In consideration for rights granted by MBI to WPD under this Agreement, WPD agrees to pay MBI a running royalty, pursuant to the MD Anderson License Agreements ("pass-through royalties") calculated as the sum of the following:

a. percentage of Net Sales, as set forth in Section 4.1(d)(i) of the June 2010 Agreement, for any Sublicensed Product approved for dermatological use, covered by the Patent Rights and/or Technology Rights licensed to MBI pursuant to the June 2010 Agreement;

b. percentage of Net Sales, as set forth in Section 4.1(d)(ii) of the June 2010 Agreement, for any Sublicensed Product approved for non-dermatological use, covered by the Patent Rights and/or Technology Rights licensed to MBI pursuant to the June 2010 Agreement;

c. percentage of Net Sales, as set forth in Section 4.1(d) of the April 2012 Agreement, for any Sublicensed Product covered by the Patent Rights and/or Technology Rights licensed to Intertech Bio Corporation (thereafter, assigned from Intertech Bio Corporation to MBI pursuant to the November 2015 Assignment) pursuant to the April 2012 Agreement;

d. percentage of Net Sales, as set forth in Section 4.1(d) of the June 2017 Agreement, for any Sublicensed Product covered by the Patent and/or Technology Rights licensed to MBI pursuant to the June 2017 Agreement;

e. percentage of Net Sales, as set forth in Section 4.1(d)(i) of the February 2018 Agreement, for any Sublicensed Product approved for dermatological use, covered by the Patent Rights and/or Technology Rights licensed to MBI pursuant to the February 2018 Agreement; and

f. percentage of Net Sales, as set forth in Section 4.1(d)(ii) of the February 2018 Agreement, for any Sublicensed Product approved for non-dermatological use, covered by the Patent Rights and/or Technology Rights licensed to MBI pursuant to the February 2018 Agreement.

Each of the above royalty amounts shall be due and payable pursuant to Section 4.1(d) of the applicable MD Anderson License Agreement. Additionally, the pass-thru royalties payable shall be reduced to the extent such reduction is taken by or provided to MBI pursuant to the applicable MD Anderson License Agreement, and shall be further subject to any sections of the applicable MD Anderson License Agreement that modify or change the terms or payment of the pass-thru royalties to be made by MBI. MBI shall notify WPD of any reduction taken by or provided to MBI pursuant to any of the applicable MD Anderson License Agreements.

6.2 In further consideration for the rights granted by MBI to WPD under this Agreement, as long as this Agreement has not been terminated, WPD agrees to pay MBI a royalty percentage in addition to the pass-through royalty ("override royalty percentage") equal to 1.0% of Net Sales of any Sublicensed Product, provided, however, if WPD spends: (i) more than one million dollars (U.S. $1,000,000) in excess of the CRDE Min, the override royalty percentage will decrease to 0.75% of Net Sales; or (ii) more than three million dollars (U.S. $3,000,000) in excess of the CRDE Min, the override royalty percentage will decrease to 0.5% of Net Sales.

6.3 Minimum annual royalties ("Minimum Annual Royalties") will be due and payable (without invoice) by WPD to MBI as follows:

a. With respect to a Sublicensed Product covered by Patent Rights and/or Technology Rights licensed to MBI pursuant to the June 2010 Agreement: the amount payable and due as set forth in Section 4.1(e) of the June 2010 Agreement;

b. With respect to a Sublicensed Product covered by Patent Rights and/or Technology Rights licensed to Intertech Bio Corporation (assigned to MBI pursuant to the November 2015 Assignment) pursuant to the April 2012 Agreement: the amount payable and due as set forth in Section 4.1(e) of the April 2012 Agreement;

c. With respect to a Sublicensed Product covered by Patent Rights and/or Technology Rights licensed to MBI pursuant to the February 2018 Agreement: the amount, payable and due as set forth in Section 4.1(e) of the February 2018 Agreement.

Each of the Minimum Annual Royalties shall be due and payable pursuant to Section 4.1(e) of the applicable MD Anderson License Agreement, under the same terms and conditions set forth in the applicable MD Anderson License Agreement. Running royalties accrued under Section 6.1 actually paid to MBI for Net Sales made during the twelve-month period preceding an anniversary of the applicable effective date may be credited against the Minimum Annual Royalties due on that anniversary date. Notwithstanding the foregoing, to the extent MBI's obligation to pay a Minimum Annual Royalty pursuant to the applicable MD Anderson License Agreement ceases, WPD's obligation hereunder shall cease.

6.4 WPD shall pay milestone payments to MBI as follows:

a. With respect to a Sublicensed Product covered by Patent Rights and/or Technology Rights licensed to MBI pursuant to the June 2010 Agreement: the amount(s), payable and due as set forth in Section 4.1(f)(1) of the June 2010 Agreement, upon commencement of the first Phase III Study in respect of a Sublicensed Product;

b. With respect to a Sublicensed Product covered by Patent Rights and/or Technology Rights licensed to Intertech Bio Corporation (assigned to MBI pursuant to the November 2015 Assignment) pursuant to the April 2012 Agreement: the amount(s), payable and due as set forth in Sections 4.1(f)(1), 4.1(f)(2), 4.1(f)(3) and 4.1(f)(4) of the April 2012 Agreement, upon commencement of the first Phase II and Phase III Study in respect of a Sublicensed Product; and upon receiving Market Approval for the first time in respect of a Sublicensed Product;

