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

FORM 10-K

X ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended **December 31, 2023**
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	**47-4671997**
(State or Other Jurisdiction of Incorporation or Organization)	(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 X

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 X

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 X 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 X No ☐

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

Large accelerated filer ☐
Non-accelerated filer X
Accelerated filer ☐
Smaller reporting company X
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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

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 $16 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 14, 2024 was 2,227,516.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of this registrant's definitive proxy statement for its 2024 Annual Meeting of Stockholders to be filed with the SEC no later than 120 days after the end of the registrant's fiscal year are incorporated herein by reference in Part III of this Annual Report on Form 10-K.

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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:

- 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;
- The success or the lack thereof, including the ability to recruit subjects on a timely basis, for a variety of reasons, of our clinical trials through all phases of clinical development;
- Our ability to satisfy any requirements imposed by the United States (US) Food and Drug Administration (FDA) (or its foreign equivalents) as a condition of our clinical trials proceeding or beginning as planned;
- World-wide events including the war in Ukraine and in Israel, the COVID-19 pandemic, and the general supply chain shortages effect on our clinical trials, clinical drug candidate supplies, preclinical activities and our ability to raise future financing;
- Our ability to obtain additional funding to commence or continue our clinical trials, fund operations and develop our product candidates;
- The need to obtain and retain regulatory approval of our drug candidates, both in the United States and in Europe, 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;
- Our ability to source our drug products at reasonable prices;
- 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;
- 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

BUSINESS

Our Business Summary

We are a clinical stage pharmaceutical company with a growing pipeline, including Phase 2 clinical programs for hard-to-treat cancers and viruses. We have three core technologies, each of which have had one or more drugs successfully complete a Phase 1 clinical trial, based substantially on discoveries made at and licensed from the University of Texas MD Anderson Cancer Center (MD Anderson) in Houston, Texas. Three of our six drug candidates have shown human activity in clinical trials and are currently or have been in Phase 1B/2 or Phase 2 clinical trials. Since our inception, our drugs have completed, are currently in, or have been permitted to proceed in thirteen clinical trials. Annamycin is our lead molecule and is in three Phase 1B/2 clinical trials - one for treating Acute Myeloid Leukemia (AML) and two for treating Soft Tissue Sarcoma metastasized to the lungs (STS lung metastases, STS lung mets, or Advanced STS).

One of our core management beliefs is that anthracyclines represent the most important treatment for AML and Advanced STS, and we believe Annamycin may, for the first time ever, allow a majority of these patients to benefit from this treatment. This belief leads us to currently focus mainly on the development of Annamycin.

Our Core Technologies

Our core technologies consist of the following programs:

a) Annamycin or L-Annamycin is a "next generation" anthracycline (one of the most common classes of chemotherapy), designed to be different than currently approved anthracyclines, which are limited in utility because of cardiotoxicity risks and their susceptibility to multidrug resistance mechanisms. Annamycin was designed to avoid multidrug resistance and to be non-cardiotoxic and has shown no cardiotoxicity in subjects treated in clinical trials to date. Furthermore, we have demonstrated safe dosing beyond the dose limitations imposed by regulatory authorities upon currently prescribed anthracyclines due to their inherent cardiotoxicity. Annamycin is demonstrating efficacy in two of its Phase 1B/2 trials as described further below in subjects with AML and Advanced STS. We believe that Annamycin has potential to fill an unmet need as a second line therapy (2nd line or 2L) in AML and potentially as first line therapy in Advanced STS.

As part of our Annamycin clinical trials, we have engaged an independent expert in assessing cardiotoxicity associated with chemotherapy at the Cleveland Clinic (Expert or Independent Expert). The data made available to the Expert includes left ventricular ejection fraction (LVEF) as determined by echocardiograms, and ECHO strain imaging, as well as Troponin levels (a biochemical marker of acute heart damage). "ECHO strain imaging" is a method in echocardiography (medical ultrasound) for measuring regional or global deformation (contraction or beating) of the myocardium (heart muscle). By strain rate imaging, the simultaneous function of different regions can be displayed and measured. Cardiac health biomarkers such as blood Troponin levels are considered an indicator of potential long-term heart damage. The Expert has issued and will continue to issue periodic reports as additional data are provided to him in batches of subject data. Such data include some data which are preliminary and subject to change. In our discussions regarding the lack of Annamycin's cardiotoxicity, we rely on the Expert's assessment.

Annamycin benefits from a promising advancement in lipid enabled drug delivery developed in collaboration with and exclusively licensed from MD Anderson. The unique patent-pending lipid composition allows us to combine a new concept in chemotherapeutic agents within a lipid structure that helps target the delivery of the payload and reduce the potential for toxicity. In the case of Annamycin, our unique use of lipid technology enables improved tissue/organ distribution, and as demonstrated in multiple clinical trials, dramatically reduced toxicity, including cardiotoxicity.

b) Our WP1066 Portfolio includes WP1066, WP1193 and WP1220, three of several Immune/Transcription Modulators in the portfolio designed to inhibit p-STAT3 (phosphorylated signal transducer and activator of transcription) among other transcription factors associated with tumor activity. These also stimulate a natural immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs). WP1066, in oral formulation, has been in two clinical trials, including compassionate use cases. WP1066 and WP1193 are being tested in preclinical programs in intravenous (IV) formulations. WP1066 and WP1220 have been in clinical trials in a topical formulation. WP1066 and WP1220 have both independently successfully completed Phase 1 clinical trials and have demonstrated efficacy as described further below.

c) Our WP1122 Portfolio contains compounds (including WP1122, WP1096, and WP1097) designed to exploit the potential uses of inhibitors of glycolysis such as 2-deoxy-D-glucose (2-DG). We believe such compounds may provide an opportunity to cut off the fuel supply of tumors by taking advantage of their high degree of dependence on glucose in comparison to healthy cells, as well as viruses that also depend upon glycolysis and glycosylation to infect and replicate. WP1122 has completed a Phase 1 clinical study, successfully establishing a Recommended Phase 2 Dose or RP2D.

Our Focus

We are focused on internally funded ("internally" and "externally" funded trials are defined in the Funding Strategy section below) development of:

1) Annamycin in combination with Cytarabine (also known as Ara-C, the combination with Annamycin of which is referred to as AnnAraC) for the treatment of AML.

2) Annamycin for the treatment of STS metastasized to the lungs.

3) A better formulation for delivery of a molecule from the WP1066 portfolio to possibly further support future externally funded oncology clinical trials. Such a formulation will require additional preclinical work prior to a clinical trial.

We have established an RP2D for WP1122 to potentially enable future externally funded oncology and virology trials. Beyond this, we support development of our core technologies through several externally funded clinical trials and primarily externally funded non-clinical research, with the potential for further studies in the future.

Our Clinical Trials

We are currently conducting three Phase 1B/2 trials with Annamycin, two internally funded and one mainly externally funded. One additional externally funded Phase 1B/2 clinical trial with WP1066 in combination with radiation is planned to begin in 2024. In terms of developing preclinical data, we conduct research utilizing our own employees, as well as outside consultants, in our own lab, as well as contracted facilities and we sponsor research at MD Anderson, the University of Texas Medical Branch (UTMB), and the University of Warsaw to expand the science of our core technologies and to identify possible combinations with other approved drugs. We have a National Institutes of Health (NIH) funded preclinical study with WP1096 (from the WP1122 portfolio) for the treatment of the Tacaribe Arenavirus.

As summarized below, we and our external investigators have multiple active INDs/CTAs (Investigational New Drug authorization in the US or Clinical Trial Authorization in Europe). Under these INDs/CTAs, we have under development, approved, have in progress, or have completed thirteen internally and externally funded clinical trials. Additionally, we are anticipating advancing Annamycin in combination with Cytarabine for the treatment of AML in a Phase 2B/3 clinical trial beginning in late 2024 or early 2025. Depending on when MB-107 (our Phase 1B/2 clinical study with Annamycin as a monotherapy treating soft tissue sarcoma pulmonary metastases) concludes, we may see additional partially or fully externally funded clinical research with Annamycin for the treatment of advanced STS. Below in Table 1 we are summarizing all of the thirteen clinical trials concluded, in progress, or approved/ allowed by the FDA or its European equivalent. See the discussion following the Table 1 for more detailed information, especially on safety and human activity.

Table 1 - Clinical Summary as of this filing
Unless CSR Completed – Data are as of March 19, 2024 - preliminary and subject to change

Drug Candidate	Trial / Indication / Location	Phase (Funding Source: Internal unless noted as External)	Status	Comments	Safety Summary	Human Activity Summary
Annamycin	MB-104 / R/R AML / US	1	P1 Concluded; P2 replaced with MB-105	Maximum Dose allowed per protocol 120 mg/m^2	Met safety endpoints; no cardiotoxicity reported	14.3% MLFS (subtherapeutic dose level when compared to MB-105)
Annamycin	MB-105 / R/R AML / Poland	1/2	P1 concluded; P2 replaced with MB-106	Maximum Dose and RP2D 240 mg/m^2	Met safety endpoints; no cardiotoxicity reported	80% ORR in last cohort (3 CRi and 1 PR)
Annamycin in Combination with Cytarabine	MB-106 / R/R AML / Europe	1B/2	20 subjects recruited to date. Phase 2 recruiting as 1st line and therapy; 2nd line recruitment stopped at 10 subjects	Seven sites recruiting in Poland and Italy	No cardiotoxicity reported to date	Phase 1B/2 All-Comers (n=18): CRc rate of 39% & ORR 50%; As 2nd Line (n=10): CRc rate of 60% & ORR 70%
Annamycin	MB-107 / STS Lung Metastases / US	1B/2	Phase 1 completed; Phase 2 in progress - treated stopped; following OS	Treating Phase 2 subjects and estimate completion of Phase 2 in 2023	No cardiotoxicity reported to date	Preliminary data - Phase 1 67% (10 of 15) of subjects showed SD or better through 2+ cycles; Phase 2 (O/S ongoing) 63% (9 of 14) subjects show SD through 2+ cycles
Annamycin	IIT / STS Lung Metastases / Poland	1B/2 External	Phase 1b in progress; First subject treated in Q4-2022	Investigator led trial weekly dosing regimen versus traditional chemotherapy dosing	6 subjects enrolled and treated; More detail below	Still in dose escalation phase: 50% have received greater than 2 cycles (~2 months of SD)
WP1066	IIT / Adult GBM / US	1 External	Closed prior to completion by site	Investigator left for another institution	No drug related serious adverse events noted	No activity demonstrated. RP2D or MTD not established.
WP1066	IND cleared for GBM	1	Open to an investigator to lead a study	Trial has not begun	Trial has not begun	Trial has not begun
WP1066 in combination with radiation	IND allowed for Adult GBM / US	2 External	Open to an investigator to lead a study	Used as reference for next trial	Trial has not begun	Trial has not begun
WP1066 in combination with radiation therapy	IND allowed for IIT led Adult GBM / US	1B/2 External	Investigator expected to begin recruiting in 2024	Trial has not begun	Trial has not begun	Trial has not begun
WP1066	IIT / Pediatric Brain Tumors / US	1 External	Concluded in February 2023 with a dose level at 8mg/kg	Concluded 10 subjects enrolled and treated over 3 dose levels up to 8 mg/kg	No drug related serious adverse events noted	1 DIPG subject had a temporary clinical response
WP1220	MB-201 / CTCL / Poland	1B / Proof of Concept	Concluded and CSR completed	Believe results warrant a Phase 2 study	Met safety endpoints	60% of subjects documented PR
WP1122	MB-301 / COVID-19 / UK	1A	Completed; Established RP2D	Drug at RP2D was tolerable and safe	Met safety endpoints	N/A as in healthy volunteer subjects
WP1122	IND approved for GBM	1B/2 External	Exploring for an investigator to lead a study	Trial has not begun	Trial has not begun	Trial has not begun

Notes for Table 1: 1) In MB-104 MLFS means "morphological leukemia-free state"; 2) In MB-105 we consider complete responses (CR) or complete response with incomplete recovery of the bone marrow (CRi) as where the bone marrow aspirate (BMAs) show leukemic blasts of less than 5%; 3) This is a summary of the detailed clinical discussion below and does not include compassionate use/right-to-try usage of our drug candidates; 4) Complete Response Composite (CRc) includes CRs and CRis; 5) Overall Response Rate (ORR) includes CRc and Partial Response (PR); 6) "Met safety endpoints" means that no drug-related serious and unexpected adverse events occurred as defined in the trial protocol 7) All data presented are preliminary unless a CSR or an investigator's final report has been issued for the trial referenced - specifically the data for MB-106 and MB-107 are preliminary and subject to change; 8) With regard to safety and human activity summaries please see the detailed discussion below; 9) MB-106 Phase 1 included "all-comers" or subjects with unlimited lines of prior therapy while Phase 2 included only subjects as 1st thru 3rd line of therapy, and 10) MB-107 Phase 2 has no ongoing treatment active and is following nine of fifteen subjects for overall survival (OS).

In the US and Europe, since our inception, we or independent investigators have approval to begin, are currently conducting or have completed thirteen internally or externally funded clinical trials for four of our drug candidates – Annamycin, WP1066, WP1220, and WP1122, as listed above. All of the clinical trials are or were in the Phase 1 or 2 stage. Starting in 2021 through 2023, there have been eight "right-to-try" (or their foreign equivalent) uses of Annamycin and WP1066.

Our clinical trials focused on Annamycin in 2023 with two internally funded and one externally funded Phase 1B/2 clinical trials. We concluded recruitment and treatment in the MB-107 Phase 1B/2 all comers clinical trial using Annamycin as a single agent for the treatment of STS lung mets during 2023. In this trial we are still monitoring progression free survival (PFS) and overall survival (OS) as we move into 2024. In our MB-106 Phase 1B/2 all-comers (see discussion below) clinical trial using Annamycin in combination with Cytarabine for the treatment of AML, we concluded recruitment and treatment as 2nd line therapy on of January 31, 2024, and are continuing recruitment where treatment is either 1st line (Poland only) or 3rd line (Poland and Italy) with 20 subjects recruited thus far out of a planned maximum of 28 subjects. In using the term "all-comers" for this trial, we did not limit the number of prior therapies for subjects entering the trial in the Phase 1 portion of MB-106. In the Phase 2 portion we did limit the number of prior therapies to two. For subjects with one prior therapy, we plan on utilizing the 2nd line data for an end of Phase 2 meeting with the FDA in the first half of 2024. Additionally, recruiting and treatment continue for the externally funded Phase 1B/2 clinical trial studying an alternative dosing schedule of Annamycin for the treatment of STS lung mets in Poland, which is discussed further below. All of these Phase 1B/2 clinical trials are open label, so we periodically announce safety and efficacy data.

In February 2023, the externally funded Phase 1 clinical trial with WP1066 for the treatment of pediatric brain tumors concluded. We expect one externally funded Phase 1B/2 clinical trial for WP1066 in combination with radiation for the treatment of GBM and other brain tumors in 2024. One more pediatric clinical trial may occur in the future, subject to the results of the other two possible clinical trials.

Human Activity Shown in Our Clinical Trials

The following data regarding human activity are all from our studies. All data are preliminary and subject to change, unless a clinical study report (CSR) has been published or the investigator-initiated study has concluded and issued its annual report. "Right-to-try" data are preliminary until published. Specifically, the data from MB-106 and MB-107 are preliminary and subject to change. Such activity may or may not be repeated in future clinical trials, including potentially pivotal and/or confirmatory clinical trials. While we believe such data are encouraging, the FDA or its foreign counterpart will ultimately determine if such data and future data are individually conclusive and support future clinical trials or approval.

Three of our drug candidates have shown activity in humans to date.

- Annamycin has shown human activity in AML and STS lung mets as follows:

  - AML: Prior to 2021, our MB-104 US Phase 1 trial for Annamycin as a single agent therapy in relapsed or refractory AML successfully met its safety endpoint (including the absence of cardiotoxicity) and demonstrated human activity in the reduction of circulating bone marrow leukemic blasts despite the trial being conducted at what were expected to be subtherapeutic dosages (not exceeding 120 mg/m2) based on the European AML study. This US study's CSR was issued in 2021.
  - AML: In 2022, we completed our MB-105 Phase 1 single agent trial for Annamycin in relapsed or refractory AML with fifteen subjects receiving the full dose per the protocol and identifying an RP2D and we demonstrated an 80% overall response rate (ORR) in the five subjects in the last cohort. These subjects with a median age of 65 were heavily pretreated with a median of 6 prior therapies. Three subjects achieved a PR and one achieved a CRi. Regarding the PRs, two of the three PR subjects' repeat BMA's had a blast count below 5% at the end of therapy, which we believe qualifies as a CRi under current literature and standards. We therefore consider the results in the last cohort as 60% CRi and 20% PR with a total of 80% ORR.
  - AML: During 2023, we started our MB-106 clinical trial with Annamycin in combination with Cytarabine (AnnAraC) for the treatment of AML in an all-comers trial, accepting subjects with a wide range of prior therapies in the Phase 1 portion with a limit of two prior therapies in the Phase 2 portion. The total recruited to date is 20 where one subject just began treatment and another subject has not been evaluated for efficacy. To date we have a composite complete response (CRc) rate of 39% in all subjects (n= 18). This is comprised of a CR rate of 33% and CRi of 6%. The 19th subject, being treated as a 3rd line therapy, had two BMAs tested where they have been inconclusive, and we are awaiting further testing. This subject will move the CRc to either 42% or 37% (n=19). Durability data are developing with one CR and one CRi having relapsed to date. Durability of CRs is confirmed by repeat BMAs. The first CR subject was treated in February 2023 and remains durable to date. The median age of all subjects recruited is 69, ranging from 19 to 78. This trial may enroll up to 28 subjects, although recruitment for subjects as 2nd line therapy ended in January 2024. The trial continues recruitment for treatment as 1st line and 3rd line therapy. Since we intend to position AnnAraC for approval as a 2nd line therapy, we believe that the most important data from this trial are the results in 2nd line subjects (excluding subjects who are either 1st line or 3rd line and beyond). When stratified for that population (n=10), the CRc rate is 60%, being comprised of a CR rate of 50% and a CRi of 10%.
  - STS Lung Mets: In 2022 our MB-107 trial treating STS lung metastases demonstrated a preliminary response of stable disease or better in 67% (10 of 15) of subjects – defined as stable disease (SD) or better after two cycles of Annamycin (approximately six weeks) in the Phase 1 portion of the study. Our median progression free survival (PFS) was 2.6 months for subjects receiving the study drug dose per the Phase 1 protocol. In the ongoing Phase 2 portion of the trial, we have demonstrated to date a preliminary response of 64% (9 of 14) of subjects showing SD through 2 or more cycles. This is in a subject population where the median progression free survival time in patients with soft tissue sarcoma with metastases (not just lung metastases) that have failed initial systemic therapy has been documented to be approximately 1.6 to 2.0 months, without effective therapy which includes subjects treated with a placebo. (A. Comandone, F. Petrelli, A Boglione, S. Barn: Salvage Therapy in Advanced Adult Soft Tissue Sarcoma. The Oncologist 2017;22:1518–1527).
  - STS Lung Mets IIT STS Lung Mets: In late 2022 an investigator-initiated trial (IIT) with Annamycin treating STS lung mets with weekly dosing began. Six subjects have been enrolled and treated to date (3 in cohort 1 at 35 mg/m2; 3 in Cohort 2 at 60 mg/m2)). A dose limiting toxicity or DLT was noted. The cohort was expanded and a 4th subject in Cohort 2 has been identified, consented in February 2024 and is currently in screening. The preliminary data to date is 50% (3 of 6) have received greater than 2 cycles (approximately 2 months) of therapy where we have assumed stable disease (SD) through 2 cycles. One of these three subjects has initiated cycle 5 (where we have assumed SD through 4 cycles). This is all based on preliminary data from the IIT dosing tracker. The data is preliminary and subject to change. We are pending an update from the IIT.
  - No Cardiotoxicity: To date, out of the 82 subjects treated in the MB-104, MB-105, MB-106 and MB-107 trials mentioned above, 63 subjects' data have been reviewed by our Independent Expert who has reported seeing no signs or symptoms of cardiotoxicity among the subjects reviewed. In March 2024, we were notified of an increase in one subject's troponin levels and the Expert opined that the subject had other factors relatable to the increase in the troponins and deemed this event unrelated to Annamycin. Data are sent periodically to our Independent Expert to be reviewed and we intend to have all subjects' data reviewed. Clinical data where a CSR or its equivalent has not been published are considered preliminary and subject to change.

- WP1066 has shown the following human activity:

    - In an IIT of WP1066 in an oral formulation (our lead inhibitor of p-STAT3) for the treatment of pediatric brain tumors, both a clinical and an objective response were demonstrated in a subject with diffuse intrinsic pontine glioma (DIPG), one of several indications for which WP1066 has been granted a "rare pediatric disease" designation, which could potentially qualify WP1066 for a priority review voucher if the FDA were to approve a New Drug Application (NDA) for treatment of that disease. In the IIT pediatric trial, two subjects (n=8) received at least 4 cycles (each cycle = 28 days) prior to progression.

- WP1220 (part of the WP1066 portfolio) has shown the following activity:

    - The CSR for this study was issued in 2021 for a clinical trial of WP1220, another drug candidate which is a topical formulation in the WP1066 Portfolio, studied for the topical treatment of cutaneous T-cell lymphoma (CTCL) and documented a PR (the target lesion decreasing 50% or more) in 60% of subjects (three out of five) that was confirmed by a subsequent evaluation one month later with one of the subjects having a near total resolution of their lesions (93% decrease). The median time to PR was 56 days. Stable disease was the best response documented for the remaining 40% of subjects (two out of five), resulting in clinical benefit for 100% of subjects. All subjects (100%) survived up to 112 days of follow-up.

Our Drug Candidate Programs

Annamycin Program

Overview

One of our core management beliefs is that anthracyclines represent the most important treatment for AML and Advanced STS, and we believe Annamycin may allow, for the first time ever, a majority of these patients to benefit from this treatment. This belief leads us to currently focus mainly on the development of Annamycin.

To further explain this, we consider Annamycin to be a "next generation" anthracycline, unlike any currently approved anthracyclines, as it is designed to avoid multidrug resistance mechanisms and cardiotoxicity, recognizing that the efficacy of all currently approved anthracyclines is limited by both multidrug resistance and cardiotoxicity. Our preclinical studies and clinical trials support this intended design. The lack of cardiotoxicity and the potential for efficacy of Annamycin have been demonstrated in 82 subjects treated to date. The efficacy data have been generated, mainly in 2023. To that end, we believe that Annamycin has potential to fill an unmet need as a second line therapy (2nd line) in AML and potentially as a first line therapy (1st line) in Advanced STS.

The FDA granted ODD to Annamycin for the treatment of AML and for soft tissue sarcoma patients, which means the agency believes we have established a medically plausible basis for using the drug for those indications. The FDA also granted Fast Track-Designation (FTD) for Annamycin for both the treatment of AML and Soft Tissue Sarcoma. A drug that receives Fast Track-Designation (FTD) is eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers;
- Eligibility for other FDA expedited programs, if relevant criteria are met; and
- Rolling review by FDA of the NDA, rather than waiting until every section of the NDA is complete before beginning review of the application, which is the typical process.

The Importance of Lower Cardiotoxicity and Multi-Drug Resistance for 2nd Line Therapy

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. 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 reproducing cancer cells. Acute leukemia is one of a number of cancers that are usually treated with anthracyclines in "fit" patients. 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 clinical data of efficacy are borne out in subsequent clinical trials, of which there can be no assurance, Annamycin may ultimately provide clinically meaningful benefits over currently approved anthracyclines in treating certain cancers, especially as a 2nd line therapy.

The potential for cardiotoxicity in pediatric leukemia patients, whose life spans can be severely shortened by the induction therapy intended to cure them of acute leukemia, represents a significant risk. 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 further reduce cardiotoxicity. If this same characteristic continues to be shown 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 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 an "ABCB1 transporter"; otherwise referred to as "MDR1 mechanisms") 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. Although significant further study is necessary, 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. We believe that the encouraging preliminary efficacy being demonstrated in our clinical trials in 2nd line AML therapy may, in part, be the result of Annamycin's ability to avoid MDR1 mechanisms.

Annamycin in preclinical studies has shown a lack of cardiotoxicity and this also has been shown in our clinical trials to date, as reported by our Expert. Clinical data where a CSR or its equivalent has not been published are considered preliminary and subject to change. Our Expert has issued and will continue to issue periodic reports as additional data are provided in batches of subject data.

To date, we have received a several independent assessments for the absence of cardiotoxicity in subjects treated with Annamycin. We now have independent assessments covering 63 subjects that have been treated with Annamycin in four different clinical trials in the U.S. and Europe with no evidence of cardiotoxicity. To date, 62 of all 82 subjects treated (which includes the 63 subjects independently assessed) were treated above the FDA's lifetime maximum anthracycline limit of 550 mg/m2, with 1 subject having been treated with 3420 mg/m2 (or roughly six times the FDA approved lifetime anthracycline exposure) of standard anthracyclines and Annamycin and there has been no evidence of cardiotoxicity. After review of the data provided, the Independent Expert, in their most recent report and as stated in previous reports, concluded that there was no evidence of cardiotoxicity.

In March 2024, we were notified of an increase in one subject's troponin levels seven weeks post cycle one and prior to initiation of a second cycle. Immediately post the second treatment the troponin levels decreased. All of the relevant subject's data were reviewed by our Expert. In the report of the Expert, the subject had other factors relatable to the increase in the troponins and deemed this event unrelated to the study drug Annamycin. We consider all data, including this data, preliminary and subject to change until a CSR is published.

We believe the Expert's reports are particularly relevant in light of a recently published retrospective study showing that the incidence of heart failure more than doubles for cancer patients treated with anthracyclines compared to cancer patients not receiving anthracyclines (C Larson, et al. Anthracycline and Heart Failure in Patients Treated for Breast Cancer or Lymphoma, 1985-2010. JAMA Network Open. 2023;6(2):e2254669. doi:10.1001/jamanetworkopen.2022.54669). Given the heart-damaging impact of prior treatment with currently prescribed anthracyclines, and considering that the subject population that we are enrolling in our Annamycin trials (multiple prior therapies, including anthracyclines known to be cardiotoxic, many elderly, and other comorbidities) we believe that there is a high likelihood that a cardiac event will occur in the future that we will not be able to disassociate from our study drug. We believe that the potential for such future incidences, however, does not outweigh the significant elimination of cardiotoxicity to date as reflected in the Expert's reports.

The Importance of the Unmet Need in 2nd Line Therapies for AML

There are approximately 160,000 people with AML worldwide with about 20,000 newly diagnosed patients annually in the U.S. Anthracyclines are an important class of first line tools for physicians and while effective, their maximum lifetime dose in patients is limited due to concerns over cardiotoxicity. The following discussion, which includes estimates based on current literature and our discussions with key opinion leaders, suggests that approximately 60% of AML patients continue to have a significant unmet need. This is based on the reality that effective treatment options are limited. We estimate that only around 40% of AML patients are afforded an opportunity to overcome their disease through a curative bone marrow transplant or through lasting remission. We believe this aligns with the published statistic that the 5-year survival rate for AML is only 29%.

While the standard of care treatment can be complex, regionally variable (especially since not all current AML drugs are approved in all countries), and highly individualized (based on a range of factors including gene mutations), all AML patients are initially categorized based on their ability to undergo intensive chemotherapy. As a result, we estimate around 50% of patients are deemed "Fit" for standard intensive first-line treatment and the other 50% are deemed "Un-Fit."

Those who are deemed "Fit" are most often treated with the "standard" induction therapy of three days of intravenous daunorubicin or equivalent anthracycline, and seven days of intravenous cytarabine, also known as Ara-C. We estimate that only about 36% of these patients, or approximately 18% of overall AML patients, will have a durable CR to first line therapy, meaning the cancerous cells in their bone marrow have been reduced to 5% or less. At this point, they either qualify for a bone marrow transplant or hope for the remission to become long lasting. Bone marrow transplants (BMT) can be successful in as many as 80% of eligible patients. However, since so few patients actually get to this point, we estimate that only a minor subset (approximately 14%) of all AML patients reach this positive outcome, through the standard first-line pathway for "fit" patients.

The 50% of patients who are deemed "Un-Fit" for first-line intensive chemotherapy treatment are usually treated with a combination of Venetoclax and azacytidine, also known as "Ven-Aza". The success rate, as we estimate, in this group of patients is only around 37%, or approximately 19% of all AML patients, achieving a durable CR and qualifying for a BMT or achieving long-term remission. Similarly, we estimate that as many as 80% of these responding patients will benefit from a bone marrow transplant or experience lasting remission. But again, this means that only a small subset of the deemed "Un-Fit" patients, approximately 15% of all AML patients, achieve this positive outcome.

In recent years, new targeted therapies have been approved (mostly in the US) and have become available to 2nd line patients (those patients for whom the 1st line therapies discussed above have failed), adding a new alternative. Unfortunately, we believe success here has been relatively limited. Five such drugs have been approved to date, but each is only relevant to a subset of AML patients who happen to have the requisite genetic mutation and response rates are relatively low. We estimate that only about 21% of 2nd line patients will achieve a durable CR which means only another 11% of the AML population is given a chance to beat their disease with a successful bone marrow transplant or lasting remission. This leaves, based on our estimates, about 58% of all AML patients who will ultimately succumb to their disease.

We believe this is not an acceptable outcome and are advancing Annamycin for the treatment of AML via our clinical trials. In multiple clinical studies, subjects treated with Annamycin have shown no signs of cardiotoxicity, allowing physicians to dose higher than the currently set limits for other anthracyclines or potentially treat traditionally "unfit" subjects. The subjects treated to date have included those who were initially deemed unfit for intensive chemotherapy and the initial, preliminary data suggest that Annamycin's safety and tolerability profile may make the product suitable for those patients, too.

Annamycin Clinical Trials – AML

We have studied Annamycin in three internally funded AML clinical trials, one of which is still under way. These trials are MB-104, MB-105, and MB-106. In MB-105 and MB-106, we began seeing what we believe to be potentially significant efficacy in AML. Below is a discussion of these three trials with a focus on the most recent two.

Below in Table 2 is a summary of the preliminary responses in the concluded MB-105 monotherapy trial and the MB-106 combination therapy trial to date, both for the treatment of AML.

***Table 2* - Summary of Annamycin Responses in MB-105 & MB-106 AML Studies as of March 19, 2024**

Study	Study MB-105 Monotherapy - Last Cohort at 240 mg/m2 (RP2D)	Study MB-106 Combination Therapy– Phase 1B/2 All Lines (Range 1-7)	Study MB-106Combination Therapy– Phase 1B/21st Line	Study MB-106Combination Therapy– Phase 1B/2 As 2nd Line Only
Therapy	Annamycin - Single Agent	Ara-C + Annamycin "5+3"	Ara-C + Annamycin"5+3"	Ara-C + Annamycin"5+3"
All Subjects				
Recruited	5	20	3	10
Subjects Not Yet Evaluable	0	2	1	0
Subjects Evaluable To Date	5	18	2	10
Subjects Evaluable Not Dosed Per Protocol		2	0	1
Median Prior Therapies	6	1	0	1
Median Age - Years (Range)	65 (62-73)	69 (19-78)	49 (19-69)	71 (53 - 78)
Complete Responses (CR)	0	6	1	5
CR with incomplete recovery (CRi)	3	1	0	1
Total Complete Response(s) (CRc)	3	7	1	6
Complete Response (CR) Rate	0%	33%	50%	50%
Complete Response Composite (CRc) Rate	60%	39%	50%	60%
Partial Responses (PRs)	1	2	0	1
CRc Relapsed To Date	1	1	0	1
BMT To Date	0	1	0	1
Durability of CR	Not followed (1)	Developing (2,3,4,5)	Developing (2,3,4)	Developing (2,3,4)

Notes for Table 2: 1) Data from MB-105 is showing only the five subjects treated per protocol in the last cohort and are shown as this cohort was at the recommended phase 2 dose or RP2D. 2) Data from MB-106 is for intent to Treat subjects; 3) Data from MB-106 is preliminary and subject to change; 4) Durability is developing; and 5) The 19th subject, being treated as a 3rd line therapy, had two BMAs tested where they have been inconclusive, and we are awaiting further testing. This subject will move the CRc in the "MB-106 Phase 1B/2 All Lines" column to either 42% or 37% (n=19).

MB-104: A Phase 1 clinical trial of Annamycin as a single agent for the treatment of relapsed and refractory (R/R) AML in the US was successfully completed in 2020. The FDA requested that we demonstrate that Annamycin could be safely administered to subjects 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. Our Independent Expert, as discussed above, noted that after review of the data for the subjects in this trial there were no signs of cardiotoxicity.

MB-105: As a result of discussions with the FDA after MB-104, we focused our continuing efforts on establishing an RP2D for Annamycin in our Phase 1/2 single agent R/R AML clinical trial in Europe. In December 2018, we began treatment at the final dose of MB-104 of 120 mg/m2. In February 2022, we successfully concluded the Phase 1 portion of that trial and established the RP2D of 240 mg/m2. A total of 20 subjects were enrolled in this trial. Significant adverse events (AE's) $\geq$ grade 3 in this trial (n=20) were: neutropenia 65%, thrombocytopenia 50%, anemia 40%, febrile neutropenia 30%, and pancytopenia 10%. Drug related serious adverse events (SAE's) were: thrombocytopenia and anemia 25% each, febrile neutropenia 20%, neutropenia 10%, and mucosal inflammation, neutropenic infection, hepatocellular injury, hypotension, hepatotoxicity, sepsis and infusion related reaction 5% each.

Additionally, our Expert noted that after review of the data for the nineteen of the twenty subjects in this trial there were no signs of cardiotoxicity. One subject who received a partial dose of Annamycin and left the trial had no post-treatment evaluations performed. Additionally, 15 subjects were taken over the LTMAD and exposed as high as 1800 mg/m2 as allowed by the protocol.

In the final cohort, five subjects received a full course of Annamycin and demonstrated an ORR of 80% with one CRi and three PRs. However, in two of the PRs, as noted by the site, subjects' bone marrow blast counts were successfully decreased to below 5%, however these subjects were still designated as a PR by the sub-investigator at that site. We include these subjects as CRis since their results met the definition of CRi per the protocol and thus believe that a CRi rate of 60% would be more accurate.

As a part of our ongoing sponsored research at MD Anderson, animal testing indicated that the combination of Annamycin with Ara-C (AnnAraC) provides a synergistic effect that is more effective in AML mouse models than either drug alone. These data were presented at the 62nd Annual Meeting & Exposition of the American Society for Hematology (ASH) under the title: "High Efficacy of Liposomal Annamycin (L-ANN or L-Annamycin) in Combination with Cytarabine (AnnAraC) 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 AnnAraC, median survival ranged from 56 to 76 days, thus expanding median survival by 585%, with some animals having no signs of any tumors after treatment. Additionally, when looking at median overall survival (OS) for the mice in the study, AnnAraC demonstrated a 68% improvement in the OS compared to Annamycin as a single agent and a 241% increase in OS compared to Cytarabine alone. We believe these experiments supported initiation of clinical development of the combination of Annamycin and Ara-C in AML patients.

This combination was achieved via a promising advancement in lipid enabled drug delivery developed in collaboration with and exclusively licensed from MD Anderson. The unique patent-pending lipid composition allows us to combine a new concept in chemotherapeutic agents within a lipid structure that helps target the delivery of the payload and reduce the potential for toxicity. In the case of Annamycin, our unique use of lipid technology enables improved tissue/organ distribution and, as demonstrated in multiple clinical trials, dramatically reduced toxicity, including avoiding cardiotoxicity.

Although Annamycin had already shown human activity as a single agent in its two Phase 1 AML clinical trials and had shown no signs of cardiotoxicity, the observed synergy in vitro and confirmatory in vivo data suggested that the AnnAraC could be more effective in a clinical setting than Annamycin as a single agent. This would be consistent with the current practice to use Ara-C in combination with other anthracyclines in AML patients. The most common first-line therapy for fit AML patients currently 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 Annamycin for the currently used anthracycline in a similar 7+3 (or as is the case in MB-106, 5+3), regimen would therefore represent a familiar and well-practiced treatment modality. Beyond that, we believed 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 currently limiting the use of anthracycline-based intensive chemotherapy. Thus, we began focusing our efforts on a clinical trial studying AnnAraC for the treatment of AML in Europe.

MB-106: On May 2, 2023, we announced successful completion of the first cohort in our Phase 1B portion of our Phase 1B/2 clinical trial using Annamycin in combination with Cytarabine for the treatment of AML. This study is utilizing a "5+3" regimen where Annamycin is administered with three days of infusion along with the five days of infusion of Cytarabine. As we noted, this combination strategy is similar to the familiar "7+3" induction therapy that is considered to be a standard of care in AML, where seven days of Cytarabine infusions are paired with three days of an approved anthracycline (typically, daunorubicin).

In the first cohort 3 subjects were treated, all of whom were relapsed from multiple prior therapies. Annamycin was dosed at 190 mg/m2, along with Cytarabine at 2.0 g/m2/day for five days (total dose of 10g/m2).

The median number of prior therapies for these three subjects in the first cohort was five (range of one to six). One subject, who was 78 years of age at the time of the study initiation and enrolled after a single prior multi-year therapy, achieved a CR that has continued to be durable at 12 months. This subject has received a second and recently a third course of treatment, during the ensuing 11 months, at the direction of the treating physician. This subject has not experienced a relapse to date. The other two subjects were shown to have disease progression.

At the recommendation of the safety review committee, we deemed the first cohort dose as safe and opened the second cohort with the Annamycin dose being increased to 230 mg/m2. On August 7, 2023, we successfully completed the second cohort at 230 mg/m2 of Annamycin in this combination study. Four subjects were treated in this cohort, one is believed to be relapsed from one or more prior therapies and three are believed to be refractory to up to three prior therapies. One subject was replaced due to a Serious Adverse Event (SAE) experienced on first day of dosing. The SAE was determined to be unrelated to Annamycin and definitively related to Cytarabine: an allergic reaction to the Cytarabine infusion. At the recommendation of the safety review committee, we deemed the second cohort dose as safe and as the recommended expansion phase dose and opened recruitment, including for both first line therapy and for subjects who are refractory to or relapsed after induction therapy, to the Phase 2 portion of the trial. The median number of prior therapies for the three evaluable subjects in the second cohort was two (range of one to three) and the median age was 67. One subject, who was 64 years of age at the time of enrollment into the study with one prior therapy, was deemed a CR (complete response), which was shown to be durable at approximately three months, at which point the subject proceeded to a bone marrow transplant. The other two subjects were shown to have disease progression.

On October 2, 2023, we announced the initial subjects had been treated in the Phase 2 portion of MB-106. To date, 20 subjects have been enrolled in the full MB-106 Phase 1B/2 study. At the end of January 2024, we completed recruiting the desired number of 2nd line subjects and began preparation for an End of Phase 2 (EoP2) meeting with the FDA. In addition, we expanded the MB-106 study protocol to include 1st line subjects to provide data to enable the designing of a potential confirmatory Phase 3 post-approval study, however we do not expect the addition of this cohort to delay our EoP2 meeting. Our current planned pathway for approval for Annamycin in combination with Cytarabine for the treatment of AML is as a 2nd line therapy. Therefore, our focus is primarily on securing an accelerated approval pathway for the treatment of 2nd line subjects (those who were relapsed from or refractory to a 1st line AML therapy, regardless of whether the subject was deemed "fit" or "unfit").

As mentioned previously, the MB-106 clinical trial with Annamycin in combination with Cytarabine for the treatment of AML is an "all-comers" (as discussed above) trial, accepting subjects with a wide range of prior therapies. The total subjects recruited to date is 20 where one first-line subject just began treatment and another third-line subject has not yet been fully evaluated. Currently, we have a composite complete response (CRc) rate of 39% in all evaluable subjects (n= 18). This is comprised of a CR rate of 33% and CRi rate of 6%. We believe that the most important subgroup in this trial to be subjects for whom AnnAraC is their 2nd line of therapy. When stratified for that population (n=10), the CRc rate is 60% being comprised of a CR rate of 50% and a CRi rate of 10%. The 19th subject, being treated as a 3rd line therapy, had two BMAs that were inconclusive, and we are awaiting further testing. This subject will move the CRc for the full trial to either 42% or 37% (n=19), depending on the final assessment of the BMA.

Durability data are developing with one CR having relapsed to date with 4.5 months of durability. The first CR subject was treated in February 2023 and remains durable to date. Durability of CRc's is confirmed by repeat bone marrow aspirates (BMAs). The median age of all subjects recruited is 69, ranging from 19 to 78. This trial may enroll up to 28 subjects with recruitment for subjects as 2nd line therapy having ended in January 2024. The trial continues recruitment for treatment as 1st line and 3rd line therapy.

The first CR subject was treated in February of 2023 and has not relapsed to date, having received a third course of AnnAraC in February 2024. One CR has relapsed to date as noted in Table 2 above. The relapse occurred at the same study site where a subsequent review of the anti-microbial standard of care for patients during the peri-chemotherapy infusion period was not consistent with the standard of care recommended by the leading medical organizations. This site also had a significantly greater rate of infections than was reported at the other study sites. These infections precluded the use of an additional course of chemotherapy, which has been utilized in most patients who have achieved a durable CR or CRi at the other MB-106 study sites. We believe that this lack of additional courses of AnnAraC may (and we stress "may") have contributed to the only relapse in MB-106 following a CR and the only death to a CRi subject to date. The death was not deemed disease progression and occurred after a series of infections. This subject was scheduled for a BMT.

We have also begun recruiting 1st line subjects into this trial to provide data for a possible future confirmatory Phase 3 clinical trial in 1st line patients. The first two subjects for whom AnnAraC was considered 1st line therapy have been treated, and upon evaluation it was determined that the treatment resulted in a CR for one of the subjects. The other subject was deemed a treatment failure, withdrew from our study, received a different therapy, and subsequently expired.

Currently, the median age of the recruited subjects in MB-106 is 69 years (range of age is 19 to 78 years) with a median number of prior therapies for AML of 1 (range of 0 to 6). The trial has recruited 20 subjects to date with 2 (1 from the 2nd line of therapy population) subjects withdrawing from the trial due to adverse events and 1 other subject not yet having a bone marrow aspirate fully evaluable. We may recruit up to 28 subjects in the Phase 1B/2 clinical trial, however, having already recruited the desired number of 2nd line subjects to support our EoP2 meeting with the FDA, we may elect to complete this trial with fewer than 28 subjects. At our current rate of progress, we expect to conclude the trial and report topline data in 1H 2024.