c. With respect to a Sublicensed Product covered by Patent Rights and/or Technology Rights licensed to MBI pursuant to the June 2017 Agreement: the amount(s), payable and due as set forth in Sections 4.1(e)(1), 4.1(e)(2) and 4.1(e)(3) of the June 2017 Agreement upon commencement of the first Phase III Study in respect of a Sublicensed Product; and upon receiving Regulatory Approval for the first time in respect of a Sublicensed Product; and

d. With respect to a Sublicensed Product covered by Patent Rights and/or Technology Rights licensed to MBI pursuant to the February 2018 Agreement: the amount(s), payable and due as set forth in Section 4.1(f)(1) of the February 2018 Agreement, upon commencement of the first Phase III Study in respect of a Sublicensed Product.

Each of the milestone payments shall be due and payable pursuant to Section 4.1(e) or 4.1(f) of the applicable MD Anderson License Agreement, under the same terms and conditions set forth in the applicable MD Anderson License Agreement.

6.5 During the Term, to the extent MBI is required to make any payments to UTMDACC or the Board pursuant to Sections 4.1(d), (e), or (g) of the June 2010 Agreement, April 2012 Agreement, and February 2018 Agreement, or Section 4.1(f) of the June 2017 Agreement, or any other consideration, whether a milestone payment or royalty, as a result of the research and development or Sale of a Sublicensed Product, and not contemplated by the terms of this Agreement, WPD shall be required to advance or reimburse MBI such payments upon demand by MBI and an accounting showing the calculations for such payments. Such requirement to advance or reimburse MBI for payments made to the UTMDACC or the Board pursuant to Sections 4.1(g) of the June 2010 Agreement, April 2012 Agreement, and February 2018 Agreement, or Section 4.1(f) of the June 2017 Agreement shall not apply to any obligation on MBI to pay the UTMDACC or the Board relating to the override royalty paid to MBI pursuant to Section 6.2 of this Agreement.

ARTICLE VII.
MAINTENANCE AND ADDITIONAL PATENTS

7.1 MBI shall be responsible for the prosecution and maintenance of the Sublicensed Patent Rights, subject to Section 7.2 of this Agreement.

7.2 WPD shall consult with MBI in the event that WPD determines that any additional patent applications ("Additional Patents") for the Sublicensed Subject Matter in the Sublicensed Territory should be filed. Should MBI and WPD agree that an Additional Patent covering an invention in the Sublicensed Territory shall be filed, then MBI, at all times subject to the terms of the applicable MD Anderson License Agreements, will prepare and file appropriate patent applications covering the invention so identified. In such instance, WPD shall be responsible for all costs of searching, preparing, filing, prosecuting and maintaining the Additional Patents in the Sublicensed Territories. For purposes of clarity only, (i) WPD shall not be responsible for any part of the Annual Maintenance Fee, as that term may be defined in any applicable MD Anderson License Agreement, or any other maintenance fees for the Sublicensed Patent Rights except for maintenance fees for any Additional Patents, and (ii) WPD shall not be responsible for any other costs specified under Article VI of any of the MD Anderson License Agreement unless such costs are specifically assigned to WPD under the terms of this Agreement.

7.3 MBI shall own any and all rights, titles, and interests, including all intellectual property rights, in any and all variations, modifications, improvements, or enhancements of or relating to the Sublicensed Subject Matter (whether patentable or not) (collectively "Improvements") whether conceived, developed, created or reduced to practice by MBI or WPD (regardless of whether WPD-Incorporated IP is utilized) during the term of this Agreement. As between WPD and MBI, WPD shall own all rights and title and interests including all intellectual property rights in all intellectual property or other subject matter developed or acquired independent of the Sublicensed Subject Matter and owned by WPD or licensed from third parties by WPD ("WPD Intellectual Property"). MBI acknowledges that in the course of developing the Sublicensed Product, WPD may incorporate in the Sublicensed Product certain WPD Intellectual Property that is developed and owned by WPD prior to the Effective Date ("WPD-Incorporated IP").

a. MBI hereby grants WPD an exclusive license under the Improvements to research, develop, manufacture, have manufactured, use, import, offer to sell and sell Sublicensed Products in the Sublicensed Territory.

b. WPD hereby grants MBI an exclusive license under WPD-Incorporated IP to research, develop, manufacture, have manufactured, use, import, offer to sell and sell Licensed Products in any territory outside of the Sublicensed Territories. WPD hereby grants MBI a non-exclusive license under the WPD-Incorporated IP to research develop, manufacture, have manufactured, use, import, offer to sell Licensed Products in the Sublicensed Territories upon expiration or earlier termination of this Agreement.