There continues to be no evidence of cardiotoxicity as reported by an independent Expert's reports following assessments of 4 subjects' data from this trial (included in the Expert evaluations of 63 subjects from all our Annamycin clinical trials). The balance of the subjects in the trial will be reviewed by the Independent Expert in the near future.

In all subjects enrolled to date (n=20) in MB-106 adverse events (Grade $\leq$3) are as follows: thrombocytopenia 47.4%; neutropenia 31.5%; anemia 21.1%; and infections (pneumonia, sepsis, septic shock and staphylococcal bacteremia) 10.5%. Two subjects experienced adverse events and were not dosed per protocol with one having an allergic reaction to Annamycin, the first we have seen in over 70 subjects dosed in our multiple Annamycin clinical trials; the second adverse event was due to an allergic reaction to cytarabine. The CR/CRis have been spread across 3 different sites in two different countries (Poland and Italy) and 7 out of 9 sites participating in the study have recruited subjects to date.

We have been and intend to continue reporting top-line results in all of our clinical trials on a quarterly basis or when a recruiting or regulatory milestone is achieved. Top-line results will include reporting of any drug-related adverse events (AEs) and assessment of cardiotoxicity, as described above. Top-line results will also include the number of partial responses (PRs) and complete responses (CRs), each of which is essentially a function of the magnitude of reduction in a subject's BMA. For purposes of these clinical trials, a CR means that the subject's BMA reduced to 5% or less with recovery of neutrophils (or white blood cells) and platelets, CRi means a CR where there was incomplete recovery of neutrophils and/or platelet counts, and a PR means the subject's BMA reduced by 50% and resulted in a blast count of 25% or less.

MB-108: The strategy to begin the next AML study, which we intend to be a pivotal study, is to approach the FDA or its foreign equivalent for Annamycin to be a 2nd line therapy and design an accelerated approval pivotal trial, with a follow-on confirmatory Phase 3 trial. As mentioned above, we have now concluded the recruitment of subjects for 2nd line treatment in MB-106, enabling evaluation of the necessary data for submission to the regulatory authorities as support for such a trial.

The data above regarding human activity are all from our studies and are preliminary and subject to change, unless a clinical study report (CSR) has been published or the investigator-initiated study has concluded and issued its annual report. "Right-to-try" data are preliminary until published. Such activity may or may not be repeated in future clinical trials, including potentially pivotal and/or confirmatory clinical trials. While we believe such data are encouraging, the FDA or its foreign counterpart will ultimately determine if such data and future data are individually conclusive and supports future clinical trials or approval.

Annamycin Clinical Trials – STS Lung Metastases

We announced in April 2019 that our ongoing sponsored nonclinical research at MD Anderson demonstrated that Annamycin may improve survival in an aggressive form of triple negative breast cancer metastasized to the lungs in animal models. Annamycin was previously shown to be significantly more potent than doxorubicin in both Lewis lung carcinoma in animal models and in 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 have also seen activity in colon cancer metastasized to the lungs. The particular animal models used in our testing are considered to represent very aggressive forms of cancer.

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 as well as a reversal of tumor activity resulting in an almost complete reduction of tumor burden. Such preclinical results may not be replicated in human clinical trials.

We announced in early 2021 that Annamycin demonstrated consistently high antitumor activity in tested animal models of different types of lung-localized cancers, including sarcoma. These promising findings correlate with a high uptake of Annamycin to the lungs in animal models. We found in our studies that Annamycin uptake to the lungs is over 30-fold higher than that of doxorubicin, the primary first-line chemotherapy for advanced soft tissue sarcoma. The limited pulmonary uptake of doxorubicin in animal models may help explain its limited 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.

In February 2021, we announced that a preclinical study in animals had suggested a possible 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 these data are a promising indication of the possibility of Annamycin's impact on other cancers metastasized to the lungs. We caution that these are preclinical animal data and we can provide no assurance that we will see similar results in our clinical trials, let alone ultimately obtain approval of Annamycin for this use.

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, when we began our own clinical trial MB-107 using Annamycin against STS lung metastases, we were aware of only a very few 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 these promising preclinical data, we believe the ultimate market opportunity for Annamycin could be larger than just STS lung metastases. As such, we may expand our clinical trials into these areas in the near term using externally funded trials.

MB-107**:** In December 2020, the FDA allowed our IND to go into effect to study Annamycin for the treatment of soft tissue sarcoma lung metastases. This allowed us to begin a Phase 1b/2 clinical trial in the US for subjects with STS lung metastases after first-line therapy for their disease. The trial began in the first half of 2021. The Phase 1B was concluded in July 2022. On September 21, 2023, we announced the completion of enrollment in the Phase 2 portion of our U.S. Phase 1B/2 clinical trial evaluating Annamycin as monotherapy for the treatment of soft tissue sarcoma lung metastases. Subjects who had stable disease at the time of study discontinuation will continue to be followed for progression free response and overall survival.

All subjects had pulmonary metastases from soft tissue sarcoma and at least one prior therapy. There was no limit on how many prior therapies a subject could have prior to entering this study. Most subjects were heavily treated with other therapies prior to entering our trial with our treatment representing the fourth median therapy for all subjects in the Phase 1B and Phase 2 portion of the trial (range of two to twelve). As of March 1,2024, as reported by the investigation sites, nine subjects in Phase 2 are alive whose OS is currently below the Phase 2 median OS, so OS data are not available at this time for that phase.

Below in Table 3 is a summary of progression free survival for evaluable subjects, as discussed further below, by groupings and median overall survival for all subjects evaluable in Phase 1B:

Table 3 MB-107 Summary as of March 1, 2024

Progression Free Survival Months (mos)	All Subjects	Phase 1B All Subjects	Phase 2 All Subjects	All Subjects Treated at ≤ 330 mg/m2	All Subjects with 2 or Fewer Prior Therapies (≤2PT)	All Subjects ≤ 330 mg/m2 & < 2PT
1 mos or >	100%	100%	100%	100%	100%	100%
2 mos or >	59%	67%	53%	61%	83%	78%
3 mos or >	25%	27%	24%	30%	42%	56%
4 mos or >	16%	13%	18%	22%	25%	33%
5 mos or >	9%	7%	12%	13%	8%	11%
6 mos or >	6%	0%	12%	9%	8%	11%
n =	32	15	17	17	12	9
Median Mos	2.3	2.6	2.0	2.1	2.7	3.1
Median O/S mos	Developing	11.3	Developing	Developing	Developing	Developing

Overall survival (OS); Not available for Phase 2 subjects at this time, as data continues to develop (N/A)

In the Phase 1B portion of the trial, subjects were treated from 210 mg/m2 to 390 mg/m2. In the Phase 2 portion of the trial, an exploratory RP2D of 360 mg/m2 was initiated for the first 3 subjects and a final RP2D of 330 mg/m2 was determined and 15 subjects were treated.

Including the 3 subjects treated at the same dose in the Phase 1B portion of this trial, this equates to seventeen total subjects measurable for efficacy at the 330 mg/m2 dose level. Including all measurable subjects at all dose levels in the Phase 1B portion of the trial, thirty-two subjects were treated with at least one cycle in this study and twenty-seven received at least two cycles of treatment. For the Phase 2 subjects, the median time to entering the MB-107 trial from the time of initial diagnosis is estimated, based on clinical data to date, to be approximately 20 months, and these subjects have been mostly heavily treated previously for STS lung mets prior to entering our study.

Once all data are collected, we plan a more in-depth presentation of the topline data for this study in 2024. Based on the data as shown in Table 3 above, we believe the following observations are in order:

- Very few trials for subjects with such advanced (median = 20 months from initial diagnosis; all with lung metastases in MB-107) disease progression have been published, making comparisons to historical performance difficult.
- With this in mind, median OS for subjects in the Phase 1B portion of this study is currently at 11.3 months, which we believe is notable based on current literature.
- Overall median PFS for the trial is 2.3 months (range 1.2 to 6.9 months) with seven subjects discontinuing early due to thrombocytopenia. Five of these subjects negatively impacted this median PFS, which we believe was exacerbated by the extreme advanced stage of the patients and their being weakened by prior therapies.
- Median PFS improved to 3.1 months for lower doses of Annamycin (≤330 mg/m2) versus the maximum dose used in the trial and for subjects who had fewer prior therapies or PT (≤2).
- These data suggest to us that Annamycin may be best positioned as a first line alternative to the current standard of care with an anthracycline and where an anticipated combination of high patient response rate, significant improvement in OS and the absence of cardiotoxicity may improve patient outcomes.

The data above regarding human activity are all from our studies and are preliminary and subject to change, unless a CSR has been published or the investigator-initiated study has concluded and issued its annual report. "Right-to-try" data are preliminary until published. Such activity may or may not be repeated in future clinical trials, including potentially pivotal and/or confirmatory clinical trials. While we believe such data are encouraging, the FDA or its foreign counterpart will ultimately determine if such data and future data are individually conclusive and supports future clinical trials or approval.

IIT STS Lung Mets or Rutkowski Trial NIO-0002**:** We have collaborated with physicians in Poland at the Maria Sklodowska-Curie National Research Institute of Oncology (MSCNRIO) and are currently supporting a physician-sponsored (externally funded) clinical trial there with study drug. We previously announced their facilitation of a grant equivalent to $1.5 million to fund a Phase 1B/2 clinical trial of Annamycin for the treatment of STS lung metastases. The grant-funded clinical trial is led by Prof. Piotr Rutkowski, MD, PhD, Head of Department of Soft Tissue/Bone Sarcoma and Melanoma at MSCNRIO, and it will be operated independently of our study in the US.

The trial has a dosing regimen of once per week rather than once every 21 days as in the US trial. This trial began dosing subjects in late 2022. Six subjects have been enrolled and treated to date (three in cohort 1 at 35 mg/m2; three in Cohort 2 at 60 mg/m2)). A DLT was noted. The cohort was expanded and a fourth subject in Cohort 2 has been identified, consented in February 2024 and is currently in screening. The preliminary data to date is 50% (3 of 6) have received greater than two cycles (approximately 2 months) of therapy where we have assumed stable disease (SD) through two cycles. One of these three subjects has initiated cycle 5 (with us assuming SD through four cycles). This is all based on a preliminary data from the IIT dosing tracker. The data are preliminary and subject to change.

Previously, this trial was facilitated by WPD Pharmaceuticals (WPD), based in Poland. In March of 2023, WPD assigned their rights and duties related to the grant-funded trial at MSCNRIO to us as part of WPD's termination of its sublicense.

The WP1066 Portfolio Program

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.

We believe our WP1066 Portfolio (including lead drug candidates WP1066 and WP1220), 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. Since 2021, we have been working on developing an appropriate IV formulation for WP1066 or its analogs. As a result of these studies, we believe we have now identified a candidate formulation that is worthy of IND-enabling preclinical testing, which is now underway. Furthermore, we retained an option to license WP1732 but in January 2024 we notified MD Anderson of our intent to terminate the option.

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 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 externally funded studies to build on this preclinical evidence and preliminary animal model data.

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).

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 world. 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 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 well suited to treat a wide range of tumors and possibly 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.

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 the 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 Trials for the WP1066 Portfolio

At the 2019 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 these 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.

In February 2023, the Emory physician-sponsored clinical trial for the treatment of pediatric brain tumors with WP1066 concluded with treating a total of ten subjects in all three cohorts of the Phase 1 dose escalation portion of the trial. The third cohort dosing was deemed safe at 8mg/kg. In that trial, one of the subjects in the first cohort with DIPG showed an apparent response to the treatment with both clinical improvement and radiologic reduction of tumor size. In the ten subjects treated, eight subjects discontinued due to progression or refusal to continue after two cycles. One subject received four cycles prior to progression and one subject received five cycles prior to progression. We caution that this is preliminary data, and no conclusions should be drawn from these events. It is our belief that Emory will continue with a study of WP1066 into a Phase 2 program once further progress is made in a similar adult study.

The data above regarding human activity are all from our studies and are preliminary and subject to change, unless a CSR has been published or the investigator-initiated study has concluded and issued its annual report. "Right-to-try" data are preliminary until published. Such activity may or may not be repeated in future clinical trials, including potentially pivotal and/or confirmatory clinical trials. While we believe such data are encouraging, the FDA or its foreign counterpart will ultimately determine if such data and future data are individually conclusive and supports future clinical trials or approval.

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 CTCL cell lines has suggested that WP1220 may be effective in inhibiting CTCL. Based on these data, we are open to discussions with various pharmaceutical companies for further development of this molecule. CTCL is a potentially deadly form of skin cancer for which there are limited treatment options.

Clinical Activity WP1220

In February 2020, we announced the final data from our CTCL clinical trial of WP1220, which were 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 five subjects enrolled, eleven lesions were assessed according to the CAILS scoring system. The only related AE was mild contact dermatitis in one subject that the investigator deemed was not related to the drug. Four of the five subjects improved in CAILS scores on index lesions, with one exhibiting stable disease, with a median reduction of 56% (range 25-94%). Three of the subjects exhibited a PR. Improvement was noted within seven days of treatment initiation and maintained 1 month after discontinuation. Of the eleven 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, topically applied WP1220 had no safety issues and appeared to be effective in MF. Topical application of WP1220 does not appear to result in systemic exposure to the drug, which is desirable in the case of a topical drug targeting a dermatologic condition.

Alternate Formulation for the WP1066 Portfolio

WP1220 and its close analogs are highly insoluble compounds and as such, WP1066 is currently administered orally. Unfortunately, the present formulation has an undesirable taste profile, and its bioavailability when delivered orally may not be optimum. Although preliminary data from physician-sponsored brain tumor trials indicate that the oral administration of WP1066 results 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 a different oral delivery or intravenous (IV) administration. In 2020, we began developing IV formulation methods for WP1066 and/or its analogs that might address these issues. Recently, we have succeeded in identifying a promising candidate for IV formulation and we have begun IND-enabling preclinical work, however there can be no assurance that this effort will be successful.

The WP1122 Portfolio Program

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 stop 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 25,400 new cases of brain and other nervous system cancers will occur in the United States in 2024, resulting in 18,760 deaths (https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2024-cancer-facts-figures.html). 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 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 looked to establish a RP2D for WP1122 in a Phase 1 clinical trial and certain countries had established accelerated COVID-19 focused programs for Phase 1 trials such as the United Kingdom.

An early 2021 study in India of 2-DG in COVID-19 subjects was conducted by the Institute of Nuclear Medicine and Allied Sciences (INMAS), a lab of the Defense Research and Development Organization (DRDO), in collaboration with Dr Reddy's Laboratories (DRL), Hyderabad, India. INMAS-DRDO scientists initiated a Phase 2 clinical trial on 2-DG in COVID-19 subjects in May 2020 during the first wave of the pandemic. This was followed by a Phase 3 study and an approval in May 2021, by Drugs Controller General India (DCGI) for emergency use of 2-DG as an adjunct therapy in subjects with moderate to severe COVID-19.

Given that WP1122 is a 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 relevant to the potential for WP1122 to be useful in treating COVID-19. The Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom had access to this and other data in approving our CTA, as discussed below, and did not require an animal testing model.

Clinical Trial for COVID-19 with WP1122

On October 19, 2021, we announced that we received authorization from the MHRA to commence a Phase 1a clinical trial of WP1122 in the United Kingdom. The Phase 1a study in healthy human volunteers investigated the effects of a single ascending dose (SAD) and multiple days of ascending dosing (MAD) of WP1122 administered as an oral solution.

On October 14, 2022, we provided an update on the preliminary results from the second MAD cohort of our Phase 1a study of WP1122. This cohort consisted of an initial 4 subjects, who were scheduled to be dosed daily for 7 days with 64 mg/kg/day of WP1122 or placebo in the dose escalation trial evaluating the safety and PK of WP1122. In conjunction with the study SRC, we stopped the second MAD cohort when 2 subjects experienced non-serious adverse events that, although asymptomatic, met the stoppage criteria in the protocol. Although we considered the potential to open a third MAD cohort (2a) to dose subjects at a reduced dose level of 48mg/kg/day for 7 days, we subsequently determined that the primary objectives of this Phase 1a study had already been met by establishing a safe and tolerable dose and that continued testing with healthy volunteers would not be a wise use of resources.

In late October 2022, after further review of the data and in discussions with our clinical team, we determined that the maximum tolerated dose (MTD) for WP1122 is a daily cumulative dose of 32 mg/kg in two divided doses for seven days, and we concluded the Phase 1a study of WP1122. We believe this will advance future studies of WP1122 in antiviral and oncology indications. We have concluded and published the clinical study report for this trial.

With an IND active for WP1122 for the treatment of glioblastoma, we have concluded that advancing WP1122 in these indications will occur only if external funds are available.

Potential Clinical Trial for GBM with WP1122

On December 1, 2021, we announced that the FDA allowed our IND application to study WP1122 for the treatment of GBM to go forward. With this IND cleared, we seek a partner to conduct an externally funded Phase 1 open label, single arm, dose escalation study of the safety, pharmacokinetics, and efficacy of oral WP1122 in adult subjects with GBM. Such a trial would enable parallel development of WP1122 as a cancer therapy. Consistent with our strategy of leveraging external funding for many of our clinical trials, we intend to seek opportunities for an investigator-initiated clinical trial of WP1122 in cancer patients going forward. There is no assurance that we will be successful in finding an investigator with access to externally sourced funds.

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.

Funding Strategy

By "internally funded" we mean that the primary costs of the preclinical activity and clinical trials are funded and sponsored by us. By "externally funded" we mean that the preclinical work is performed by external collaborators and the clinical trials are physician-sponsored or IITs. 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. For externally funded preclinical activities and clinical trials, we do provide drug product and other supporting activities for which costs are shown in our financial statements.

Working Environment

Our headquarters and laboratory are in Houston, Texas, and our workforce, as of year-end 2023, consisted of eighteen full and part-time employees, in the US which are leveraged with other service providers and contractors worldwide working in a primarily virtual environment. 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 the best value for our shareholders either via potential outlicensing or collaborative opportunities with other pharmaceutical companies with existing marketing, sales and distribution or via the development of contracted marketing, sales and distribution capability if and when our drugs are approved.

The spread of COVID-19 caused significant volatility in US and international markets, including Poland, where we conduct some of our clinical trials, and Italy, where our Annamycin drug supply is produced. In 2022, there was limited temporary interruption of our drug supply, and the ability to monitor activities was limited at most Polish clinics where we are conducting trials. The impact of the pandemic appears to have abated, although in the past this was shown to be a volatile situation that could return at any time.

Additionally, war, terrorism, geopolitical uncertainties (such as the current war in Ukraine and in Israel) and other business interruptions could cause damage to, disrupt or cancel the conduct of our clinical trials on a global or regional basis, which could have a material adverse effect on our business, clinical sites, drug suppliers or vendors with which we do business. Such events could also decrease the availability of subjects interested or able to enroll in our clinical trials or make it difficult or impossible for us to deliver products and services to our clinical investigational sites. In addition, territorial invasions can lead to cybersecurity attacks on technology companies, such as ours, located outside of the conflict zone. In the event of prolonged business interruptions due to geopolitical events, we could incur significant losses, require substantial recovery time and experience significant expenditures in order to resume our business or clinical operations. While having operations in neighboring Poland, we have no operations directly in Russia or Ukraine, but we do not and cannot know if the current uncertainties in these geopolitical areas, which are unfolding in real-time, will escalate and result in broad economic and security conditions or rationing of medical supplies or production facilities, which could limit our ability to conduct clinical trials or result in material implications for our business. In addition, our insurance policies typically contain a war exclusion of some description and we do not know how our insurers are likely to respond in the event of a loss alleged to have been caused by geopolitical uncertainties.

We cannot determine whether these events will materially impact our overall business and operations, recruitment, and our drug supply in the future.

Our Intellectual Property and FDA Designations

We have obtained worldwide, exclusive licenses from MD Anderson to issued US patents and pending US patent applications for each of our drug candidates, as well as pending foreign patent applications or issued foreign patents. With respect to certain patents or patent applications, we are co-owners with MD Anderson, in which instances we have exclusively licensed MD Anderson's rights in those patents or patent applications. Where MD Anderson has sole ownership of patents licensed to us, MD Anderson is responsible for the prosecution and maintenance of those patent applications, with input from us and at our expense. Where MD Anderson jointly owns patent applications with us, we are responsible for prosecution and maintenance of those patents and patent applications at our expense. As new discoveries arise with respect to our drug candidates, we and MD Anderson seek to protect our rights to those inventions by filing new patent applications. There can be no assurance that patent applications will issue as patents or, with respect to issued patents, that they will provide us with significant protection.

Issued patents generally expire 20 years after their filing date, subject to adjustment or extension under certain circumstances. For instance, the expiration of US patents may be adjusted to account for prosecution delays, if any, by the United States Patent and Trademark Office (USPTO). Some jurisdictions, including the US and countries belonging to the European Patent Convention, will extend the expiration of an unexpired patent for an approved pharmaceutical product by some portion of time required for clinical development and regulatory review. We intend to seek patent term extensions for patents claiming our product candidates where available. In addition, certain pharmaceutical regulatory bodies, including the US FDA and the European Medicines Agency (EMA), provide some period of exclusivity for new pharmaceutical products independent of patent protection. In the US, regulatory exclusivity can range from three (3) years for a product with a previously approved active pharmaceutical ingredient to seven (7) years for a novel product designated as an Orphan Drug.