7.4 To the extent that MBI and not UTMDACC or any other third party, has control over the preparation, filing prosecution and maintenance of a patent application or patent:

a. MBI shall keep WPD reasonably informed of the status of any patent application or patent directed to the Sublicensed Patent Rights in the Sublicensed Territories, and will provide WPD with a copy of any patent applications included within the Sublicensed Patent Rights in the Sublicensed Territories, as well as copies of any material documents received or filed during the prosecution of Additional Patents in the Sublicensed Territories included within the Sublicensed Patent Rights;

b. MBI shall not knowingly abandon any such patent application or patent included within the Additional Patents without reasonable advanced notice to WPD; If WPD is not in default on any of its obligations under this Agreement, MBI shall consider in good faith any requests made by WPD to continue prosecution, but the final decision to continue or abandon shall be in MBI's sole discretion. The parties agree that they share a common legal interest to get valid enforceable patents and that each party will maintain as privileged all information received pursuant to this section 7.4. In addition such information shall be considered to fall within the definition of "Confidential Information" as set forth in Article XIII.

ARTICLE VIII.
INFRINGEMENT BY THIRD PARTIES

8.1 Subject to any limitations as may be set forth in the MD Anderson License Agreements and Dermin License Agreements WPD, at its expense, shall have the first right to (but shall not be obligated to) enforce any patent included within the Sublicensed Patent Rights against infringement by third parties in the Sublicensed Territories. After reimbursement of reasonable legal costs and expenses related to such recovery incurred by WPD, WPD agrees to pay MBI (a) the applicable royalty detailed in Section 6.1 and 6.2 above for any monetary recovery that is for sales of Sublicensed Product lost due to the infringement, and fifty percent (50%) of related punitive damages received by WPD or its affiliates; or (b) fifty percent (50%) of reasonable royalties awarded and received by WPD or its affiliates, and fifty percent (50%) of related punitive damages received by WPD or its affiliates in any monetary recovery in which the award is for reasonable royalties.

8.2 If either WPD or MBI becomes aware of any infringement or potential infringement of the Sublicensed Patent Rights, each shall promptly notify the other of such in writing. If WPD does not file suit against a potential infringer or take alternative action reasonably acceptable to MBI to end such infringement or potential infringement, within three (3) months of knowledge thereof, then, provided that such infringement is still on going, MBI may, at its sole discretion, enforce any patent licensed hereunder on behalf of itself and WPD, with MBI retaining all recoveries from such enforcement. In addition, in resolution of such infringement, MBI may grant non-exclusive license rights to the alleged infringer notwithstanding WPD's exclusive license rights granted herein.

8.3 In any suit or dispute involving an infringer, the Parties agree to cooperate fully with each other. Each Party shall cooperate with the other including provision of documents and witnesses in the conduct of litigation against any third party infringement, whether they have commenced it or not. At the request and expense of the Party bringing suit, the other Party will permit access during regular business hours, to all relevant personnel, records, papers, information, samples, specimens and the like in its possession.

ARTICLE IX.
PATENT MARKINGS

9.1 WPD agrees that all packaging containing individual Sublicensed Products, documentation therefor, and, when possible, actual Sublicensed Products sold by WPD will be permanently and legibly marked with the number of any applicable patents licensed hereunder in accordance with each country's patent laws to the extent such marking is necessary or required to fully preserve Sublicensed Patent Rights in such country.

ARTICLE X.
REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 Each Party represents and warrants that:

a. it is duly organized and validly existing under the laws of its state or country of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

b. it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

c. this Agreement is legally binding upon it and enforceable in accordance with its terms; that the execution, delivery and performance of this Agreement by it does not conflict with any Agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any governmental entity having jurisdiction over it; and

d. it has not granted, and will not grant during the term of the Agreement, any right to any third party that would conflict with the rights granted to the other Party hereunder; that it has (or will have at the time performance is due) maintained, and will maintain, and keep in full force and effect, all agreements, permits and licenses necessary to perform its obligations hereunder; and in complying with the terms and conditions of this Agreement and carrying out any obligations hereunder, it will comply (and it will ensure that its subcontractor's comply) with all applicable laws, regulations, ordinances, statutes, and decrees or proclamations of all governmental entities having jurisdiction over such Party.

10.2 Except for the rights of any party to the MD Anderson License Agreements, Dermin License Agreements, and the Government of the United States of America ("Government") as set forth below and except as may otherwise be set forth in this Agreement, MBI represents and warrants that:

a. MBI is the exclusive licensee of the Sublicensed Patent Rights and is entitled to grant the rights and licenses specified herein, subject to the terms and conditions of the MD Anderson License Agreements, Dermin License Agreements and/or any rights of the Government;

b. as of the Effective Date, all right, title, and interest of Moleculin, LLC under the June 2010 Agreement is owned by MBI;

c. as of the Effective Date, all right, title and interest of Intertech Bio Corporation under the April 2012 Agreement has been sold, assigned and transferred to MBI and is owned by MBI;

d. as of the Effective Date, MBI is entitled to the benefit of each of the Dermin License Agreements as licensor, and is entitled to exercise the rights of the licensor in each of the Dermin License Agreements;

e. MBI has not entered into any agreement granting any rights, interest or claim in or to any Sublicensed Patent Rights, if any, to any third party that conflicts with or is inconsistent with the rights granted to WPD pursuant to this Agreement;

f. to MBI's knowledge, as of the Effective Date of this Agreement, the patents encompassed by the Sublicensed Patent Rights are, or upon issuance will be, valid, and enforceable patents, no third party is infringing or threatened to infringe any such Sublicensed Patent Rights, and no third party has challenged or threatened to challenge the scope, validity, or enforceability of such patents or Sublicensed Patent Rights, nor is MBI aware of any valid basis for any such challenge;

g. MBI will consult with and keep WPD reasonably informed of the status of any patent application or patent related to the Sublicensed Patent Rights, subject to Section 7.4 of this Agreement;

h. to MBI's knowledge, as of the Effective Date of this Agreement, there are no third party patents or intellectual property rights which would be infringed by WPD's exercise of the rights granted to WPD under this Agreement; and

i. to MBI's knowledge, as of the Effective Date of this Agreement, there are no other patents, patent applications or intellectual property rights created or owned by MBI which would be infringed by WPD's exercise of the rights granted to WPD under this Agreement.