We have obtained ODD from the FDA for Annamycin for the treatment of AML and STS; for WP1066 for the treatment of GBM; and, for WP1122 for the treatment of GBM. We have other FDA designations as discussed below. Detailed discussion of potentially relevant regulatory exclusivities can be found under Regulatory Exclusivities below.

The following provides a general description of our patent portfolio and is not intended to represent an assessment of claim limitations or claim scope.

Annamycin

We have pending patent applications directed to the synthetic processes for lyophilized Annamycin and for reconstitution of our Annamycin drug product candidate. We have exclusively licensed MD Anderson's rights in these applications, which are co-owned by MD Anderson and us. The applications are pending in jurisdictions worldwide, including but not limited to Australia, Brazil, Canada, China, European Patent Organization, Japan, Israel, India, South Korea, Mexico, and the US. Both applications have a filing date of June 25, 2020. We also have rights to a patent application, filed on November 23, 2020, directed to the use of Annamycin for the treatment of certain lung cancers.

p-STAT3 Inhibitors

WP1066. We have rights to four issued US patents for WP1066. These patents claim WP1066 and other molecules, as well as methods of treating disease using WP1066. Foreign counterparts to the US patents are issued in Canada, China, Europe, Israel, India, Japan and South Korea. These patents have an international filing date in December 2004, and in certain instances have had the patent term adjusted.

WP1220. We have rights to three issued US patents which claim compositions of WP1220, as well as foreign counterparts issued in China, Eurasia, Europe, Japan, Mexico, New Zealand, Singapore and Ukraine. These patents have an international filing date in June 2009. In addition, we have rights to an issued US patent for the treatment of skin disorders using WP1220, with a filing date in September 2009.

WP1122

We have rights to an issued US patent with claims to compositions of WP1122 and methods for treating cancer using WP1122, with an international filing date in June 2009. We also have rights to foreign counterparts issued in China, Europe, and Japan. In addition, we have rights to US and foreign patent applications directed to the treatment of viral diseases with WP1122 and other anti-metabolites including WP1096 and WP1097, with a filing date in March 2021.

FDA Designations

To further enhance our intellectual property, we have the following FDA designations for our drug candidates as shown. The importance of these designations is discussed further below in the section titled *Regulatory Exclusivities*.

Drug Candidate	FDA ODD - Indication	FDA Fast Track - Designation (FTD)	FDA Rare Pediatric Disease Priority Review Voucher (PRV) Program
Annamycin	Yes – AML, Soft Tissue Sarcoma	Yes – AML, Soft Tissue Sarcoma	No
WP1066	Yes - GBM	No	Yes – Ependymoma, diffuse intrinsic pontine glioma (DIPG), medulloblastoma and atypical teratoid rhabdoid tumor
WP1122	Yes - GBM	Yes - GBM	No

Overview of The Market for Our Oncology Drugs

The American Cancer Society (https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2024-cancer-facts-figures.ht ml) estimates that cancer continues to be the second most common cause of death in the US, after heart disease. A total of 2.0 million new cancer cases and 611,720 deaths from cancer are expected to occur in the US in 2024, which is about 1,680 deaths a day. These statistics do not include either basal cell or squamous cell skin cancers because US cancer registries are not required to collect information on these cancers. These numbers also do not account for the effect the COVID-19 pandemic has likely had on cancer diagnoses and deaths because they are projections based on reported cases through 2019 and deaths through 2020.

Market for Annamycin

Per the American Cancer Society, digestive, reproductive, breast and respiratory cancers comprise most of expected cancer diagnoses in 2024, 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 AML comprising 27,350 of the estimated 62,770 new cases expected in the United States in 2024. The National Cancer Institute estimates that cancer-related direct medical costs in the US were $208.9 billion in 2020, which is likely an underestimate because it does not account for the growing cost of treatment; for example, the list price for many prescription medicines is 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, world-wide annual revenues generated from anthracyclines have been estimated to approximate $1 billion. 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 Cytarabine with 3 infusions of an anthracycline to induce remission (a complete response, or "CR"). This therapy had not improved since it was first used in the 1970s and we estimate that this induction therapy had a success rate of about 20% to 25%. A revision to this therapy was approved in the form of a drug called Vyxeos, which combines 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).

Until more recent new drug approvals, palliative care or focus on overall survival versus curative treatment was the predominant treatment modality for patients not suitable for traditional chemotherapy. In 2019, AbbVie's Venclexta was approved by the FDA in combination with a hypomethylating agent (azacitidine or decitabine) or low-dose AraC (LDAC) for the treatment of newly diagnosed AML in patients who are 75 years of age or older, or for those ineligible (Un-Fit) for intensive induction chemotherapy due to co-existing medical conditions. In addition, 5 different targeted therapies have been approved in the U.S. for treatment of relapsed or refractory (2nd Line) AML patients. Despite these advancements, we believe approximately 60% of AML patients will either not qualify for or will not succeed with these available treatments, leaving a significant unmet need.

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.

The lungs are the most frequent site of metastasis from soft-tissue sarcomas. It has been estimated that as high as approximately 50% 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 metastatectomy, PM) is the preferred treatment. However, guidelines for the performance of PM for STS do not exist and decisions to operate are often made on an individual basis (American Association for Thoracic Surgery (AATS). (2016, May 16). Increasing survival in soft tissue sarcoma patients with lung metastases undergoing resection. ScienceDaily. Retrieved March 3, 2023 from www.sciencedaily.com/releases/2016/05/160516181330.htm). Metastatectomy and/or chemotherapy are the most common treatments offered to patients with metastatic sarcoma. Pulmonary metastatectomy, 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.

We believe that 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. According to our 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 first-line treatment involve surgery, off-label treatment, and stereotactic radiation therapy (SBRT). We estimate that around 80% of patients taking the first-line treatment due to relapse of the disease progress on to second-line treatment. Since we know of no approved or emerging therapies for treatment of relapsed/refractory patients, we believe that first-line therapies are often used again in second-line management. Other cancers metastasize to the lungs, including osteosarcoma, breast and colon cancers, for which the relapsed or refractory population is estimated to exceed 8,000 in the US. In addition, there are over 20,000 annual cases of testicular, thyroid, endometrial, renal and cervical cancers which metastasize to the lungs. Given this backdrop, we believe the best initial pathway for Annamycin is to pursue the second-line treatment of STS lung metastasis.

Per the American Cancer Society, in 2024, an estimated66,440 new cases of pancreatic cancer will be diagnosed in the US and 51,750 people will die from the disease. While pancreatic cancer only accounts for 3.3% of all cancer diagnoses, it has the highest mortality rate of all cancers and is the third leading cause of cancer-related deaths in the US, behind lung and colon cancer. The most effective treatment for pancreatic cancer is surgery, but fewer than 20% of cases are eligible for a surgical approach. The 80% of non-resectable pancreatic cancers are typically treated with chemotherapy and other pharmacotherapies. Global sales of drugs used for the treatment of pancreatic cancer, including Abraxane, Lynparza and Tarceva, exceeded $3 billion in 2020, though this figure includes sales for treatment of other cancers as well. Abraxane became generic in 2023 which should impact this number. There is a tremendous amount of clinical development activity in pancreatic cancer, with 551 trials ongoing, of which 32 were late-stage.

Market for Our WP1066 (STAT3) Portfolio

Our active development program for WP1066, has 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 development 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 of primary malignant brain and central nervous system tumors in the US 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 subjects 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 subject 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 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 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 management believes have a value 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. MF is considered a low-grade cutaneous lymphoma which we estimate accounts for more than half of primary CTCLs. Early-stage MF (Stages I and II; ~70% of subjects) 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 trial for the treatment of CTCL was conducted in 5 subjects, including the treatment of a total of 11 lesions and concluded with a lesion objective response rate (ORR) of 45%, no adverse events and 55% stable disease, resulting in 100% clinical benefit. 60% of the subjects responded with a PR. 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 cancer.

In addition to the market for GBM described above, pancreatic cancer is a rare and difficult to treat form of cancer. Cancers of the pancreas are a very serious health issue in the United States where pancreatic cancer is the fifth leading cause of cancer deaths following breast cancer; lung cancer, colon cancer, and prostate cancer. 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.

Our License Agreements

Sponsored Research and License Agreements with MD Anderson

We have licensed 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, 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 for the years ended December 31, 2023 and 2022, respectively. For more information about our license agreements, see Footnote 8 - Commitments and Contingencies included in our Consolidated Financial Statements set forth in this report.

We have a sponsored research agreement with MD Anderson that currently runs until the end of December 2025. In addition, the Company also has Sponsored Research Agreements with other universities, one in the US and one in Europe. The expenses recognized under the agreements, mainly related to MD Anderson, were $0.8 million and $1.1 million for the years ended December 31, 2023 and 2022, respectively.

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 MD Anderson.

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

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

Corporate History

We were founded in 2015 by Walter Klemp (our chairman and CEO), Dr. Don Picker (our Chief Science Officer) and Dr. Waldemar Priebe of MD Anderson (Chairman of our Scientific Advisory Board) in order to combine and consolidate 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 March 22, 2024, we completed a one-for-fifteen reverse stock split of our shares of common stock and proportionate reduction in the number of authorized shares of common stock from approximately 33,000,000 shares to approximately 2,000,000. The reverse stock split was effected in accordance with the authorization adopted by our stockholders at our 2023 special meeting of stockholders.

In July 2021, we formed Moleculin Amsterdam B.V., a wholly owned subsidiary, primarily to act as our legal representative for clinical trials in Europe for Moleculin Biotech, Inc.

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 classes 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, we believe that 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 treated with Venclexta in combination with azacitidine, or low-intensity therapy such as low-dose cytarabine, azacitidine or decitabine. It should be noted that, in the United States, the latter 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. A recently developed liposome formulation of daunorubicin and cytarabine called Vyxeos 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. More recently, Venetoclax was approved for the treatment of AML, targeting patients over 75 years of age or not suitable for typical chemotherapy.

Drugs attempting to target a subset of AML patients who present with specific gene mutations, such as IDH1, IDH2 and 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 are 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.

Soft-tissue sarcomas which have metastasized to the lungs are extremely difficult to treat. There are an estimated 13,600 new cases of soft-tissue sarcoma diagnosed each year, and of those that metastasize, approximately 70% of metastases occur to the lungs. The current standard of care consists of anthracycline therapy or newer-generation drugs such as pazopanib. However, only 20% of patients with STS lung metastases respond to these treatments. There are competitive efforts underway to develop new treatments for STS, including metastatic STS, but few specifically target STS metastases to the lungs.

Non-resectable pancreatic cancers are typically treated with chemotherapy and other pharmacotherapies, including Abraxane, Lynparza and Tarceva. While these products have been commercially successful, their success rates at treating pancreatic cancer are low and fatality rates remain high. This has led to a tremendous amount of clinical development activity in pancreatic cancer, with 551 trials ongoing, resulting in significant competition for pancreatic cancer patients among clinical trials, which could impact development timelines.

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

Government Regulation

Government authorities at the federal, state and local level in the US, and in analogous levels in other countries extensively regulate, among other things, the development, testing, manufacture, quality control, safety, effectiveness, approval, labeling, packaging, storage, distribution, import, export, record-keeping, reporting, promotion, advertising, distribution, 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 commercially distributed in the US, and by regulators in other countries before being marketed and commercially distributed there.

In the United States, the FDA regulates pharmaceutical products such as our product candidates 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. Obtaining regulatory approvals and complying with post-approval requirements generally is expensive, labor-intensive and time-consuming. Failure to comply with the applicable requirements may subject an applicant to administrative or judicial enforcement action, which could include refusal to permit clinical trials to be conducted, refusal to approve an application, withdrawal of an approval, issuance of a warning letter, product recall, product seizure, suspension of production or distribution, fines, refusals of government contracts, and restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Development and Approval

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;
- Submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin;
- Performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices (GCP) and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed pharmaceutical product for its intended use;
- Submission to the FDA of an NDA for marketing approval that includes substantial evidence of safety and effectiveness from results of clinical trials, as well as the results of preclinical testing, detailed information about the chemistry, manufacturing and controls, and proposed labeling and packaging for the product;
- Review of the product candidate by an FDA advisory committee, if applicable;
- 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 practice, or cGMP, requirements, 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 trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA, including agreement on post-marketing commitments, if applicable.

The development and approval process, as well as post-approval requirements and restrictions, require substantial resources, attention and effort, and the prospects for approval and continued compliance are inherently uncertain.

Preclinical Testing. Before testing any compound in humans in the US, a company must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in animals to assess the product's safety and activity. The preclinical work must be done in accordance with Good Laboratory Practice, or GLP, requirements, the Animal Welfare Act, and other applicable regulations. The sponsor must submit the preclinical data in an IND, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol. Unless the FDA notifies the sponsor otherwise, an IND becomes effective 30 days after receipt by the FDA, and the proposed clinical trial may begin. If it expresses concerns to the sponsor, FDA may impose a "clinical hold," which precludes beginning the study until the issues are resolved. Similarly, once a study has begun, the FDA may impose a clinical hold suspending further activity, pending resolution of agency concerns. Accordingly, we cannot be sure that submission of an IND will result in a clinical trial beginning or that, once begun, a clinical trial will not be suspended or terminated.

IND Application. Clinical trials involve the administration of the product candidate to healthy volunteers or subjects with the targeted disease under the supervision of qualified investigators, generally physicians not employed by or under the clinical trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, 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 for trials conducted in the US must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with FDA's good clinical practice, or GCP, regulations, which are intended to safeguard study subjects and support the validity of the resultant data. Further, each clinical trial must be reviewed and approved by an independent institutional review board (IRB) at, or servicing, each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of study participants and for determining that the risks to study participants are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that each study subject (or his or her legal representative) must sign, and is responsible for monitoring the conduct of the study until completed.

Clinical testing. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The pharmaceutical product is initially administered to humans, usually a small group of healthy human subjects, but occasionally to subjects with the targeted disease. This latter case is usually reserved for product candidates intended for severe or life-threatening diseases (such as cancer) and/or when the product may be too inherently toxic to ethically administer to healthy volunteers. Phase 1 trials generally are intended to determine the metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. Because our product candidates are being studied for treating cancers and contain cytotoxic agents, our Phase 1 studies are conducted in late-stage cancer patients whose disease has progressed after treatment with other agents, and are focused on establishing a maximum tolerable dose (MTD).

- Phase 2: Here the product candidate is evaluated in a limited patient population to develop data regarding effectiveness, to determine dosage tolerance, optimal dosage and dosing schedule, to gather additional safety information, and to identify patient populations with specific characteristics where the pharmaceutical product may be more effective.

- Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials 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, often with the understanding that the approved drug can be sold subject to a confirmatory trial to be conducted post-approval.

Additionally, post-approval studies, also referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are often used to gain additional information about use of the product for its approved indication, and may at times be required by the FDA as a condition of approval.

Clinical trials require submission of annual progress reports to the FDA, and certain events, especially safety-related information, may require making reports to the FDA, investigators, and/or the IRB, and can lead to suspension, modification, or cessation of ongoing trials. Accordingly, clinical trials may not be completed successfully within any specified period, if at all.

Concurrent with clinical trials, companies usually complete additional animal studies, develop additional information about the physical characteristics of the product candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements.

The sponsor of a clinical trial or the sponsor's designated responsible party may be required to register certain information about the trial and disclose certain results on government or independent registry websites, such as ClinicalTrials.gov. Additionally, a manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug or, as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

NDA Submission and Review. The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the pharmaceutical product candidate, proposed labeling and other relevant information are submitted to the FDA as part of an NDA seeking approval to market the product. Under the Prescription Drug User Fee Act (PDUFA), as amended, the submission of an NDA is subject to the payment of a substantial fee, although the fee may be waived under certain circumstances, which may or may not be applicable to us or our partners for any of our product candidates. In addition, under the Pediatric Research Equity Act, as amended, an NDA or supplement to an NDA generally must contain data to assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers depending on the designated pathway for submission.

The FDA first examines a submitted NDA to determine if the application is sufficiently complete to be accepted for review. If not, the agency may refuse to file the NDA, informing the sponsor of inadequacies to be addressed in a resubmitted application. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once an NDA is accepted for filing, the FDA begins an in-depth review of the application. Pursuant to goals established under PDUFA, the FDA aims to complete the review within 10 months of the 60-day filing date, which would be within 12 months of the date of submission, but that deadline is extended in certain circumstances, including by FDA requests for additional information or clarification.

The FDA also has programs intended to expedite the development and review of new drugs intended to treat serious or life-threatening conditions and address unmet medical needs and/or provide benefits over existing therapies. They include:

- Priority Review, under which FDA aims to complete the NDA review within eight months of the date of submission;
- Accelerated Approval, where a product may be approved on the basis of data demonstrating an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit;
- Fast Track, which may provide for FDA review of sections of the NDA on a rolling basis, before the complete application is submitted; and
- Breakthrough Therapy, which also provides for rolling review and other actions to expedite review of the NDA.

The availability of these programs is determined by the facts surrounding each specific product candidate, the disease or condition it is intended to treat, and the availability and characteristics of alternative treatments. Because those factors are subject to change, even if a product or application is granted designation for one (or more) of these programs, the benefits of the program may ultimately not be available. Additionally, the FDA may rescind designations for certain expedited programs (specifically, Fast Track and Breakthrough Therapy) if the agency determines the product candidate no longer meets the criteria for such programs.

The FDA review of an NDA focuses on determining, among other things, whether the proposed product candidate is safe and effective for its intended use, and whether the product candidate is being manufactured in accordance with cGMP to assure and preserve the product candidate'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. The FDA may also determine that a risk evaluation and mitigation strategy (REMS) is necessary to assure the safe use of the product. Among other things, a REMS can include restrictive conditions under which the product may be distributed, which may have a negative impact on the product's commercial success. If the FDA concludes that a REMS is needed, the NDA sponsor must submit a proposed REMS, and the product will not be approved until FDA determines that the proposed REMS is adequate.

The FDA usually will inspect the facilities at which the product candidate is manufactured, and will not approve the product candidate unless the agency 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 trial sites to assure compliance with IND study requirements and GCP. The NDA review process also includes evaluation of the proposed labeling, which is often the subject of significant back-and-forth between the sponsor and the agency.

The NDA review and approval process is lengthy and difficult, and may involve FDA requests for additional data or information, which may extend the process and/or lead the agency to refuse to approve the application. This is the case even if requested data or information are submitted, because data are not always conclusive and the FDA may interpret data differently than the sponsor does. If it decides not to approve an NDA, the FDA will issue a complete response letter, which usually describes the specific deficiencies in the NDA and may include recommended actions the applicant might take for the FDA to reconsider the application. The deficiencies may be minor, for example, requiring labeling changes, or more significant, such as requiring additional clinical trials. An applicant receiving a complete response letter may either revise and resubmit the NDA or withdraw the application.

FDA approval of an NDA may impose significant limitations that could weaken the commercial value of the product. This could take the form of a narrow indication or dosage, requiring the labeling to contain contraindications, warnings or precautions to address perceived safety issues, or mandating a REMS that significantly restricts or imposes burdens on how the product is distributed. Additionally, the FDA may require Phase 4 testing as a condition of approval. In particular, the FDA requires Phase 4 testing as a condition of accelerated approval, and may withdraw accelerated approval of a product if a sponsor fails to timely conduct such studies or if those studies fail to confirm safety or effectiveness. Such post-approval requirements can materially impact a product's commercial prospects. Post-approval modifications to a drug product, such as changes in indications, labeling or manufacturing processes or facilities, may require development and submission of additional information or data in a new or supplemental NDA, which would also require prior FDA approval.

Regulatory Exclusivities. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the US. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA grants ODD for the product for that use. The benefits of ODD include research and development tax credits and exemption from user fees, including the significant application fee otherwise required with submission of an NDA. A drug that is approved for an indication that is within the product's orphan drug designation is granted seven years of orphan drug exclusivity (ODE). During that period, the FDA generally may not approve any other application for product with the same active moiety for the same use, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with orphan drug exclusivity. A court decision in 2021 broadened the scope of ODE, but the ultimate impact of that decision is yet to be determined, as FDA has stated that it does not intend to apply the court decision to other products, and the agency has instead continued to apply the narrower scope that has long been the agency's approach.

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 that 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, which can include if 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. Significant revisions to the relevant law in the EU have been proposed and, if adopted, may affect the availability or benefits of ODD or ODE there.

Products that are approved to treat rare diseases that are serious or life-threatening and where the serious or life-threatening manifestations primarily affect patients under the age of 19 years of age may qualify for the Rare Pediatric Disease Priority Review Voucher (RPDPRV) program, in which the product sponsor receives upon approval a voucher for priority review of another product. The voucher can be used by the sponsor for a subsequent application that would not in its own right qualify for priority review, or it may be sold to another company for that use. In either case, a RPDPRV may have significant value. Under the current statutory sunset provisions for the RPDPRV program, after September 30, 2024, FDA may award a voucher for an approved rare pediatric disease product application only if the sponsor has rare pediatric disease designation for the drug, and that designation was granted by September 30, 2024. After September 30, 2026, FDA may not award any rare pediatric disease priority review vouchers. Although there has been discussion of further extending the RPDPRV program, it is unclear if any such legislation will be adopted.