10.3 WPD understands that the Sublicensed Patent Rights may have been developed under a funding agreement with the Government and, if so, that the Government may have certain rights relative thereto. This Agreement is explicitly made subject to the Government's rights under any such agreement and any applicable law or regulation. To the extent that there is a conflict between any such agreement, applicable law or regulation and this Agreement, the terms of such Government agreement, applicable law or regulation shall prevail. To MBI's knowledge, as of the Effective Date of this Agreement there are no funding agreements with the Government under which any of the Sublicensed Patent Rights were developed.

10.4 WPD understands and acknowledges that certain rights and interests to substantial portions of the Sublicensed Subject Matter have been licensed to Dermin pursuant to the Dermin License Agreements and Dermin has certain rights relative thereto that conflict with rights granted herein. This Agreement is explicitly made subject to the rights granted to Dermin pursuant to the Dermin License Agreements, and the rights granted to WPD shall be junior to such rights granted to Dermin. WPD hereby acknowledges that it has received and reviewed the Dermin License Agreements.

10.5 WPD hereby acknowledges that it has received and reviewed the MD Anderson License Agreements.

10.6 WPD understand and agrees that, except as set out in section 10.2 of this Agreement, MBI, by this Agreement, makes no representation as to the operability or fitness for any use, safety, efficacy, approvability by regulatory authorities, time and costs of development, patentability, and/or breadth of the Sublicensed Subject Matter. Except as set out in section 10.2 of this Agreement, MBI, by this Agreement, also makes no representation as to whether any patent covered by the Sublicensed Patent Rights is valid or as to whether there are any patents now held, or which will be held by others or by MBI in the Sublicensed Field. Except as set out in section 10.2 of this Agreement, MBI does not make any representation that the inventions contained in Sublicensed Patent Rights do not infringe any other patents now held or that will be held by others.

10.7 WPD, by execution hereof, acknowledges, covenants and agrees that WPD has not been induced in any way by MBI or employees of MBI to enter into this Agreement, and further represents that WPD is entering into this Agreement voluntarily.

10.8 Upon execution of this Agreement, WPD will provide MBI with a complete schedule of the equity ownership of WPD, and further agrees to update such equity ownership schedule within 30 days after the completion of each calendar quarter after the date hereof.

10.9 U.S. FCPA Compliance. WPD hereby agrees to at all times comply with the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), and WPD shall establish, institute and maintain policies and procedures designed to ensure that:

a. no agent, employee or affiliate of WPD, or any of its affiliates, takes any action, directly or indirectly, that would result in a violation by such person of the FCPA or any other anti-bribery or anti-corruption law, rule or regulation of similar purpose and scope, including, without limitation, making use of the U.S. mails or any means or instrumentality of interstate commerce in furtherance of an unlawful offer, payment, promise to pay or authorization of the unlawful payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" or any foreign political party or official thereof, of any candidate for any foreign office or any candidate for foreign political office, in contravention of the FCPA;

b. WPD, and its affiliates, shall at all times keep books, records and accounts which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of their assets and maintain a system of internal accounting controls sufficient to provide reasonable assurances that transactions are properly authorized and recorded;

c. WPD shall, and shall cause its respective affiliates, to permit MBI and its respective designated representatives, at reasonable times and upon reasonable prior notice to such parties, to review the books and records of WPD and any of its affiliates and to discuss the affairs, finances and condition of such party and any of its affiliates with the officers of such entities and any of their affiliates in relation to their compliance with this section, as applicable.

d. WPD understands and agrees that MBI may terminate this Agreement immediately and without any early termination penalty in the event that WPD, or any of its affiliates, materially violates the FCPA or any other anti-bribery or anti-corruption law. WPD understands and agrees that, if WPD, or any of its affiliates, intends to use foreign subcontractors to provide any services pursuant to this Agreement, such party and each of its affiliates is prohibited from engaging or using subcontractors for performance of services under this Agreement without prior and express authorization, in writing, by MBI. If WPD, or any of its affiliates, is authorized to engage or use subcontractors for such work, such party and each of its affiliates so involved agrees to obtain a commitment from the subcontractor to comply with the FCPA and any other anti-bribery or anti-corruption law.

ARTICLE XI.
USE OF NAME

11.1 WPD will not use the name of (or the name of any employee of) UTMDACC, System or the Board in any advertising, promotional or sale literature on its website or for the purposes of raising capital without the advanced express written consent of Board.

11.2 WPD, on behalf of itself and its parent corporation, agrees that, without the advanced express written consent of MBI, WPD (or any employees, directors or agents of such parties, or its parent corporation) may not (i) use the name of MBI; (ii) use the name of any employee, board member, science advisory board member, or contractor of MBI (except in the case of contractors that WPD has a direct relationship with); or (iii) refer to any of the technologies, drug candidates, or intellectual property subject to this Agreement or refer to this Agreement, on its website or in any press releases, marketing or promotional materials.

ARTICLE XII.
INDEMNIFICATION

12.1 Each Party (the "Indemnifying Party") hereby agrees to indemnify and hold harmless the other Party and its officers, directors, employees, consultants, contractors, sublicensees and agents (collectively, the "Indemnified Party") from and against any and all losses, damages and other amounts payable to a claimant, as well as reasonable attorneys' fees and costs (collectively, "Losses"), to the extent resulting from claims, suits, proceedings or causes of action ("Claims") brought by a third party against the Indemnified Party based on or arising from: (a) breach of any representation or warranty or covenant or other agreement by the Indemnifying Party contained in this Agreement**,** or (b) negligence, recklessness or willful misconduct by such Indemnifying Party.

12.2 In the event that any third party asserts a Claim with respect to any matter for which the Indemnified Party is entitled to indemnification hereunder (a "Third-Party Indemnity Claim"), then the Indemnified Party shall promptly notify the Indemnifying Party thereof;*provided, however*, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party shall relieve the Indemnifying Party from any obligation hereunder unless (and then, only to the extent that) the Indemnifying Party is prejudiced thereby. The Indemnifying Party shall have the right, exercisable by notice to the Indemnified Party within ten (10) days of receipt of notice by the Indemnifying Party from the Indemnified Party of the commencement of or assertion of any Third-Party Indemnity Claim, to control the defense, settlement, appeal or other disposition of the Third-Party Indemnity Claim with counsel reasonably acceptable to the Indemnified Party; provided that, the Indemnified Party will have the right to participate jointly therein and provided, further, that if the Indemnifying Party fails to take reasonable steps necessary to defend such Third-Party Indemnity Claim, the Indemnified Party may assume its own defense and the Indemnifying Party will be liable for the reasonable costs and expenses of the Indemnified Party in connection therewith. The Indemnifying Party will not settle any Third-Party Indemnity Claim except: (i) with the approval of the Indemnified Party, which approval shall not be unreasonably withheld or delayed; and (ii) with respect to any Third-Party Indemnity Claim relating solely to the payment of money damages and which could not result in the Indemnified Party's becoming subject to injunctive or other equitable relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to Indemnify the Indemnified Party hereunder; provided, that the Indemnifying Party shall provide reasonable evidence of its ability to pay any damages claimed and with respect to any such settlement shall obtain the written release of the Indemnified Party from the Third-Party Indemnity Claim. The Indemnifying Party shall obtain the written consent of the Indemnified Party prior to ceasing to defend, settling or otherwise disposing of any Third-Party Indemnity Claim if as a result thereof the Indemnified Party would become subject to injunctive or other equitable relief or the business of the Indemnified Party would be adversely affected in any manner.

12.3 **IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY MULTIPLIED OR CONSEQUENTIAL DAMAGES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT, PROVIDED, HOWEVER, THAT THIS LIMITATION WILL NOT REDUCE OR AFFECT EITHER PARTY'S OBLIGATIONS TO INDEMNIFY THE OTHER AGAINST THIRD-PARTY INDEMNITY CLAIMS.**

ARTICLE XIII.
CONFIDENTIALITY

13.1 During the term of this Agreement and for a period of five (5) years thereafter, the Parties each agree that Confidential Information of the other party, which is disclosed to it by the other party pursuant to this Agreement: (i) shall be received and held in strict confidence, (ii) shall be used only for the purposes of this Agreement, and (iii) will not be disclosed by the recipient party (except as required by law, court order or regulation), its agents or employees without the prior written consent of the disclosing party, except to the extent that the recipient party can establish by competent written proof that particular Confidential Information:

a. Was in the public domain at the time of disclosure to the recipient party; or

b. Later became part of the public domain through no act or omission of the recipient party, its employees, agents, successors or assigns; or

c. was lawfully disclosed to the recipient party by a third party having the right to disclose it to the recipient party; or

d. was already known by the recipient party at the time of disclosure; or

e. was independently developed by the recipient party without use of the disclosing party's Confidential Information; or

f. is required by law, court order or regulation to be disclosed, provided that the recipient party so obligated to disclose the Confidential Information shall promptly notify the disclosing party of such requirement and provide the disclosing party an opportunity to challenge or limit the disclosure requirement and to seek confidential treatment or protection order, and that the Confidential Information so disclosed shall remain otherwise subject to the confidentiality and non-use obligations set forth above in this Section 13.1.

Particular Confidential Information shall not be deemed to come under any of the above exceptions merely because it is embraced by more general information that is or becomes subject to any of the above exceptions.

13.2 Subject to full compliance with Section 13.3 below, WPD may disclose MBI's Confidential Information to its employees, consultants and affiliates who have a need to know such information in order to satisfy WPD's obligations under this Agreement. Such employees, consultants and affiliates of WPD shall be required to agree to maintain the confidentiality of such information pursuant to terms no less restrictive that the ones set forth herein. MBI shall restrict the disclosure of WPD's Confidential Information to MD Anderson, those of MBI's employees, consultants and affiliates who have a need to know such information in order to satisfy MBI's obligations under this Agreement and any applicable MD Anderson License Agreement, are obliged under a written agreement with MBI to restrict the disclosure, possession, knowledge, development and use of such Confidential Information wherein such obligations are no less restrictive than those of MBI contained herein.