We received ODD for Annamycin for the treatment of AML in 2018, and in 2020 for the treatment of soft tissue sarcomas, and Fast Track Designation for Annamycin for the treatment of relapsed or refractory AML in April 2019. We received ODD for WP1066 for the treatment of glioblastoma in 2019. If WP1066 is timely approved for the treatment of any of the following pediatric diseases, we may qualify for a Rare Pediatric Disease Priority Review Voucher: ependymoma, medulloblastoma, diffuse intrinsic pontine glioma, or atypical teratoid rhabdoid tumor, provided that related statutory sunset provisions are extended.

The federal Food, Drug and Cosmetic Act (FDCA) also provides for a grant of five-year exclusivity with approval of a product containing a new chemical entity (NCE), which generally means that the active moiety has never before been approved in any drug. During this exclusivity period, which runs from the date of the product's approval, FDA may not accept for filing any Abbreviated New Drug Application (ANDA) for a generic version of the product or any 505(b)(2) NDA (generally an NDA that relies on data that are not the sponsor's and for which the sponsor has not obtained a right of reference) for a product with the same active moiety. There are circumstances under which the follow-on application can be submitted at four years, and there are provisions that operate to preclude approval of the application for an additional period of time. Also, NCE exclusivity does not block approval of a "full" NDA (generally, an NDA in which the data are the sponsor's or for which the sponsor has obtained a right of reference). The NCE exclusivity scheme is complicated and evolving; for that reason, although we believe that some of our products will qualify for five-year NCE exclusivity, we cannot be certain that will receive such exclusivity, or that if we do, the exclusivity will effectively protect our market position.

Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products.

Generic Drugs. A generic version of an approved drug is approved by means of an abbreviated new drug application (ANDA), by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the reference listed drug (RLD). Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This is instead of independently demonstrating the proposed product's safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective.

505(b)(2) NDAs. As discussed above, if a product is similar, but not identical, to an already approved product, it may be submitted for approval via an NDA under section 505(b)(2) of the FD&C Act. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on information from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, and must submit its own product-specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under 505(b)(2) may in turn serve as an RLD for subsequent applications from other sponsors.

RLD Patents. In an NDA, a sponsor must identify patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A "Paragraph I" certification is the sponsor's statement that patent information has not been filed for the RLD. A "Paragraph II" certification is the sponsor's statement that the RLD's patents have expired. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

Regulatory Exclusivities. The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. If a product is a "new chemical entity," or NCE — generally meaning that the active moiety has never before been approved in any drug — there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification.

A product that is not an NCE may qualify for a three-year period of exclusivity if the NDA contains new clinical data, (other than bioavailability studies) derived from studies conducted by or for the sponsor, that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD or listed drug NDA holder and patent owner that the application has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the regulatory stay extends until 7.5 years after the RLD approval. The FDA may approve the proposed product before the expiration of the regulatory stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation. In connection with the submission of our NDA for product in February 2023, we provided Paragraph IV certification notices to the NDA holder and patent owner of the two unexpired Orange Book-listed patents covering the reference product. As noted above, these parties have 45 days from receiving the Paragraph IV certification notices to file a patent infringement suit which would prohibit the FDA from approving our NDA for up to 30-months.

If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the regulatory stay extends until 7.5 years after the RLD approval. The FDA may approve the proposed product before the expiration of the regulatory stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Patent Term Restoration. A portion of the patent term lost during product development and FDA review of an NDA is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U.S. Patent and Trademark Office (USPTO) in consultation with the FDA, reviews and approves the application for patent term restoration.

Post-Approval Requirements

Once approved, products 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. 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. If ongoing regulatory requirements are not met, or if safety or manufacturing problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials, changes to a product's approved labeling, including the addition of new warnings and contraindications, or the implementation of other risk management measures, including distribution-related restrictions, if there are new safety information developments. Further, 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.

We rely and expect to continue to rely on third parties for the production of clinical and commercial quantities of our product candidates. Manufacturers of our product candidates are required to comply with applicable FDA manufacturing requirements contained in the agency's cGMP regulations and related policies. The cGMP regulations require, among other things, adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, 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 pharmaceutical products are required to register their establishments with the FDA and certain state agencies and the FDA inspects equipment, facilities, and processes used in manufacturing pharmaceutical products prior to approval. The FDA and certain state agencies also conduct periodic unannounced inspections to re-inspect equipment, facilities, and processes 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. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to take enforcement actions or seek sanctions, including fines, issuance of warning letters, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party manufacturers, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP and other applicable FDA regulatory requirements.

Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or NDA sponsor, 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

If we receive FDA approval of our pharmaceutical product candidates, and depending upon the timing, duration and specifics of the FDA approval of the use of our pharmaceutical product candidates, some of our product candidates 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 the 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 trials and other factors involved in the filing of the relevant NDA. We cannot be certain that any of our product candidates 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 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 trials 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.

At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the Inflation Reduction Act (IRA), among other things, (1) directs HHS to negotiate the price of certain high-cost, single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Under the IRA, certain categories of drugs are excluded from price negotiations, including drugs that receive orphan drug designation as the only FDA-approved indication. While we have obtained orphan drug designation for Annamycin, if we seek additional indications, or fail to maintain our orphan drug status, we may become subject to the price negotiation process. This could reduce the ultimate price that we receive for Annamycin, which could negatively affect our business, results of operations, financial conditions, and prospects. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

At the state level, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

International Regulation

In addition to regulations in the United States, we are 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.

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 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 outcomes are not shown to be related to our drugs.
- We are conducting important clinical trials in the US and Europe, 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 and we utilize a single source for such API for certain of 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 guarantee how long it will take regulatory agencies to review our applications for product candidates, and we may fail to obtain the necessary regulatory approvals to market our product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired.
- 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.
- As an organization, we have never conducted pivotal clinical trials, and we may be unable to do so for any product candidate we may develop.
- We may expend significant resources to pursue certain product candidates for specific indications and fail to capitalize on the potential of such product candidates for the potential treatment of other indications that may be more profitable or for which there is a greater likelihood of success.
- 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.
- We may find it difficult to enroll subjects in our clinical trials, which could delay or prevent clinical trials of our product candidates.
- 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 sufficient 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.
- Even if our product candidates otherwise qualify for approval from the FDA, 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 ODD for Annamycin, WP1066, and WP1122, but even if either product candidate is approved and receives ODE, ODE 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 two 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. Fast Track designation may also be rescinded if the FDA believes the designation is no longer supported by data from our clinical development program.
- 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.
- We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.
- Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize Annamycin and any future product candidates and may affect the prices we may set.

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.
- We will not be able to protect our intellectual property rights throughout the world.

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.
- 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 delayed recruitment in our clinical trials in the past and may return, 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.
- We may be required to make significant payments under our license agreements with MD Anderson.
- New tax laws or regulations that are enacted or existing tax laws and regulations that are interpreted, modified, or applied adversely to us or our customers may have a material adverse effect on our business and financial condition.

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.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.
- 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.
- Artificial intelligence presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information and personal data.
- Certain provisions in our organizational documents could enable our board of directors to prevent or delay a change of control.
- Shareholder activism could cause material disruption to our business.

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 drug candidates to treat patients who are extremely or terminally ill, and severe adverse outcomes, including patient deaths, that occur in our clinical trials could negatively impact our business even if such outcomes 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 drug candidates.

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 the US and Europe, and we are performing 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 and Italy. Additionally, from time to time, we perform studies to determine if there are additional countries in which we should hold current and future 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 and we utilize a single source for such API for certain of 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. For our lead product candidate, Annamycin, we currently utilize a single source to manufacture API, and if we were to lose this supplier, it could cause delays while we located a new supplier. 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.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance. We do not have control over third party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures;
- delays as a result of manufacturing problems or re-prioritization of projects at a third-party manufacturer;
- our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and commercial needs, if any;
- termination or non-renewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how or infringement of third-party intellectual property rights by our contract manufacturers; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

Any of these events could lead to preclinical study and clinical trial delays or failure to obtain regulatory approval or affect our ability to successfully commercialize future products. Some of these events could be the basis for FDA or other regulatory authority action, including clinical holds, fines, injunctions, civil penalties, license revocations, recall, seizure, total or partial suspension of production, or criminal penalties.

In addition, our product candidates involve technically complex manufacturing processes, and even slight deviations at any point in the production process may lead to production failures and may cause the production of our product candidates to be disrupted, potentially for extended periods of time. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original contract manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. Furthermore, a contract manufacturer may possess technology related to the manufacture of our product candidate that such contract manufacturer owns independently. This would increase our reliance on such contract manufacturer or require us to obtain a license from such contract manufacturer in order to have another contract manufacturer manufacture our product candidates.

Third-party manufacturers may not be able to comply with applicable cGMP regulations or similar regulatory requirements outside the US. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed, including clinical holds, fines, injunctions, civil penalties, delays, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

In addition, if we are required to change contract manufacturers for any reason, we will be required to verify that the new contract manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new contract manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers, and it may prove very difficult and time consuming to identify potential alternative manufacturers who could manufacture our product candidates. Accordingly, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

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 guarantee how long it will take regulatory agencies to review our applications for product candidates, and we may fail to obtain the necessary regulatory approvals to market our product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired.

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 trial 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 subject 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 subject 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 subjects, including subjects who are suffering from the disease the product candidate is intended to treat and who meet other eligibility criteria. Rates of subject 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 subjects and the stage and severity of disease, the nature of the protocol, the proximity of subjects 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;
- clinical sites dropping out of a clinical trial;
- time required to add new clinical 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 or inability to enroll research subjects in sufficient numbers or at the expected rate;
- high drop-out rates and high fail rates of research subjects;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or foreign regulatory authorities;
- delays or failures in obtaining required IRB approval;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
  failure to comply with GLP, GCP, cGMP or similar foreign regulatory requirements that affect the conduct of pre-clinical and clinical studies and the manufacturing of product candidates;
- greater than anticipated clinical trial costs;
- poor efficacy of our product candidates during clinical trials;
- requests by regulatory authorities for additional data or clinical trials;
- governmental or regulatory agency assessments of pre-clinical or clinical testing that differ from our interpretations or conclusions;
- governmental or regulatory delays, or changes in approval policies or regulations; or
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or vendor.

We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA or one or more other regulatory authorities outside the United States find deficiencies in our IND or similar application outside the United States or the conduct of the trial. If we experience delays in the completion of, or the termination of, any clinical trial of any of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations, cash flows and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

As an organization, we have never conducted pivotal clinical trials, and we may be unable to do so for any product candidates we may develop.

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, EMA or other regulatory agencies to market our product candidates. Carrying out pivotal clinical trials is a complicated process. As an organization, we have limited experience in successfully executing earlier-stage clinical trials, and we have not previously conducted any later stage or pivotal clinical trials. In order to do so, we will need to expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission and approval of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

We may expend significant resources to pursue certain product candidates for specific indications, and fail to capitalize on the potential of such product candidates for the potential treatment of other indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. Specifically, with regard to Annamycin, we are initially focusing our efforts on the treatment of AML and STS lung mets. As a result, we may forego or delay pursuit of opportunities with Annamycin or other product candidates for the treatment of other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Furthermore, until such time as we are able to build a broader product candidate pipeline, if ever, any adverse developments with respect to our current product candidates would have a more significant adverse effect on our overall business than if we maintained a broader portfolio of 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.

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 trials could be substantially delayed or prevented by several factors, including, but not limited to:

- failure to reach agreement with the FDA or other regulatory agency requirements for clinical trial design or scope of the development program;

  a limited number of, and competition for, suitable subjects with particular types of cancer and viruses for enrollment in our clinical trials;

- delays or failures in reaching acceptable clinical trial agreement terms with CROs or clinical trial sites;
    - delays or inability to attract clinical investigators for trials;
    - clinical sites dropping out of a clinical trial;
    - time required to add new clinical sites;
- failure of subjects to complete the clinical trial or inability to follow subjects adequately after treatment;

  failures by, changes in our relationship with, or other issues at, CROs, vendors and investigators responsible for pre-clinical testing and clinical trials;

  imposition of a clinical hold; 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.

We may find it difficult to enroll subjects in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying subjects to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends in part on the speed at which we can recruit subjects to participate in testing our product candidates. If subjects are unwilling to participate in our trials because of the COVID-19 pandemic and restrictions on travel or healthcare institution policies, negative publicity from adverse events in the biotechnology industries, public perception of vaccine safety issues or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of subjects, or those with required or desired characteristics to achieve diversity in a clinical trial, or complete our clinical trials in a timely manner. Subject enrollment is affected by a variety factors including, among others:

- severity of the disease under investigation;
- design of the trial protocol and size of the patient population required for analysis of the trial's primary endpoints;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate being tested;
- willingness or availability of subjects to participate in our clinical trials (including due to the COVID-19 pandemic);
- proximity and availability of clinical trial sites for prospective subjects;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- availability of competing vaccines and/or therapies and related clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- our ability to obtain and maintain subject consents;
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion;
- subject referral practices of physicians; and
- ability to monitor subjects adequately during and after treatment.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible subjects to participate in the clinical trials required by regulatory agencies.

Even if we enroll a sufficient number of eligible subjects to initiate our clinical trials, we may be unable to maintain participation of these subjects throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those subjects. If we have difficulty enrolling and maintaining the enrollment of a sufficient number of subjects to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

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, was in two physician-sponsored Phase 1 clinical trials, one for adult GBM and another for pediatric brain tumors. Our drug product candidate, Annamycin, is currently 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 and MD Anderson terminated that trial. While we are making arrangements to continue this research in additional physician-sponsored trials, research on WP1066 in adult GBM has been 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 sufficient 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 sufficient 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.

Significant adverse events caused by our product candidates or even competing products in development that utilize a common mechanism of action could cause us, an IRB or ethics committee, and/or regulatory authorities to interrupt, delay or halt clinical trials and could result in clinical trial challenges such as difficulties in subject recruitment, retention, and adherence, the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Serious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole. 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. In trials, both with prior developers and with ours using Annamycin, subjects have experienced adverse events. There can be no assurance that other adverse events may not emerge related to our drug. 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.

Even if our product candidates otherwise qualify for approval from the FDA, 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 our product candidates.

We are currently utilizing contract manufacturers for the production of the active pharmaceutical ingredients and the formulation of drug product candidates for our clinical trials. Additionally, even if our product candidates otherwise qualify for approval from the FDA, we do not intend to manufacture the approved pharmaceutical products. We do not currently have agreements for the commercial manufacture 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 commercial supplies of 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 products. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's cGMP requirements, 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 prevent or 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 ODD for Annamycin, WP1066, and WP1122, but even if either product candidate is approved and receives ODE, ODE may not effectively prevent approval of a competing product.

In 2017, we received notice that the FDA granted 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 and later on for WP1122, as well.

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 if either Annamycin or WP1066 is approved and ODE is granted, we cannot know that the exclusivity 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. We are conducting significant clinical trials of Annamycin in Europe based on discussions with local regulatory bodies, and our business strategy includes utilizing the results from these clinical trials in our FDA submissions. There is no assurance that the FDA will accept the results from these clinical trials, which could require us to redo such trials in order to receive approval of our product candidates in the United States. 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 two of our product candidates and may seek the same designation for one of more of our other product candidates. Such designation may not actually lead to a faster development or regulatory review or approval process. Fast Track designation may also be rescinded if the FDA believes the designation is no longer supported by data from our clinical development program.

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. FDA granted Fast Track designation to Annamycin for STS lung metastases and WP1122 for GBM. If we seek Fast Track designation for other indications on either of these or another product candidate, we may not receive it from the FDA. Additionally, 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 subject 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 subject enrollment continues and more subject data becomes 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 trials 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.

We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we or any manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. In addition, the supply chain for the manufacturing of our product candidates is complicated and can involve several parties. If we were to experience any supply chain issues, including as a result of the COVID-19 pandemic, our product supply could be seriously disrupted.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize Annamycin and any future product candidates and may affect the prices we may set.

At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the Inflation Reduction Act (IRA), among other things, (1) directs HHS to negotiate the price of certain high-cost, single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Under the IRA, certain categories of drugs are excluded from price negotiations, including drugs that receive orphan drug designation as the only FDA-approved indication. While we have obtained orphan drug designation for Annamycin, if we seek additional indications, or fail to maintain our orphan drug status, we may become subject to the price negotiation process. This could reduce the ultimate price that we receive for Annamycin, which could negatively affect our business, results of operations, financial conditions, and prospects. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

At the state level, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. We expect that the Affordable Care Act and other healthcare reform measures, including those that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from third-party payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize Annamycin, if approved.

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 US 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.

We will not be able to protect our intellectual property rights throughout the world.

We are dependent on patents licensed with MD Anderson. Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we will not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These infringing products may compete with the product candidates we may develop, without any available recourse.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Because the legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, it could be difficult for us to stop the infringement, misappropriation or violation of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and other proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly, could put our patent applications or the patent applications of our licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 our current cash resources and the proceeds from any possible future offerings, to, among other uses, advance Annamycin, WP1122 and WP1066 for certain indications 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. 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 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 our product candidates, 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 and 2 clinical trials. We have yet to receive regulatory approvals for any of our drug candidates. Additionally, we have a limited amount of drug supply and the amount of drug required may depend upon subject 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 subjects 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 subjects 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 terminated in March 2023) and Animal Lifesciences, LLC. Dr. Priebe is affiliated with both WPD Pharmaceuticals, Inc. and Animal Lifesciences, LLC.

For the sublicense agreement (and the March 2021 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 the March 2021 amendment). Due to the increase in the required development efforts and the reduction in the buyback calculation in the amendment in December 2021, we did not receive a fairness opinion on that amendment. We also 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, 2023, we incurred a net loss of $29.8 million. We had an accumulated deficit of $131.6 million as of December 31, 2023.

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.

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, 2023. 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. 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 subjects 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 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 put 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 subjects 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 delayed recruitment in our clinical trials in the past and may return, 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 delayed recruitment in clinical trials and may return. 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 subjects 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, which was replaced by the General Data Protection Regulation (GDPR) in 2016 (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 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 US 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.

We may be required to make significant payments under our license agreements with MD Anderson.

Under our agreements with MD Anderson associated with Annamycin, the WP1122 Portfolio and the WP1066 Portfolio, we are 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. If these milestone or other non-royalty obligations become due, we may not have sufficient funds available to meet our obligations. If we fail to meet our payment obligations, our license agreements could be terminated, which would materially and adversely affect our business operations and financial condition.

New tax laws or regulations that are enacted or existing tax laws and regulations that are interpreted, modified or applied adversely to us or our customers may have a material adverse effect on our business and financial condition.

New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us or our customers, which could adversely affect our business and financial condition. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Any future tax legislation could increase our U.S. tax expense and could have a material adverse impact on our business and financial condition.

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 $862.20 to a low of $5.07 (taking into account the reverse stock splits we have completed), 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, 2023, we had warrants and options outstanding to purchase an aggregate of 1,621,576 shares of common stock at an average exercise price of $28.65 per share (taking into account the reverse stock splits we have completed). 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 $862.20 to a low of $5.07 (taking into account the reverse stock splits we have completed). 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.

Because we are a smaller reporting company and a non-accelerated filer, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. However, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in this report and future annual reports on Form 10-K, as required by Section 404 of the Sarbanes-Oxley Act. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts.

We have in the past, and may in the future, discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. 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.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets, energy prices, and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets, energy prices, and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability. We currently source the API for our lead product candidate, Annamycin, from a supplier in Europe and increased energy prices in the region may result in increased costs to us for such API. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to operate. On March 10, 2023, the Federal Deposit Insurance Corporation, or the FDIC, took control and was appointed receiver of Silicon Valley Bank, or SVB. We have no exposure to SVB. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition.

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

On March 22, 2024, we completed a one-for-fifteen reverse stock split of our shares of common stock. The reverse stock split was effected in accordance with the authorization adopted by our stockholders at a special meeting of stockholders held in October 2023.

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.

Artificial intelligence presents risks and challenges that can impact our business, including by posing security risks to our confidential information , proprietary information and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

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.

Shareholder activism could cause material disruption to our business.

Publicly traded companies have increasingly become subject to campaigns by activist investors advocating corporate actions such as actions related to environment, social and governance (ESG) matters, among other issues. Responding to proxy contests and other actions by such activist investors or others in the future could be costly and time-consuming, disrupt our operations and divert the attention of our Board of Directors and senior management from the pursuit of our business strategies, which could adversely affect our results of operations and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have established policies and procedures for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We monitor cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that we use through third party providers that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct annual risk assessments and perform as needed updates to our risks to identify cybersecurity threats, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. We engage consultants, third parties and auditors in connection with our risk assessment processes. These service providers assist us in designing and implementing our cybersecurity policies and procedures, as well as monitoring and testing our safeguards. Personnel at all levels and departments are made aware of our cybersecurity policies through periodic training and communications.

As of December 31, 2023, and through the date of the filing of this report, we are not aware of any cybersecurity incidents that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, "Risk Factors," in this Annual report on Form 10-K.

Governance

One of the key responsibilities of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its cybersecurity risk oversight function through the audit committee, which provides oversight of our cybersecurity program as part of its periodic review of overall risk management program.

Our Chief Financial Officer and Head of IT and Cybersecurity, a consultant, are primarily responsible for assessing and managing our material risks from cybersecurity threats. In this regard, our Chief Executive Officer and Head of IT and Cybersecurity have assistance from service providers, other consultants and third parties. Our Chief Financial Officer has served as an executive officer for over twenty-five years, including over fifteen years as an executive officer of public companies. Our Head of IT and Cybersecurity has served as an information technology professional for over eight years and has held senior IT positions at multiple companies, where his primary responsibilities included maintaining direct oversight over his companies' cybersecurity risks.

Our Chief Financial Officer and Head of IT and Cybersecurity oversee our cybersecurity policies and procedures, including those described in "Risk Management and Strategy" above. Under such policies and procedures, our Chief Financial Officer and Head of IT and Cybersecurity are responsible for reporting to our audit committee regarding any cybersecurity incidents. The audit committee, in turn, provides periodic reports to our board of directors regarding our cybersecurity processes, including the results of cybersecurity risk assessments.

ITEM 2. PROPERTIES

Our corporate executive offices, laboratory and other spaces are 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 had an initial term of 66 months, which had a renewal option for an additional 5 years. In September 2023, the Company executed an amendment to extend the corporate office lease until August 31, 2029, with an option to renew. The Company is required to remit base monthly rent of approximately $4,700 which will increase at an average approximate rate of 2% 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 building.

In June 2022, we entered into a Second Amendment to our Lab Lease Agreement. The term of the Lease will continue through September 30, 2027, 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. In August 2019, we entered into a sublease (which was extended in 2022 in connection with the lease extension) 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 that we believe could have a material effect on our business, financial condition, results of operations or cash flows.

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 14, 2024, there were approximately 138 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.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the year ended December 31, 2023.

ITEM 6. [RESERVED]

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."

Our Business Summary

We are a clinical stage pharmaceutical company with a growing pipeline, including Phase 2 clinical programs for hard-to-treat cancers and viruses. We have three core technologies, each of which have had one or more drugs successfully complete a Phase 1 clinical trial, based substantially on discoveries made at and licensed from the University of Texas MD Anderson Cancer Center (MD Anderson) in Houston, Texas. Three of our six drug candidates have shown human activity in clinical trials and are currently or have been in Phase 1B/2 or Phase 2 clinical trials. Since our inception, our drugs have completed, are currently in, or have been permitted to proceed in thirteen clinical trials. Annamycin is our lead molecule and is in three Phase 1B/2 clinical trials - one for treating Acute Myeloid Leukemia (AML) and two for treating Soft Tissue Sarcoma metastasized to the lungs (STS lung metastases, STS lung mets, or Advanced STS).

One of our core management beliefs is that anthracyclines represent the most important treatment for AML and Advanced STS, and we believe Annamycin may, for the first time ever, allow a majority of these patients to benefit from this treatment. This belief leads us to currently focus mainly on the development of Annamycin.

Our Core Technologies

Our core technologies consist of the following:

a) Annamycin or L-Annamycin is a "next generation" anthracycline (one of the most common classes of chemotherapy), designed to be different than currently approved anthracyclines, which are limited in utility because of cardiotoxicity risks and their susceptibility to multidrug resistance mechanisms. Annamycin was designed to avoid multidrug resistance and to be non-cardiotoxic and has shown no cardiotoxicity in subjects treated in clinical trials to date. Furthermore, we have demonstrated safe dosing beyond the dose limitations imposed by regulatory authorities upon currently prescribed anthracyclines due to their inherent cardiotoxicity. Annamycin is demonstrating efficacy in two of its Phase 1B/2 trials as described further below in subjects with AML and Advanced STS. We believe that Annamycin has potential to fill an unmet need as a second line therapy (2nd line or 2L) in AML and potentially as first line therapy in Advanced STS.

As part of our Annamycin clinical trials, we have engaged an independent expert in assessing cardiotoxicity associated with chemotherapy at the Cleveland Clinic (Expert or Independent Expert). The data made available to the Expert includes left ventricular ejection fraction (LVEF) as determined by echocardiograms, and ECHO strain imaging, as well as Troponin levels (a biochemical marker of acute heart damage). "ECHO strain imaging" is a method in echocardiography (medical ultrasound) for measuring regional or global deformation (contraction or beating) of the myocardium (heart muscle). By strain rate imaging, the simultaneous function of different regions can be displayed and measured. Cardiac health biomarkers such as blood Troponin levels are considered an indicator of potential long-term heart damage. The Expert has issued and will continue to issue periodic reports as additional data are provided to him in batches of subject data. Such data include some data which are preliminary and subject to change. In our discussions regarding the lack of Annamycin's cardiotoxicity, we rely on the Expert's assessment .

Annamycin benefits from a promising advancement in lipid enabled drug delivery developed in collaboration with and exclusively licensed from MD Anderson. The unique patent-pending lipid composition allows us to combine a new concept in chemotherapeutic agents within a lipid structure that helps target the delivery of the payload and reduce the potential for toxicity. In the case of Annamycin, our unique use of lipid technology enables improved tissue/organ distribution and as demonstrated in multiple clinical trials, dramatically reduced toxicity, including cardiotoxicity.

b) Our WP1066 Portfolio includes, WP1066, WP1193 and WP1220, three of several Immune/Transcription Modulators in the portfolio designed to inhibit p-STAT3 (phosphorylated signal transducer and activator of transcription) among other transcription factors associated with tumor activity. These also stimulate a natural immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs). WP1066, in oral formulation, has been in two clinical trials, including compassionate use cases. WP1066 and WP1193 are being tested in preclinical programs in intravenous (IV) formulations. WP1066 and WP1220 have been in clinical trials in a topical formulation. WP1066 and WP1220 have both independently successfully completed Phase 1 clinical trials and have demonstrated efficacy as described further below.

c) Our WP1122 Portfolio contains compounds (including WP1122, WP1096, and WP1097) designed to exploit the potential uses of inhibitors of glycolysis such as 2-deoxy-D-glucose (2-DG). We believe such compounds may provide an opportunity to cut off the fuel supply of tumors by taking advantage of their high degree of dependence on glucose in comparison to healthy cells, as well as viruses that also depend upon glycolysis and glycosylation to infect and replicate. WP1122 has completed a Phase 1 clinical study, successfully establishing a Recommended Phase 2 Dose or RP2D.

Our Focus

We are focused on internally funded development of:

1) Annamycin in combination with Cytarabine (also known as Ara-C, the combination with Annamycin of which is referred to as AnnAraC) for the treatment of AML.

2) Annamycin for the treatment of STS metastasized to the lungs .

3) A better formulation for delivery of a molecule from the WP1066 portfolio to possibly further support future externally funded oncology clinical trials. Such a formulation will require additional preclinical work prior to a clinical trial.

We have established an RP2D for WP1122 to potentially enable future externally funded oncology and virology trials. Beyond this, we support development of our core technologies through several externally funded clinical trials and primarily externally funded non-clinical research, with the potential for further studies in the future.

Moleculin Biotech, Inc.
Results of Operations for the Year Ended December 31, 2023 as Compared to the Year Ended December 31, 2022

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,	
	2023	2022
Revenue	$ —	$ —
Operating expenses:		
Research and development	19,487	18,968
General and administrative	10,017	11,542
Depreciation and amortization	127	130
Total operating expense	29,631	30,640
Loss from operations	(29,631)	(30,640)
Other income:		
(Loss) gain from change in fair value of warrant liability	(1,044)	1,335
Other income, net	48	40
Interest income, net	1,368	240
Transaction costs allocated to warrant liabilities	(510)	
Net loss	$ (29,769)	$ (29,025)

Research and Development Expense

Research and development (R&D) expense was $19.5 million and $19.0 million for the years ended December 31, 2023 and 2022, respectively. The increase in R&D of $0.5 million is mainly related to the $1.5 million WPD sublicense termination, which enabled the reacquisition of our intellectual property rights in certain territories, including parts of the European Union. This was offset by $1.0 million in costs related to the timing of costs incurred for clinical trials and sponsored research.

General and Administrative Expense

General and administrative (G&A) expense was $10.0 million and $11.5 million for the years ended December 31, 2023 and 2022, respectively. The decrease in G&A of $1.5 million was mainly attributable to a decrease in regulatory and legal services, and consulting & advisory fees.

(Loss) Gain from Change in Fair Value of Warrant Liability

We recorded a loss of $1.0 million during the year ended December 31, 2023 as compared to a gain of $1.3 million, during the year ended December 31, 2022, 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, 2023 was $29.8 million, which included a non-cash loss of $1.0 million on warrants in 2023 as compared to a gain of $1.3 million in the prior year and approximately $2.0 million of stock-based compensation expense in 2023 as compared to $2.3 million in 2022.

Interest income, net

Interest income, net increased by approximately $1.1 million for the comparable period due to rising interest rates during the past year.

Liquidity and Capital Resources

As of December 31, 2023, we had cash and cash equivalents of $23.6 million and prepaid expenses and other current assets of $2.7 million. We also had $2.5 million of accounts payable and $4.3 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, 2023 and 2022, we used approximately $24.1 million and $27.6 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. The decreased cash outflows in 2023 was primarily due to an overall decrease in expenses, timing of payments, as well as license rights settled in stock. For the year ended December 31, 2023, there were $4.7 million in net proceeds from financing activities. In 2022, there were no net proceeds from financing activities. Cash used in investing activities for the years ended December 31, 2023 and 2022 was approximately$0.1 million.

We believe that our cash resources as of December 31, 2023, will be sufficient to fund our planned operations, which include our current Phase 1B/2 clinical programs and preparations for future clinical trials, into the fourth quarter of 2024, without the issuance of additional equity for cash. This takes into account cash outlays for preparations for clinical trials beyond the current active trials. The continuation of our Company as a going concern is dependent upon our ability to obtain necessary financing to continue operations and the attainment of profitable operations. We may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements and delay planned cash outlays or a combination thereof. We cannot provide assurance that such events or a combination thereof can be achieved.

In March 2022, we received a subpoena from the SEC requesting information and documents, including materials related to certain individuals (none of which are our officers or directors) and entities, and materials related to the development of and statements regarding our drug candidate for the treatment of COVID-19. We have received, and expect to continue to receive, periodic further requests from the SEC staff with respect to this matter. We are not aware of the specific nature of the underlying investigation by the SEC, and to the extent that this investigation relates to prior public disclosures that we have made, we believe in the accuracy and adequacy of such prior disclosures. The correspondence from the SEC transmitting the subpoena to us states that the SEC is trying to determine whether there have been any violations of federal securities laws, but that its investigation does not mean that the SEC has concluded that anyone has violated the law or that the SEC has a negative opinion of any person, entity, or security. We cannot predict when this matter will be resolved or what, if any, action the SEC may take following the conclusion of the investigation. During the year ended December 31, 2023 and 2022, we have expensed approximately $1.5 and $2.4 million, respectively, in related legal fees and expenses, which has impacted and may continue to impact our liquidity.

Stock Offerings

In December 2023, the Company entered into a Securities Purchase Agreement with an institutional investor and certain of the Company's executive officers, employees, advisors and a member of its board of directors for the sale by the Company of 240,151 shares (taking into account the reverse stock splits we have completed) of the Company's common stock, and pre-funded warrants to purchase 229,506 shares of common stock (taking into account the reverse stock splits we have completed) in lieu thereof in a registered direct offering. In a concurrent private placement, the Company also sold to the investors unregistered warrants to purchase up to an aggregate of 939,312 shares of common stock (taking into account the reverse stock splits we have completed). Subject to certain ownership limitations, each Common Warrant has an exercise price of $9.60 per share (taking into account the reverse stock splits we have completed), and expires five years from the date of stockholder approval of the Common Warrants (which occurred February 14,2024). Subject to certain ownership limitations, each Pre-Funded Warrant is exercisable into one share of common stock at a price per share of $0.001 (as adjusted from time to time in accordance with the terms thereof). The combined purchase price of one share of common stock (or pre-funded warrant in lieu thereof) and accompanying Common Warrant was $9.60 (taking into account the reverse stock splits we have completed) for the institutional investor, and $10.35 (taking into account the reverse stock splits we have completed) for the executive officers, employees, advisors and the member of the Company's board of directors who participated in the offering. The Company received gross proceeds of $4.5 million, before deducting the placement agent's fees and other offering expenses payable by the Company.

Lincoln Park Equity Lines

In June 2021, we entered into a Purchase Agreement with Lincoln Park Capital Fund (Lincoln Park Agreement). Pursuant to the terms of the Purchase Agreement, Lincoln Park agreed to purchase from us up to $20.0 million of common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, at the time we signed the Purchase Agreement, we issued 7,186 shares of common stock (taking into account the reverse stock splits we have completed) to Lincoln Park as an initial fee for its commitment to purchase shares of our common stock under the Purchase Agreement, and have agreed to issue Lincoln Park up to an additional 3,593 shares of common stock (taking into account the reverse stock splits we have completed) as commitment shares pro-rata when and if Lincoln Park purchases (at our discretion) the $20.0 million aggregate commitment. During the year ended December 31, 2023, utilizing the Lincoln Park Equity Line, we issued 15,038 shares of common stock (taking into account the reverse stock splits we have completed) (including commitment shares), at an average price of $14.10 per share (taking into account the reverse stock splits we have completed), resulting in gross proceeds of $0.2 million. In the December 2023 Offering, we agreed not to utilize the Lincoln Park Agreement or any such extension thereof, until after June 26, 2024.

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

	For the Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (24,101)	$ (27,639)
Net cash used in investing activities	(124)	(67)
Net cash provided by (used in) financing activities	4,651	(23)
Effect of exchange rate changes on cash and cash equivalents	(21)	(29)
Net change in cash and cash equivalents	$ (19,595)	$ (27,758)

As of December 31, 2023, there was $0.3 million of cash on hand in a bank account in Australia and we know of no related limitations impacting our liquidity in Australia.

Cash used in operating activities

Net cash used in operating activities was$24.1 million for the year ended December 31, 2023 compared to $27.6 million for the year ended December 31, 2022. This decrease in use of cash for operations was mainly due to an overall decrease in expenses, timing of payments, as well as license rights settled in stock.

Cash used in investing activities

Net cash used in investing activities was de minimis for the years ended December 31, 2023 and December 31, 2022, respectively.

Cash provided by financing activities

Net cash provided by financing activities was $4.7 million for the year ended December 31, 2023, consisting of the December 2023 stock offering, as well as shares issued utilizing the Lincoln Park Equity Line.

Off-Balance Sheet Transactions

We do not engage in off-balance sheet transactions.

Recent Accounting Pronouncements

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

Critical Accounting Policies and Significant Judgments and Estimates

The 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 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 complexjudgments, resulting fromthe 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 trials 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

We evaluate the recoverability of our 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. We evaluate the recoverability of our 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, Net Loss 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 being a public company.

Depreciation and Amortization. Depreciation and amortization 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

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, Compensation - Stock Compensation. 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. We issued warrants to purchase shares of common stock related to equity transactions in 2017, 2018, 2019, 2020, 2021, 2022, and 2023. 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, 2020, and 2023 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. Proceeds of the December 2023 Offering were allocated between common shares and warrants first by allocating proceeds to the warrants classified as a liability based on their fair value and then allocating the residual to the equity instruments, which includes the Pre-Funded Warrants.

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, February 2020, and December 2023 Offerings (Offerings) are included in long-term liabilities on the accompanying financial statements as of December 31, 2023 and 2022 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. 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. 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, 2023.

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 a "non-accelerated filer."

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, 2023. 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 control over financial reporting was effective as of December 31, 2023.

Changes in Internal Control Over Financial Reporting

There was no change in the Company's internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2023, that has materially affected, or is reasonably likely to materially affect, the Company's 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.

During the three months ended December 31, 2023, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

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 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023 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 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023 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 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023 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 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023 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 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023 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 below.

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	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 March 19, 2024)
3.5	Amended and Restated Bylaws of Moleculin Biotech., Inc. (incorporated by reference to exhibit 3.1 of the Form 8-K filed December 17, 2021)
4.1	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)
4.2	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)
4.3	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)
4.4	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)
4.5	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)
4.6	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)
4.7	Description of Registrant's Securities (incorporated by reference to Exhibit 4.10 of the Form 10-K filed March 24, 2022)
4.8	Form of Pre-Funded Warrant Agreement issued in December 2023 offering (incorporated by reference to Exhibit 4.1 of the Form 8-K filed December 21, 2023)
4.9	Form of Common Warrant Agreement issued in December 2023 offering (incorporated by reference to Exhibit 4.2 of the Form 8-K filed December 21, 2023)
10.1 **	Moleculin Biotech, Inc. Amended and Restated 2015 Stock Plan, as amended (incorporated by reference to Exhibit 4.5 of the Form S-8 file number 333-272814)
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	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)
10.8	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)
10.9	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)
10.10	Lease Agreement for 5300 Memorial (incorporated by reference to Exhibit 10.1 of the Form 10-Q filed May 14, 2018)

10.11 †	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)
10.12	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)
10.13	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)
10.14	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)
10.15	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)
10.16	Purchase Agreement dated June 25, 2021 by and between Moleculin Biotech, Inc. and Lincoln Park Capital Fund, LLC. (incorporated by reference to Exhibit 10.1 of the Form 8-K filed June 25, 2021)
10.17	Registration Rights Agreement dated June 25, 2021 by and between Moleculin Biotech, Inc. and Lincoln Park Capital Fund, LLC. (incorporated by reference to Exhibit 10.2 of the Form 8-K filed June 25, 2021)
10.18 +	Amendment No. 3 to Patent and Technology License Agreement between the Parties dated April 2, 2012, dated May 20, 2020, entered into between the Company and the Board of Regents of The University of Texas System, on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.1 of the Form 10-Q filed August 12, 2020)
10.19 +	Amendment No. 4 to Patent and Technology License Agreement between the Parties dated April 2, 2012, dated June 15, 2021, entered into between the Company and the Board of Regents of The University of Texas System, on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.4 of the Form 10-Q filed August 12, 2021)
10.20 +	Patent And Technology License Agreement dated June 29, 2017 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 10.30 of the Form 10-K filed March 24, 2022)
10.21 +	Amendment No. 1 to the Patent And Technology License Agreement dated June 29, 2017 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 10.31 of the Form 10-K filed March 24, 2022)
10.22 +	Patent And Technology License Agreement dated December 2, 2021 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 10.32 of the Form 10-K filed March 24, 2022)
10.23 +	Patent And Technology License Agreement dated December 3, 2021 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 10.33 of the Form 10-K filed March 24, 2022)
10.24 +	Patent And Technology License Agreement dated February 3, 2022 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 10.34 of the Form 10-K filed March 24, 2022)
10.25 +	Patent and Technology License Agreement dated October 21, 2022 by and between The Board 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 10.27 of the Form 10-K filed March 22, 2023)
10.26	First Amendment to Commercial Lease Agreement (incorporated by reference to Exhibit 10.1 of the Form 10-Q filed November 13, 2023)
10.27	Form of Securities Purchase Agreement from December 2023 offering (incorporated by reference to Exhibit 10.1 of the Form 8-K filed December 21, 2023)
10.28	Form of Placement Agency Agreement from December 2023 offering (incorporated by reference to Exhibit 10.2 of the Form 8-K filed December 21, 2023)
10.29	Amended and Restated Employment Agreement between Moleculin Biotech, Inc. and Walter V. Klemp dated January 4, 2024 (incorporated by reference to Exhibit 10.1 of the Form 8-K filed January 5, 2024)
10.30	Amended and Restated Employment Agreement between Moleculin Biotech, Inc. and Jonathan P. Foster dated January 4, 2024 (incorporated by reference to Exhibit 10.2 of the Form 8-K filed January 5, 2024)
10.31	Employment Agreement between Moleculin Biotech, Inc. and Donald Picker dated January 4, 2024 (incorporated by reference to Exhibit 10.3 of the Form 8-K filed January 5, 2024)

21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21 of the Form 10-K filed March 22, 2023)
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
97*	Moleculin Biotech, Inc. Restatement Recoupment Policy

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.

+ Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

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 22, 2024

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 22, 2024
/s/ Jonathan P. Foster Jonathan P. Foster	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 22, 2024
/s/ Robert George Robert George	Director	March 22, 2024
/s/ Michael Cannon Michael Cannon	Director	March 22, 2024
/s/ John Climaco John Climaco	Director	March 22, 2024
/s/ Elizabeth Cermak Elizabeth Cermak	Director	March 22, 2024
/s/ Joy Yan Joy Yan	Director	March 22, 2024

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 subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going concern
The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred an accumulated deficit of $131.6 million since inception and has not generated any revenue from operations. These conditions, along with other matters as set forth in Note 2, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding 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.

Critical audit matters
Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there were no critical audit matters.

/s/ GRANT THORNTON LLP

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

Fort Lauderdale, Florida
March 22, 2024

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

	December 31,	
	2023	**2022**
Assets		
Current Assets:		
Cash and cash equivalents	$ 23,550	$ 43,145
Prepaid expenses and other current assets	2,723	2,451
Total current assets	26,273	45,596
Furniture and equipment, net of accumulated depreciation of $896 and $769, respectively	272	275
Intangible assets	11,148	11,148
Operating lease right-of-use asset	524	403
Total Assets	$ 38,217	$ 57,422
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 2,498	$ 2,095
Accrued expenses and other current liabilities	4,317	2,724
Total current liabilities	6,815	4,819
Operating lease liability - long-term, net of current portion	474	335
Warrant liability - long-term	4,855	77
Total Liabilities	12,144	5,231
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, 2023 and December 31, 2022, 2,227,516 and 1,908,523 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	33	29
Additional paid-in capital	157,653	153,985
Accumulated other comprehensive (loss) income	(9)	12
Accumulated deficit	(131,604)	(101,835)
Total stockholders' equity	26,073	52,191
Total liabilities and stockholders' equity	$ 38,217	$ 57,422

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)

	Year Ended December 31,	
	2023	**2022**
Revenue	$ —	$ —
Operating expenses:		
Research and development	19,487	18,968
General and administrative	10,017	11,542
Depreciation and amortization	127	130
Total operating expenses	29,631	30,640
Loss from operations	(29,631)	(30,640)
Other income:		
(Loss) gain from change in fair value of warrant liability	(1,044)	1,335
Transaction costs allocated to warrant liabilities	(510)	—
Other income, net	48	40
Interest income, net	1,368	240
Net loss	$ (29,769)	$ (29,025)
Net loss per common share - basic and diluted	$ (15.07)	$ (15.22)
Weighted average common shares outstanding, basic and diluted	1,975,610	1,906,960
Comprehensive loss:		
Net loss	$ (29,769)	$ (29,025)
Other comprehensive (loss) income:		
Foreign currency translation	(21)	(29)
Comprehensive loss	$ (29,790)	$ (29,054)

See accompanying notes to these consolidated financial statements.