13.3 Each Party shall protect the other party's Confidential Information with at least the same degree of care as it uses to protect its own confidential information, but at no time less than a reasonable degree of care. This obligation will exist while this Agreement is in force and for a period of five (5) years thereafter.

13.4 WPD acknowledges that subject to the MD Anderson License Agreement, UTMDACC and MBI reserve the right to publish the general scientific findings from research related to Licensed Subject Matter, with due regard to the protection of WPD's Confidential Information. MBI will submit manuscripts of any proposed publication to WPD at least twenty (20) calendar days before publication, and WPD shall have the right to review and comment upon the publication in order to protect WPD's Confidential Information. Upon WPD's request, publication may be delayed up to sixty (60) additional calendar days to enable WPD to file adequate intellectual property protection desired by WPD of WPD's Confidential Information that would otherwise be affected by the publication.

13.5 Data Privacy and Security Laws. WPD and its subsidiaries (if any) will at all times during the Term be in material compliance with all applicable data privacy and security laws and regulations, and the Company and its subsidiaries (if any) have taken or will take commercially reasonable actions to comply with the European Union General Data Protection Regulation ("GDPR") (EU 2016/679) and all other applicable laws and regulations with respect to Personal Data (defined below) that have been announced as of the date hereof as becoming effective within 12 months after the date hereof, and for which any non-compliance with same would be reasonably likely to create a material liability (collectively, the "Privacy Laws"). To the Company's knowledge, the Company and its subsidiaries (if any) have been and currently are in material compliance with the GDPR. To ensure material compliance with the Privacy Laws, the Company and its subsidiaries (if any) have taken, and currently take, commercially reasonable steps reasonably designed to ensure compliance in all material respects with Privacy Laws relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data that the Company has collected, and collects, or is in the Company's possession or will be in the Company's possession during the Term. "Personal Data" means "personal data" as defined by GDPR.

ARTICLE XIV.
ASSIGNMENT

14.1 Neither Party shall assign any of its rights or obligations under this Agreement not specifically transferable by its terms without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed; except in connection with the merger or acquisition of a Party by a third party, or the sale of all or substantially all of such Party's assets to which this Agreement relates to a third party. For any assignment to be effective the assignee must assume in writing (a copy of which writing will be provided to the other Party) all of the assigning Party's interests, rights, duties, liabilities and obligations under the Agreement and agree to comply with all terms and conditions of the Agreement as if the assignee were the original party to the Agreement. Notwithstanding the foregoing, WPD may not assign this Agreement without the approval of MBI if such assignment would require the approval of MD Anderson or the payment to MD Anderson of any consideration.

ARTICLE XV.
TERM AND TERMINATION

15.1 The term of this Agreement will commence on the Effective Date and remain in full force and effect until the expiration of the last patent within the Sublicensed Patents, unless earlier termination by either (i) termination of all of the MD Anderson License Agreements, or (ii) pursuant to the terms of this Agreement ("Term").

15.2 Subject to any rights herein which survive termination, this Agreement will earlier terminate in its entirety:

a. Automatically, if WPD becomes bankrupt or insolvent and/or if the business of WPD shall be placed in the hands of a receiver or trustee, whether by voluntary act of WPD or otherwise; or

b. Upon thirty (30) calendar days written notice from MBI, if WPD materially breaches or defaults on the payment or report obligations of Article VI, or use of name obligations of Article XI, or any obligation set forth in Article IV, unless before the end of such thirty (30) calendar day notice period, WPD has cured the material default or breach to MBI's reasonable satisfaction, and so notifies MBI, stating the manner of the cure; or

c. Upon ninety (90) calendar days written notice from MBI if WPD materially breaches or defaults on any other obligation under this Agreement, unless, before the end of such ninety (90) calendar day period, WPD has cured the material default or breach to MBI's reasonable satisfaction, and so notifies MBI, stating the manner of the cure; or

d. At any time by mutual written agreement between WPD and MBI upon one hundred eighty (180) calendar days written notice to all Parties and subject to any terms herein which survive termination; or

e. Immediately, upon written notice from MBI, if WPD brings any action before any court, agency or tribunal seeking to invalidate or otherwise challenge the enforceability of MBI's, UTMDACC's or the Board's ownership of any patent included in the Sublicensed Patent Rights. Any dispute regarding the validity, enforceability or ownership of any patent included in the Patent Rights shall be litigated in the courts located in Houston, Texas, and WPD agrees not to challenge personal jurisdiction in that forum. To the extent that WPD unsuccessfully challenges the validity or enforceability of any patent included in the Patent Rights, WPD agrees to reimburse MBI, UTMDACC and Board for all costs and fees (including attorney's fees) paid by MBI, UTMDACC and Board in defending against such challenge. WPD understands and agrees that, in the event WPD successfully challenges the validity or enforceability of any patent included in the Patent Rights, all payments or other consideration made or otherwise provided by WPD to MBI, UTMDACC or the Board prior to a final, non-appealable adjudication of invalidity and/or unenforceability shall be non-refundable.