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

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (29,769)	$ (29,025)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	127	130
Stock-based compensation	1,984	2,275
License rights expense settled in stock	772	—
Change in fair value of warrant liability	1,044	(1,335)
Operating lease, net	119	92
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(272)	(857)
Accounts payable	403	731
Accrued expenses and other current liabilities	1,491	350
Net cash used in operating activities	(24,101)	(27,639)
Cash flows from investing activities:		
Purchase of fixed assets	(124)	(67)
Net cash used in investing activities	(124)	(67)
Cash flows from financing activities:		
Payment of tax liability for vested restricted stock units	(25)	(23)
Proceeds from sale of common stock, pre-funded and common warrants, net of issuance costs	4,166	—
Transaction costs allocated to warrant liabilities	510	—
Net cash provided by (used in) financing activities	4,651	(23)
Effect of exchange rate changes on cash and cash equivalents	(21)	(29)
Net change in cash and cash equivalents	(19,595)	(27,758)
Cash and cash equivalents, at beginning of year	43,145	70,903
Cash and cash equivalents, at end of year	$ 23,550	$ 43,145
Supplemental disclosures of cash flow information:		
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued liabilities	$ 26	$ —
Offering costs included in accounts payable and accrued liabilities	$ 115	$ —
Issuance of common stock to acquire license rights	$ 772	$ —

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		Additional Paid-In-Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Stockholders' Equity
	Shares	Par Value Amount				
Balance at December 31, 2021	1,905,223	$ 29	$ 151,733	$ (72,810)	$ 41	$ 78,993
Common stock issued upon vesting of restricted stock units (net of shares withheld for payment of tax liability)	3,300	—	(23)	—	—	(23)
Stock based compensation	—	—	2,275			2,275
Net loss	—	—	—	(29,025)	—	(29,025)
Cumulative translation adjustment	—	—	—	—	(29)	(29)
Balance at December 31, 2022	1,908,523	$ 29	$ 153,985	$ (101,835)	$ 12	$ 52,191
Issued for cash - sale of common stock, pre-funded and common warrants, net of allocated issuance costs of $57	240,151	3	728	—	—	731
Issuance of common stock with equity purchase agreement	15,038	—	210	—	—	210
Common stock issued for license rights	54,808	1	771	—	—	772
Common stock issued upon vesting of restricted stock units (net of shares withheld for payment of tax liability)	8,996	—	(25)	—	—	(25)
Stock based compensation	—	—	1,984	—	—	1,984
Net loss	—	—	—	(29,769)	—	(29,769)
Cumulative translation adjustment	—	—	—	—	(21)	(21)
Balance at December 31, 2023	2,227,516	$ 33	$ 157,653	$ (131,604)	$ (9)	$ 26,073

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 clinical programs for hard-to-treat cancers and viruses. The Company has three core technologies, each of which have had one or more drugs successfully complete a Phase 1 clinical trial, based substantially on discoveries made at and licensed from MD Anderson Cancer Center (MD Anderson) in Houston, Texas. The Company has two wholly owned subsidiaries, Moleculin Australia Pty. Ltd., which was set up to perform certain preclinical development and Moleculin Amsterdam B.V., which acts as its legal representative for clinical trials in Europe. The Company utilizes its own internal resources and funds to conduct some of these trials and also has trials being conducted via physician-sponsored trials. The physician-sponsored trials utilize primarily external funds, such as grant funds, which are not presented in these financial statements. The Company does not have manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, the Company does not have a sales organization. The Company's overall strategy is to seek potential out-licensing or outsourcing opportunities with development/commercialization strategic partners who are better suited for the marketing, sales and distribution of its drugs, if approved.

In 2019, the Company sublicensed its technologies to Animal Life Sciences, Inc. (ALI), to enable research and commercialization for non-human use and share development data. As part of this agreement, ALI issued to the Company a 10% equity interest in ALI.

On May 5, 2023, the Company received a letter from the Nasdaq Capital Market (Nasdaq) notifying the Company that for the prior 30 consecutive business days the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued inclusion on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2) (Bid Price Rule). The deficiency letter did not result in the immediate delisting of the Company's common stock from the Nasdaq. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided an initial period of 180 calendar days, until November 1, 2023, to regain compliance with the Bid Price Rule. On November 2, 2023, the Company received a 180-calendar day extension, until April 29, 2024, from the Nasdaq to regain compliance with Bid Price Rule. On October 3, 2023, the Company held a Special Meeting of Stockholders (special meeting). The Company's stockholders granted the Board of Directors the authority to effect an amendment to the Company's amended and restated certificate of incorporation to effect a reverse stock split of the outstanding shares of the Company's common stock, at a reverse stock split ratio of between 1-for-5 and 1-for-20 as determined by the Board in its sole discretion, prior to the one-year anniversary of the Special Meeting. On March 5, 2024, the Board of Directors approved a reverse 1-for-15 reverse stock split effective 11:59 P.M. (Eastern time) on March 21, 2024, with trading to commence on a split-adjusted basis on March 22, 2024.

If, at any time before April 29, 2024, the bid price for the Company's common stock closes at $1.00 or more for a minimum of 10 consecutive business days, the Nasdaq Staff will provide written notification to the Company that it complies with the Bid Price Rule, unless the Staff exercises its discretion to extend this 10 day period pursuant to Nasdaq Listing Rule 5810(c)(3)(G). If the Company does not regain compliance with the Bid Price Rule by April 29, 2024, the Nasdaq Staff will provide written notification to the Company that its common stock may be delisted. The Company would then be entitled to appeal the Nasdaq Staff's determination to a NASDAQ Listing Qualifications Panel and request a hearing. There can be no assurance that, if the Company does appeal a delisting determination by the Nasdaq Staff to the NASDAQ Listing Qualifications Panel, that such appeal would be successful. There can be no assurance that the Company will be able to regain compliance with the Bid Price Rule.

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

Reverse Stock Split - On March 22, 2024, pursuant to authority granted by our stockholders, the Company effected a one-for-fifteen 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 11:59 P.M. (Eastern time) on March 21, 2024, with trading to commence on a split-adjusted basis on March 22, 2024. The amendment provides that, at the effective time, every fifteen 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 at $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 (US GAAP), 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 subsidiaries. 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, the Company views its operations and manages its business as one segment. As a result, the financial information disclosed herein represents all of the material financial information related to its principal operating segment.

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

Going Concern and Liquidity - These consolidated financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The continuation of the Company as a going concern is dependent upon the ability of the Company to obtain necessary financing to continue operations and the attainment of profitable operations. As of December 31, 2023, the Company had an accumulated deficit of $131.6 million since inception and had not yet generated any revenues from operations. Additionally, management anticipates that its cash on hand of $23.6 million as of December 31, 2023 is not sufficient to fund its planned operations for a period of at least one year from when these consolidated financial statements are issued. These factors raise substantial doubt regarding the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company intends to seek additional funding through one or more of the following: a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements and delay planned cash outlays or a combination thereof. There can be no assurance that such events or a combination thereof can be achieved.

In March 2022, the Company received a subpoena from the SEC requesting information and documents, including materials related to certain individuals (none of which are the Company's officers or directors) and entities, and materials related to the development of and statements regarding the Company's drug candidate for the treatment of COVID-19. The Company has received, and expects to continue to receive, periodic further requests from the SEC staff with respect to this matter. The Company is not aware of the specific nature of the underlying investigation by the SEC, and to the extent that this investigation relates to prior public disclosures that it has made, the Company believes in the accuracy and adequacy of such prior disclosures. The correspondence from the SEC transmitting the subpoena to the Company states that the SEC is trying to determine whether there have been any violations of federal securities laws, but that its investigation does not mean that the SEC has concluded that anyone has violated the law or that the SEC has a negative opinion of any person, entity, or security. The Company cannot predict when this matter will be resolved or what, if any, action the SEC may take following the conclusion of the investigation. The Company expensed approximately $1.5 million and $2.4 million in related general and administrative fees and expenses for the twelve months ended December 31, 2023 and 2022 respectively, which has impacted and may continue to impact our liquidity. The Company is in the process of filing a claim with its insurance carriers related to this loss which may cover a portion of the related expenses but not all. The claim is currently under review by the insurance company. The claim has not yet been approved nor has a reimbursement amount been determined. Accordingly, the Company has not recorded any provision for insurance reimbursement as of December 31, 2023. The Company expects to record any potential insurance reimbursement at the time that the amount to be reimbursed is determined and approved by the insurance carrier.

Cash and Cash Equivalents - Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company maintains cash accounts principally at one financial institution in the US, which at times, may exceed the Federal Deposit Insurance Corporation's limit of $250,000. The Company considers all highly liquid accounts with original maturities of three months or less to be cash equivalents. The Company has not experienced any losses from cash balances in excess of the insurance limit. The Company's management does not believe the Company is exposed to significant credit risk at this time due to the financial condition of the financial institution where its cash is held. As of December 31, 2023, there was $0.3 million of cash on hand in a bank account in Australia and there is no known limitations impacting the Company's liquidity in Australia.

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

	December 31,	
	2023	**2022**
Prepaid sponsored research	$ 1,515	$ 1,028
Prepaid insurance	564	600
Vendor prepayments and deposits	545	801
Non-trade receivables	95	2
Related-party receivables	4	20
Total prepaid expenses and other current assets	$ 2,723	$ 2,451

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 improvements	Shorter of estimated useful lives or the term of the lease
Computer equipment	2
Software	3
Machinery and equipment	2 to 5
Furniture and office equipment	2 to 7

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. 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. The Company evaluates 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.

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 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.

Sublicense Arrangement - The Company has a sublicense arrangement which consists of an investment in ALI in which it does not have the ability to exercise significant influence over its operating and financial activities. Management evaluates this investment for possible impairment quarterly.

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

The Company has categorized its assets and liabilities that are valued at fair value on a recurring basis into three-level fair value hierarchy in accordance with US 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 its warrant liability discussed in Note 5.

The following table provides the financial assets and liabilities reported at fair value and measured on a recurring basis at December 31, 2023 and 2022 (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, 2023	$ 4,855	$ —	$ —	$ 4,855
December 31, 2022	$ 77	$ —	$ —	$ 77

The following table provides a summary of changes in fair value associated with the Level 3 liabilities for the years ended December 31, 2023 and 2022 (in thousands):

	Warrant Liability Long-Term
December 31, 2021	$ 1,412
Change in fair value - net	(1,335)
December 31, 2022	$ 77
Issuances of warrants	3,734
Change in fair value - net	1,044
December 31, 2023	$ 4,855

The above table of Level 3 liabilities begins with the valuation as of December 31, 2021 and adjusts the balances for changes that occurred during the years. The ending balance of the Level 3 financial instrument presented above represent the Company's 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 the Company's foreign subsidiaries is the local currency. For the Company's non-US subsidiaries that transact in a functional currency other than the US 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 the Company's foreign operations into US 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 grant date fair values. The grant date fair value of stock options and equity classified warrants are calculated 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. Compensation expense related to awards to non-employees with performance-based vesting conditions is recognized based on the grant date fair value.

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. Shares of the Company's common stock underlying pre-funded warrants are included in the calculation of basic and diluted earnings per share. 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, 2023, and 2022, approximately 0.5 million and 0.4 million (taking into account the reverse stock splits we have completed) of potentially dilutive shares were excluded from the computation of diluted loss per share due to their antidilutive effect.

Research and Development Costs - Research and development costs are expensed as incurred. These costs consist primarily of salaries and benefits of research and development personnel, costs related to research activities, preclinical studies, clinical trials, drug manufacturing and allocated overhead and facility-related expenses.

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 December 2023, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. ASU 2023-09 improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. This guidance will be effective for the annual periods beginning the year ended December 31, 2025. Early adoption is permitted. The Company is currently assessing the impact of ASU 2023-09 on its disclosures.

There are no other effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

3. Intangible Assets

In conjunction with its acquisition of Moleculin, LLC in 2016, the Company recognized an intangible asset for acquired in-process research and development (IPR&D) related to the acquired WP1066 portfolio. As the Company's 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, 2023 and 2022, respectively.

4. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities at December 31, 2023 and 2022 consist of the following components (in thousands):

	December 31,	
	2023	2022
Accrued research and development	$ 2,845	$ 1,337
Accrued payroll and bonuses	765	748
Accrued legal, regulatory, professional and other	547	437
Operating lease liability - current	100	116
Accrued liabilities due to related party	60	86
Total accrued expenses and other current liabilities	$ 4,317	$ 2,724

Additionally, accounts payable includes $67,000 and $64,000 as of December 31, 2023 and 2022, respectively, for related party payables (operating costs reimbursements).

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, Compensation - Stock Compensation. 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 are reflected as a warrant liability on the Company's consolidated balance sheet. 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 the Company's 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, 2023 and 2022, the Company has the following warrants outstanding:

	Number of Shares Under Outstanding Warrants at December 31, 2023	Number of Shares Under Outstanding Warrants at December 31, 2022	Weighted Average Exercise Price at December 31, 2023	Remaining Contractual Life at December 31, 2023 (Years)
Liability Classified Warrants (1)				
Issued February 2018	—	25,264	$ —	—
Issued June 2018 (2)	—	8,256	—	—
Issued March 2019	17,568	17,568	99.00	0.2
Issued April 2019	58,334	58,334	157.50	0.3
Issued February 2020	67,667	67,667	94.50	1.6
Issued December 2023	939,312	—	9.60	5.0
	1,082,881	177,089	$ 24.30	
Equity Classified Warrants				
Issued April 2020 - Consulting	1,112	1,112	$ 102.60	1.3
Issued December 2020 - Consulting	556	556	70.80	2.0
Issued April 2021 - Consulting	4,767	4,767	54.45	2.3
Issued August 2021 - Consulting	16,667	16,667	46.20	7.6
Issued June 2022 - Consulting	3,334	3,334	22.35	8.5
Issued September 2022 - Consulting	16,667	16,667	18.60	8.7
Issued June 2023 - Consulting	10,000	—	9.00	9.5
Issued August 2023 - Consulting	6,667	—	9.30	4.6
Issued December 2023 - Pre-Funded Warrants	229,506	—	0.001	5.0
	289,276	43,103	$ 6.00	
Balance outstanding	1,372,157	220,192	$ 23.55	

(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.

(2) Taking into account the reverse stock splits we have completed, includes warrants to purchase 7,892 shares at an exercise price of $181.80, expiring December 22, 2023, and warrants to purchase 365 shares at an exercise price of $208.80, expiring June 21, 2023.

In March 2024, the Company issued a consultant a ten-year warrant to purchase up to 3,334 shares of common stock (taking into account the reverse stock splits we have completed). The warrants vest annually over a four-year term.

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 on zero coupon US 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.

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

	Year Ended December 31,	
	2023	2022
Risk-free interest rate	3.8% to 5.4%	4.2% to 4.8%
Volatility	79.5% to 108.7%	63.1% to 76.3%
Expected life (years)	0.3 to 5.0	0.1 to 2.6
Dividend yield	—%	—%

A summary of the Company's liability classified warrant activity during the year ended December 31, 2023 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, 2022	177,089	94.500 to252.0000	$ 142.35	1.7
Granted	939,312	9.600 to9.6060	$ 9.60	5.0
Expired	(33,520)	208.800 to252.0000	$ 243.30	—
Outstanding at December 31, 2023	1,082,881	9.600 to181.8080	$ —	5.1
Vested and Exercisable at December 31, 2023	143,568	94.500 to181.8080	$ 120.60	0.9

For a summary of the changes in fair value associated with the Company's warrant liability for the years ended December 31, 2023 and 2022, see Note 2. Basis of presentation, principles of consolidation and significant accounting policies – Fair Value of Financial Instruments.

Equity Classified Warrants

In December 2023, the Company entered into a Securities Purchase Agreement with an institutional investor and certain of the Company's executive officers, employees, advisors and a member of its board of directors for the sale by the Company of 240,151 shares (taking into account the reverse stock splits we have completed) of the Company's common stock, and pre-funded warrants to purchase 229,506 shares of common stock (taking into account the reverse stock splits we have completed) in lieu thereof in a registered direct offering (Pre-Funded Warrants). In a concurrent private placement, the Company also sold to the investors unregistered warrants to purchase up to an aggregate of 939,312 shares of common stock. Subject to certain ownership limitations, each of the Common Warrants will become exercisable on the effective date of such stockholder approval as may be required by the applicable rules and regulations of the Nasdaq Stock Market with respect to issuance of all of the Common Warrants and the common stock upon the exercise thereof. Subject to certain ownership limitations, each Common Warrant will have an exercise price of $9.60 per share, expire five years from the date of stockholder approval and will become exercisable beginning on the effective date of stockholder approval for the shares issuable upon the exercise of the Common Warrants. Subject to certain ownership limitations, each Pre-Funded Warrant is exercisable into one share of common stock at a price per share of $0.001 (as adjusted from time to time in accordance with the terms thereof). The combined purchase price of one share of common stock (or pre-funded warrant in lieu thereof) and accompanying Common Warrant was $9.60 for the institutional investor, and $10.35 for the executive officers, employees, advisors and the member of the Company's board of directors who participated in the offering. The Company received gross proceeds of $4.5 million, before deducting the placement agent's fees and other offering expenses payable by the Company. Proceeds of the December 2023 Offering were allocated between common shares and warrants first by allocating proceeds to the warrants classified as a liability based on their fair value and then allocating the residual to the equity instruments, which includes the Pre-Funded Warrants. Transaction costs related to the issuance of shares were recognized in stockholder's equity (deficit), while costs of $510,000 allocated to warrant liabilities were expensed for the year ended December 31, 2023.

In August 2023, the Company granted equity-classified warrants to a consultant to purchase up to 6,667 shares (taking into account the reverse stock splits we have completed) of Company common stock with a five-year term and an exercise price of $9.30. The warrants vest based on performance of certain services. As of December 31, 2023, no related vesting criteria were met.

In June 2023, the Company granted equity-classified warrants to purchase 10,000 shares of common stock with a ten-year term and an exercise price of $9.00 vesting annually over four years while services are being performed.

In September 2022, the Company entered into a portfolio advisory agreement with a related party entity, associated with Dr. Waldemar Priebe, and in connection with the agreement, the Company granted equity-classified warrants to purchase 16,667 shares of common stock (taking into account the reverse stock splits we have completed) with a ten-year term and an exercise price of $18.60. The September 2022 warrants vest as follows: (a) 50% vests upon execution of the agreement, provided the advisor does not terminate the agreement prior to the first anniversary of the agreement; and (b) 50% vests 60 days after the end of the one-year term, subject to the Company's Board of Directors determining that the services provided have been adequately performed.

In June 2022, the Company granted equity-classified warrants to purchase 3,334 shares of common stock with a ten-year term and an exercise price of $22.35 vesting annually over four years while services are being performed.

At December 31, 2023 the Company had 289,276 equity classified warrants outstanding of which 266,350 warrants were exercisable (taking into account the reverse stock splits we have completed). At December 31, 2022, the Company had 43,103 equity classified warrants outstanding of which 26,724 were exercisable (taking into account the reverse stock splits we have completed).

The Company recorded stock compensation expense for the non-employee consulting agreements of $196,000 and $398,000 for the years ended December 31, 2023 and 2022, respectively. At December 31, 2023, there was $353,000 of unrecognized stock compensation expense related to the Company's equity-classified warrants.

6. Equity

Preferred Stock

The Company's certificate of incorporation authorizes the Company to issue these shares in one or more series, to determine the designations and the powers, preferences and relative, participating, optional or other special rights and the qualifications, limitations and restrictions thereof, including the dividend rights, conversion or exchange rights, voting rights (including the number of votes per share), redemption rights and terms, liquidation preferences, sinking fund provisions and the number of shares constituting the series. No preferred stock was issued or outstanding as of December 31, 2023.