f. Notwithstanding any terms to the contrary, if WPD has defaulted or been late on its payment obligations pursuant to this Agreement for a period of five (5) calendar days after notice from MBI of such default or failure to pay on any two (2) occasions in a twelve (12)-month period. Notwithstanding the foregoing, WPD may avoid termination under this Section, if WPD pays all past due amounts and a default waiver fee of $50,000.00 within thirty (30) calendar days following the receipt of written notice from MBI identifying the second payment default in the twelve (12) month period. WPD may avoid termination as provided in the foregoing sentence (by payment of all past due amounts and default waiver fee) a maximum of three (3) times during the Term of this Agreement. For purposes of clarification, a separate default waiver fee of $50,000.00 shall be due each time WPD seeks to avoid termination under this provision. It is understood that time is of the essence with respect to the default waiver fees, and these fees are not subject to the thirty (30) day cure period specified in Section 15.2(b); or

15.3 Early Termination or Amendment Rights. MBI shall have the right, in its sole discretion, to terminate this Agreement in whole, or to materially amend the Agreement by removing a portion of the Sublicensed Subject Matter or Sublicensed Territory related to a Buyback Event (defined below), at any time in connection with the completion of any Buyback Event by paying to WPD the Buyback Consideration (defined below), provided however that MBI's right to terminate this Agreement shall only be exercised if the Buyback Consideration payable to WPD is reasonably expected to exceed the Minimum Buyback Consideration (defined below).

a. "Buyback Event" means the occurrence of any of the following:

   i. MBI entering into a license or sublicense agreement with an unaffiliated third party pursuant to which such MBI grants such third party a license or sublicense to all or to a material portion of the Sublicensed Subject Matter within all or substantially all of the Sublicensed Territories;

   ii. MBI, directly or indirectly, in one or more related transactions, effecting any merger or consolidation of MBI with or into another entity;

   iii. MBI, directly or indirectly, effecting any sale, license, assignment, transfer, conveyance or other disposition of all or to a material portion of its assets in one or a series of related transactions; or

   iv. MBI, directly or indirectly, in one or more related transactions, consummating a stock or share purchase agreement or other business combination with another entity or group of entities whereby such other entity or group acquires more than 50% of the outstanding shares of MBI common stock.

b. "Buyback Consideration" means:

   i. With respect to a Buyback Event set forth in 15.3(a)(i) above, the Buyback Consideration shall consists of the Buyback Percentage (as defined below) multiplied by the cash and non-cash consideration paid to MBI by the third party licensee pursuant to the license or sublicense agreement, less any transaction costs. To the extent the Buyback Consideration consists of non-cash consideration, the value of such Buyback Consideration shall be determined in good faith by MBI.

   ii. With respect to a Buyback Event set forth in 15.3(a)(ii)-(iv) above, the Buyback Consideration shall consists of the Buyback Percentage multiplied by b) the cash or non-cash consideration paid to MBI or to MBI's shareholders as part of the Buyback Event, less any transaction costs. To the extent the Buyback Consideration consists of non-cash consideration, the value of such Buyback Consideration, less any transaction costs, shall be determined in good faith by MBI.

   iii. To the extent any Buyback Consideration is payable to MBI over time, MBI shall be permitted to pay WPD such Buyback Consideration, less any transaction costs, as and when received by MBI. To the extent any Buyback Consideration is payable to WPD over time, MBI shall provide WPD with a written statement showing the expected value of such Buyback Consideration.

c. "Buyback Percentage" means the lesser of:

i. the greater of:

1. Two percent (2%) upon execution of this Agreement; or

2. 10% multiplied by a fraction (A) the numerator of which is the total dollar amount of expenditures made by or on behalf of WPD or any of its affiliates that qualify as Commercially Reasonable Development Efforts under this Agreement, up to a maximum of $6.5 million; and (B) the denominator of which is $6.5 million.

or

ii. A percentage equal to a) the percentage of of the world heathcare spend (as defined by the most recent World Heathcare Organization report) represented by the countries being removed from the Sublicensed Territory versus the countries involved in the Buyback Event world healthcare spend multiplied by b) a fraction (1) the numerator of which is the total dollar amount of expenditures made by or on behalf of WPD or any of its affiliates that qualify as Commercially Reasonable Development Efforts under this Agreement, up to a maximum of $6.5 million; and (2) the denominator of which is $6.5 million.

d. "Minimum Buyback Consideration" means as of the date of the Buyback Event the sum of:

i. the total amount expended by or on behalf of WPD or any of its affiliates on Commercially Reasonable Development Efforts;

ii. the total amount of grants from governmental agencies, in connection with WPD's Commercially Reasonable Development Efforts (not otherwise included in 15.3(d)(i) above; and

iii. any fees or penalties incurred by or on behalf of WPD in connection with the return or reimbursement of any financial support and in-kind contributions from third parties, including grants from governmental and non-governmental agencies.

15.4 Upon termination of this Agreement:

a. Nothing herein will be construed to release either Party of any obligation maturing prior to the effective date of termination; and

b. The Parties agree that the provisions of Article XI (Use of Name), Article XII (Indemnification), Article XIII (Confidentiality) and Section 7.3(b) of this Agreement shall survive termination of this Agreement; and

c. WPD may for a period of one (1) year after the effective date of termination, sell all Sublicensed Product(s) and parts thereof that it has on hand at the date of termination, if WPD pays the earned royalty thereon and any other amounts due pursuant to the terms of this Agreement; and

d. Subject to Section 15.3(c) above, WPD agrees to cease and desist any use and all sale of the Sublicensed Subject Matter and Sublicensed Products; and

e. all rights granted by MBI to WPD hereunder shall revert to MBI or otherwise cease; provided, however, if this Agreement is not earlier terminated during the Term pursuant to termination of the MD Anderson License Agreement or pursuant to Section 15.2 of this Agreement, then all rights granted by MBI to WPD shall be granted in perpetuity.

ARTICLE XVI.
MISCELLANEOUS

16.1 The Parties shall execute and deliver any and all additional papers, documents, and other instruments and shall do any and all further acts and things reasonably necessary, if any, in connection with the performance of its obligation hereunder to carry out the intent of this Agreement.

16.2 This Agreement, including exhibits and schedules (if any) contains the entire understanding of the Parties, and supersedes all prior agreements and understandings between the Parties. This Agreement may be amended only by a written instrument signed by the Parties.

16.3 The waiver by any Party of any term or condition of this Agreement, or any part hereof, shall not be deemed a waiver of any other term or condition of this Agreement, or of any later breach of this Agreement.

16.4 Any notice required by this Agreement will be given by personal delivery (including delivery by reputable messenger services such as Federal Express) or by prepaid, first class, certified mail, return receipt requested, addressed to:

If to WPD:

WPD Pharmaceuticals sp. z o.o
Attention: CEO
ul. Żwirki i Wigury 101,
02-089 Warszawa, Poland

If to MBI:

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

16.5 This Agreement may be executed in counterparts, all of which together shall constitute a single agreement.

16.6 This Agreement will be governed by, construed and enforced in accordance with the laws of the State of Texas. Any dispute between the Parties regarding or related to this Agreement shall be litigated in the courts located in Houston, Texas, and WPD agrees not to challenge personal jurisdiction in that forum.

16.7 If any provision of this Agreement or application thereof to anyone is adjudicated to be invalid or unenforceable, such invalidity or unenforceability shall not affect any provision or application of this Agreement which can be given effect without the invalid or unenforceable provision or application, and shall not invalidate or render unenforceable such provision or application. Further, the judicial or other competent authority making such determination shall have the power to limit, construe or reduce the duration, scope, activity and/or area of such provision, and/or delete specific words or phrases as necessary to render, such provision enforceable.

16.8 The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof. The Exhibits (if any) to this Agreement are incorporated herein by reference and will be deemed a part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular will include the plural, and vice versa, (d) the words "include," "includes" and "including" will be deemed to be followed by the phrase "but not limited to", "without limitation", "inter alia" or words of similar import, (e) the word "or" will be deemed to include the word "and" (e.g., "and/or") and (f) references to "ARTICLE," "Section," "subsection", "clause" or other subdivision, or to a Schedule or Exhibit, without reference to a document are to the specified provision, Schedule or Exhibit of this Agreement. This Agreement will be construed as if it were drafted jointly by the Parties and shall not be strictly construed against either Party.

16.9 Except for the payment of any amount due hereunder (other than any amount disputed in good faith), neither Party shall be liable to the other for any failure or delay in the fulfillment of its obligations under this Agreement, when any such failure or delay is caused by fire, flood, earthquakes, locusts, explosions, sabotage, terrorism, lack of adequate raw materials (caused by matters beyond the reasonable control of the performing Party), civil commotions, riots, invasions, wars, peril of the sea, acts, restraints, requisitions, regulations, or directions of government authorities (caused by matters beyond the reasonable control of the performing Party), acts of God, or any similar cause beyond the reasonable control of the performing Party (each, a "Force Majeure Event"). In the event that either Party is prevented from discharging its obligations under this Agreement on account of a Force Majeure Event, the performing Party will notify the other Party forthwith, and will nevertheless make every endeavor, in the utmost good faith, to discharge its obligations, even if in a partial or compromised manner. For clarity, a Force Majeure Event shall not excuse a Party from its obligation to pay any money due hereunder.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement by their duly authorized representatives with full right, power and authority to enter into and perform under this Agreement.

Moleculin Biotech Inc.	**WPD Pharmaceuticals SP. z o.o.**
By: /s/ Walter Klemp	By: /s/ Mariusz Olejniczak
Walter Klemp, CEO	Mariusz Olejniczak
Date: 3/22/2021	Date: 3/22/2021

Exhibit A

The Sublicensed Territory

Poland, Estonia, Latvia, Lithuania, Belarus, Ukraine, 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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 24, 2021, 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, 2020. 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, File No. 333-252676 and File No. 333-235686) and on Forms S-8 (File No. 333-212619, File No. 333-225867, and File No. 333-248240).

/s/ GRANT THORNTON LLP
Houston, Texas
March 24, 2021

Exhibit 31.1

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

I, Walter V. 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 24, 2021

By: /s/ Walter V. Klemp
Walter V. 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 P. 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 24, 2021

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 endedDecember 31, 2020 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Walter V. 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 24, 2021

By: /s/ Walter V. Klemp
Walter V. 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 endedDecember 31, 2020 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan P. 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 24, 2021

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.