Common Stock

2023 Stock Issuances

In December 2023, the Company entered into a Securities Purchase Agreement with an institutional investor and certain of the Company's executive officers, employees, advisors and a member of its board of directors for the sale by the Company of 240,151 shares of the Company's common stock, and pre-funded warrants to purchase 229,506 shares of common stock in lieu thereof in a registered direct offering. In a concurrent private placement, the Company also sold to the investors unregistered warrants to purchase up to an aggregate of 939,312 shares of common stock. Subject to certain ownership limitations, each of the Common Warrants will become exercisable on the effective date of such stockholder approval as may be required by the applicable rules and regulations of the Nasdaq Stock Market with respect to issuance of all of the Common Warrants and the common stock upon the exercise thereof. Subject to certain ownership limitations, each Common Warrant will have an exercise price of $9.60 per share, expire five years from the date of stockholder approval and will become exercisable beginning on the effective date of stockholder approval for the shares issuable upon the exercise of the Common Warrants. Subject to certain ownership limitations, each Pre-Funded Warrant is exercisable into one share of common stock at a price per share of $0.001 (as adjusted from time to time in accordance with the terms thereof). The combined purchase price of one share of common stock (or pre-funded warrant in lieu thereof) and accompanying Common Warrant was $9.60 for the institutional investor, and $10.35 for the executive officers, employees, advisors and the member of the Company's board of directors who participated in the offering. The Company received gross proceeds of $4.5 million, before deducting the placement agent's fees and other offering expenses payable by the Company. All figures herein are taking into account the one-for-fifteen reverse stock split completed March 22, 2024.

Lincoln Park Equity Line

During the year ended December 31, 2023, pursuant to the 2021 Lincoln Park purchase agreement, the Company issued to Lincoln Park 15,038 shares of common stock (taking into account the reverse stock splits we have completed) for gross proceeds of $0.2 million. The 2021 Lincoln Park Agreement, which has $19.8 million available as of December 31, 2023, terminates on July 1, 2024. The Company is in discussions with Lincoln Park Capital to effect the extension of this agreement. The Company intends to seek an extension of this agreement prior to termination, however no agreement has been reached through to the date that these consolidated financial statements were issued. In the December 2023 Offering, the Company agreed not to utilize the Lincoln Park Agreement or any such extension thereof, until after June 26, 2024.

2015 Stock Plan, Stock-based Compensation and Outstanding Awards

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, June 2020, May 2022, and May 2023. The expiration date of the plan is December 5, 2025. The awards under the 2015 Stock Plan can be in the form of stock options, stock awards, stock unit awards, or stock appreciation rights. In May 2023 and 2022, the 2015 Stock Plan (Plan) was amended to authorize an additional 116,667 shares and 133,334 shares, respectively, such that 366,667 total shares may be issued under the Plan. In March 2024, the Company issued 3,334 shares of common stock to a consultant. All figures herein are taking into account the one-for-fifteen reverse stock split completed March 22, 2024.

Under the terms of the Company's 2015 Stock Plan, as amended, and approved by its stockholders in May 2023, 366,667 shares of the Company's common stock (taking into account the reverse stock splits we have completed) 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, 2023, there were 3,794 shares (taking into account the reverse stock splits we have completed) remaining to be granted under the 2015 Stock Plan.

Stock-based compensation expense for the years ended December 31, 2023 and 2022 is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
General and administrative	$ 1,439	$ 1,467
Research and development	545	808
Total stock-based compensation	$ 1,984	$ 2,275

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 BSM 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 in 2020, the Company used the volatility of its own stock in the BSM as it now has sufficient historic data in its stock price. The risk-free rate for periods within the contractual life of the option is based on the US 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,	
	2023	2022
Risk-free interest rate	3.9% to 4.6%	1.6% to 3.3%
Volatility	96.0% to 101.2%	107.0% to 113.2%
Expected life (years)	5.5 to 6.3	5.3 to 6.3
Expected dividend yield	—%	—%

Stock option activity for the year ended December 31, 2023 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, 2022	151,690	$ 66.60	$ 87.45	7.8	$ —
Granted	101,400	$ 7.35	$ 9.00		
Forfeited	(3,610)	$ 9.15	$ 11.10		
Expired	(56)	$ 157.50	$ 224.10		
Outstanding, December 31, 2023	249,424	$ 43.35	$ 56.70	7.9	$ 378,606
Exercisable, December 31, 2023	93,337	$ 88.65	$ 119.40	6.1	$ —

Options granted during 2023 and 2022 have an aggregated grant date fair value of $0.7 million and $1.1 million, respectively, that was calculated using the Black-Scholes option-pricing model. At December 31, 2023, total compensation cost not yet recognized was $1.9 million and the weighted average period over which this amount is expected to be recognized is 2.3 years. The aggregate fair value of options vested was $1.3 million and $1.5 million in the years ended December 31, 2023 and 2022, respectively.

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, 2023 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (years)
Unvested Shares, December 31, 2022	40,499	$ 33.60	3.1
Granted	65,292	$ 9.00	
Vested	(11,901)	$ 41.55	
Unvested Shares, December 31, 2023	93,890	$ 15.45	7.3

As of December 31, 2023, total compensation cost not yet recognized was $1.2 million and the weighted average period over which this amount is expected to be recognized is 2.7 years. In June 2023, the Company granted 65,292 shares of restricted stock units with a weighted average fair value of $9.00 per share at the date of grant (taking into account the reverse stock splits we have completed), which vest annually in four installments. In June 2022, the Company granted 30,156 shares of restricted stock units with a weighted average fair value of $22.35 per share (taking into account the reverse stock splits we have completed) at the date of grant, which vest annually in four equal installments.

In December 2023, the Company granted to the Company's executive officers 73,334 performance-based restricted stock units (taking into account the reverse stock splits we have completed) (PSU). Each PSU will vest upon both (A) the approval of a plan amendment by the Company's stockholders; and (B) the first of the following to occur: (a) a licensing transaction with a valuation, at the time, in excess of $150 million, which valuation shall be determined by the Board; (b) the filing of a new drug application; or (c) upon a Change in Control (as defined in the Plan), in each case subject to the respective executive officer's continued service with the Company as of each such vesting date. Recognition of stock-based compensation expense associated with these performance-based stock options commences when the performance condition is considered probable of achievement, using management's best estimates, which consider the inherent risk and uncertainty regarding the future outcomes of the milestones. As of the date of issuance and through December 31, 2023, none of the performance goals were deemed probable, and as a result, no expense was recognized for these performance-based vesting awards.

7. Income Taxes

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

	Year Ended December 31,	
	2023	2022
Current expense (benefit):		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Current income tax benefit	—	—
Deferred expense (benefit):		
Federal	—	—
State	—	—
Foreign	—	—
Deferred income tax expense	—	—
Total	$ —	$ —

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

	Year Ended December 31,	
	2023	2022
Valuation allowance at beginning of period	$ 25,696	$ 18,823
Change charged to expense (income)	6,612	6,873
Release of valuation allowance	—	—
Valuation allowance at end of period	$ 32,308	$ 25,696

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,			
	2023		2022	
	Amount	Percent	Amount	Percent
Federal tax benefit at statutory rate	$ 6,251	21.0%	$ 6,096	21.0%
State tax benefit net of federal	118	0.4%	347	1.2%
Foreign rate differential	59	0.2%	10	0.0%
Stock warrant costs	(219)	(0.8)%	280	1.0%
Other permanent differences	(73)	(0.2)%	(145)	(0.5)%
Permanent provision to return items	662	2.3%	395	1.4%
Stock compensation change	(82)	(0.3)%	(49)	(0.2)%
Uncertain tax provision	(103)	(0.4)%	(61)	(0.2)%
Increase in valuation allowance	(6,613)	(22.2)%	(6,873)	(23.7)%
Total tax (expense) benefit	$ —	—%	$ —	—%

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

	Year Ended December 31,	
	2023	2022
Deferred tax assets:		
Start-up costs	$ 9,621	$ 7,727
Federal net operating loss carryforwards	11,598	11,024
174 R&D Carryforward	6,636	3,572
State tax loss carryforwards	258	237
Foreign net operating loss carryforwards	377	161
Fixed Assets	9	—
Tax credit carryforward	1,919	1,335
ROU Liability	123	96
Deferred compensation	1,879	1,630
Total deferred tax assets	$ 32,420	$ 25,782
Less valuation allowance	(32,308)	(25,696)
Net deferred tax assets	$ 112	$ 86
Deferred tax liabilities:		
ROU Asset	$ (112)	$ (86)
Total deferred tax liabilities	$ (112)	$ (86)
Net deferred taxes	$ —	$ —

The Company has incurred net operating losses since inception. As of December 31, 2023, the Company had total US federal operating loss carry forwards of approximately $52 million. Of this, $6.1 million will expire commencing in 2035, with the rest having no set expiration date. The value of these carryforwards depends on the Company's ability to generate taxable income. Additionally, because federal tax laws limit the time during which the net operating loss carryforwards may be applied against future taxes, if the Company fails to generate taxable income prior to the expiration dates of the carry forwards the Company may not be able to fully utilize the net operating loss carryforwards to reduce future income taxes. Under the new tax laws, net operating loss carry forwards will not expire beginning for losses generated in the 2018 tax year. However, these net operating losses will only be able to offset 80% of future taxable income. Finally, the Company has not undertaken a detailed analysis of the application of IRC Section 382 with respect to limitations on the utilization of net operating loss carryforwards and other deferred tax assets. However, the Company believes that this matter is not material to the overall tax position within the financial statements due to the full valuation allowance against the net operating losses and the lack of utilization of the net operating losses during tax years open under statute.

The Company conducts business in various locations and, as a result, files income tax returns in the United States federal jurisdiction, in multiple state jurisdictions, and internationally as required. As of December 31, 2023, the Company had state operating losses of approximately $2.7 million which expire commencing in 2036. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the US 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, 2023. A valuation allowance of $32.3 million and $25.7 million has been established at December 31, 2023 and 2022, respectively. The change in the valuation allowance for the year ended December 31, 2023 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 US federal R&D tax credits. For the 2023 tax year, there may be a potential Australian research and development tax credit, as the Company is increasing research and development activities in Australia. The Company estimates the amount of cash refund it expects to receive related to the Australian research and development tax incentive program and records the incentives when it is probable that 1) the Company will comply with relevant conditions of the program and 2) there is reasonable assurance the claim will be recovered. During the years ended December 31, 2023 and 2022, respectively, the Company has not recorded the Australian tax incentive as it is not yet probable that the terms and claim will be recovered. The federal research credits will begin to expire in the years 2037 through 2041, if not utilized.

The Company has a liability for unrecognized tax benefits of $0.3 million (excluding accrued interest and penalties) as of December 31, 2023. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

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

	Year Ended December 31,	
	2023	2022
Balance, beginning of year	$ 236	$ 175
Additions for tax positions related to the current year	103	—
Additions for tax positions related to prior years	—	61
Reductions due to lapse of statutes of limitations	—	—
Decreases related to settlements with tax authorities	—	—
Balance, end of year	$ 339	$ 236

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, 2023 within the next year.

Starting in 2022, changes to Internal Revenue Code Section 174 made by the Tax Cuts and Jobs Act of 2017 no longer permit an immediate deduction for research and development expenditures in the tax year that such costs are incurred. As a result the Company capitalized such costs in its 2023 and 2022 income tax provision, resulting in an increase in deferred tax assets.

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 for the years ended December 31, 2023, and December 31, 2022, respectively.

Lease Obligations Payable

In September 2023, the Company executed an amendment to extend the corporate office lease until August 31, 2029, with an option to renew. The Company is required to remit base monthly rent of approximately $4,700 which will increase at an average approximate rate of 2% 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 building. The leased space is located in Houston, Texas. The corporate office lease is classified as an operating lease.

In June 2022, the Company entered into a Second Amendment to its Lease Agreement (Lab Lease) which it uses for lab space. The term of the Lease will continue through September 30, 2027, 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 (which was extended in 2022 in connection with the lease extension) 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 $49,000 and $45,000 in sublease income from the related party for the years ended December 31, 2023 and December 31, 2022, respectively. Sublease income is recorded as other income on the Company's consolidated statement of operations and comprehensive loss.

The following summarizes quantitative information about the Company's operating leases for the years ended December 31, 2023, and December 31, 2022, respectively (in thousands):

	Year Ended December 31,	
	2023	2022
Lease cost:		
Operating lease cost	$ 137	$ 124
Variable lease cost	19	29
Total	$ 156	$ 153

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

	Year Ended December 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 134	$ 129

As of December 31, 2023, 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, 2023
2024	$ 146
2025	159
2026	164
2027	141
2028	61
2029 and thereafter	41
Total lease payments	712
Less: imputed interest	(138)
Present value of operating lease liabilities	$ 574

As of December 31, 2023, the weighted average remaining lease term for operating leases is 4.6 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, for the submission of an NDA to the FDA and for the receipt of marketing approval for sale of a license product can cost 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 $258,000 and $264,000, respectively, for the years ended December 31, 2023 and 2022.

Annamycin

On June 29, 2017, the Company entered into a Patent and Technology License Agreement with MD Anderson licensing certain technology related to the method of preparing Liposomal Annamycin and on December 17, 2021 the Company entered into an amendment to this agreement to include certain technology related to the method of reconstituting Liposomal Annamycin. On December 2, 2021, the Company entered into a Patent and Technology License Agreement with MD Anderson licensing certain technology related to lung targeted therapies with Annamycin. The terms and payments of these agreements are included in the summary above under Commitments and Contingencies – Licenses – MD Anderson. The terms of these agreements extend until the later of 20 years from the effective date of the agreements, or the expiration of the last-to-expire licensed patent. In addition, commencing on the four-year anniversary of each agreement, MD Anderson has the right to remove any jurisdiction from such agreement, upon 90 days' notice, if the Company has not commercialized or is not using commercially reasonable efforts actively and effectively to attempt to commercialize a licensed invention in such jurisdiction.

WP1122 Portfolio

The rights and obligations to an April 2012 Patent and Technology License Agreement entered into by and between IntertechBio and MD Anderson (2012 Agreement) have been assigned to MBI. Therefore, MBI has obtained a royalty-bearing, worldwide, exclusive license to intellectual property, including patent rights, related to its WP1122 Portfolio and to its drug product candidate, WP1122. On October 21, 2022, the Company entered into a new patent and technology license agreement (2022 Agreement) with MD Anderson for an additional molecule under the WP1122 Portfolio. On December 3, 2021, the Company entered into a new patent and technology license agreement (2021 Agreement) with MD Anderson licensing certain technology related to WP1122 anti-viral treatments. The 2012 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. On August 3, 2021, the Company filed a CTA for the application of WP1122 in the United Kingdom to commence a Phase 1a clinical trial of WP1122. MD Anderson agreed that this CTA filing would further extend the deadline to file an IND with the FDA for a Phase I study until February 2022. In December 2021, the Company submitted an IND for the treatment of GBM with WP1122 to the FDA, thus meeting the IND filing milestone. The term of the 2012 agreement extends until the later of 15 years from the effective date of the agreement, or the expiration of the last-to-expire licensed patent. In addition, MD Anderson may terminate the 2012 agreement if the Company fails to commence a Phase 2 study for licensed product prior to November 20, 2024. The term of the 2021 agreement extends until the later of 20 years from the effective date of the agreement, or the expiration of the last-to-expire licensed patent.

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 (2010 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. On February 3, 2022, the Company entered into a new patent and technology license agreement (2022 Agreement) with MD Anderson licensing certain technology related to WP1066 checkpoint inhibitors. In January 2024 the Company notified MD Anderson that it was terminating this license. In consideration for these agreements, 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 under the 2010 Agreement. 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 term of the 2010 Agreement extends until the later of 15 years from the effective date of the agreement, or the expiration of the last-to-expire licensed patent.

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). Upon payment of the option repurchase payment in 2019, the HPI Out-Licensing Agreement was terminated and 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. The Company has two current agreements with HPI. The first agreement, which was renewed in May 2022, continues a prior consulting arrangement with HPI and requires payments for $43,500 per quarter. 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. Total expenses related to HPI were $234,000 for the years ended December 31, 2023 and 2022.

Sponsored Research Agreements with MD Anderson

MBI has a Sponsored Laboratory Study Agreement with MD Anderson expiring December 31, 2025. In October 2023, the Company entered into an amendment to the Sponsored Research Agreement with MD Anderson for total payments to MD Anderson of $0.8 million to support the continuation of the project. In addition, the Company also has Sponsored Research Agreements with other universities, one in the US and one in Europe. The expenses recognized under the agreements were $775,000 and $1,133,000, respectively for the years ended December 31, 2023 and 2022.

Other Licenses

WPD Pharmaceuticals

Since February 2019, the Company was party to a sublicense agreement with WPD Pharmaceuticals (WPD), pursuant to which it sublicensed to WPD certain intellectual property rights, including rights to Annamycin, its WP1122 portfolio, and its WP1066 portfolio (as amended, WPD Agreement). WPD is affiliated with Dr. Waldemar Priebe, the Company's founder. 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 March 2023, the Company and WPD agreed to terminate the WPD Agreement. Pursuant to the termination, the Company agreed to pay WPD (or its designees) $700,000 in cash and shares of its common stock valued at $800,000. In connection with the termination, WPD agreed to assign all of its rights and obligations related to the Phase 1b/2 clinical trial of Annamycin for the treatment of STS lung metastases being conducted at Maria Sklodowska-Curie National Research Institute.

With the termination of the WPD Agreement, the Company now holds the worldwide rights to all of its licensed intellectual property, other than the rights related to non-human animals.

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 (ALI Agreement). ALI is affiliated with Dr. Waldemar Priebe, one of its founders. 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.

Other Guarantees

Bank Guarantee and Letter of Credit

In December 2023, the Company entered into a letter of credit with its primary banking relationship in the US, or bank guarantee, in the amount of $0.2 million, in connection to a value-added tax (VAT) registration in Poland. To date, there have been no draws or claims against this bank guarantee.

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 $5.5 million using the rate of compensation in effect at December 31, 2023.

9. Subsequent Events

Subsequent events occurring after December 31, 2023 are discussed elsewhere in these notes.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 22, 2024, with respect to the consolidated financial statements included in the Annual Report of Moleculin Biotech, Inc. on Form 10-K for the year ended December 31, 2023. We consent to the incorporation by reference of said report in the Registration Statements of Moleculin Biotech, Inc. on Form S-1 (File No. 333-276851), on Forms S-3 (File No. 333-219434, File No. 333-252676, File No. 333-235686 and File No. 333-256627) and on Forms S-8 (File No. 333-212619, File No. 333-225867, File No. 333-248240, File No. 333-266225 and File No. 333-272814).

/s/ GRANT THORNTON LLP
Fort Lauderdale, Florida
March 22, 2024

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 22, 2024

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 22, 2024

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K for the fiscal year ended December 31, 2023 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 22, 2024

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 ended December 31, 2023 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 22, 2024

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.

Moleculin Biotech, Inc.
Dodd-Frank Restatement Recoupment Policy

1. Introduction

The Board of Directors (the "Board") of Moleculin Biotech, Inc. (the "Company") has determined that it is in the best interests of the Company to adopt a policy providing for the recoupment by the Company of certain Incentive-Based Compensation paid to Executives Officers in the case of a Restatement (as defined below) (the "Policy"). In such case, the Company (a) may recoup the Incentive-Based Compensation that was paid or that vested and (b) may cancel any outstanding or unearned Incentive-Based Compensation.

2. Definitions

For purposes of this Policy, the following terms shall have the meanings set forth below:

"Committee" means the Compensation Committee of the Board of Directors of the Company.

"Erroneously Awarded Compensation" means the amount of Incentive-Based Compensation received that exceeds the amount of Incentive-Based Compensation that otherwise would have been received had it been determined based on the restated amounts resulting from a Restatement, and it must be computed without regard to any taxes paid. For Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Restatement: (a) the amount must be based on a reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received; and (b) the Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to the Nasdaq Stock Market.

"Executive Officer" means any employee of the Company who is currently, or within the period covered by this Policy, employed as the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a significant policy-making function, or any other person who performs similar significant policy-making functions for the Company, including Executive Officers of the Company's subsidiaries if they perform such policy making functions for the Company, and shall include each executive officer as determined under Item 401(b) of Regulation S-K.

"Financial Reporting Measures" mean those measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the Securities and Exchange Commission.

"Incentive-Based Compensation" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure. For purposes of this Policy, Incentive-Based Compensation is deemed received in the Company's fiscal period during which the Financial Reporting Measure specified in the award is attained, even if the payment or grant occurs after the end of that period.

"Non-Employee Board" means the members of the Board who are not employed by the Company or any affiliate thereof.

"Recoupment Rules" means Rule 10D-1 under the Securities Exchange Act of 1934 and Rule 5608 of the Nasdaq Stock Market.

"Restatement" means an accounting restatement required to be prepared by the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. The date of a Restatement shall be the earlier to occur of: (a) the date the Company's board of directors, a committee of the board of directors, or the officer or officers of the Company authorized to take such action if board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement; or (b) the date a court, regulator, or other legally authorized body directs the Company to prepare a Restatement. The Company's obligation to recover Erroneously Awarded Compensation is not dependent on if or when restated financial statements are filed.

3. Administration of this Policy

This Policy shall be administered by the Committee. The Committee shall have full power and authority to construe and interpret this Policy, and to recommend to the Non-Employee Board its determinations as to whether recoupment is required under the Policy, the amount of Incentive-Based Compensation to recoup from an Executive Officer and whether any other action should be taken pursuant to Section 6 of the Policy. Upon the approval of the Committee's recommendations by a majority of the members of the Non-Employee Board (even if less than a quorum), the final decision shall be binding and conclusive on all parties.

4. Recoupment of Incentive Compensation

In the event that the Company is required to prepare a Restatement, the Company must recover reasonably promptly the Erroneously Awarded Compensation received by a person (a) after beginning service as an Executive Officer, (b) who served as an Executive Officer at any time during the performance period for that Incentive-Based Compensation, and (c) during the recovery period described in Section 5 below. Recovery is subject only to those exceptions set forth in the Recoupment Rules.

The Committee can recommend that the Non-Employee Board recoup from the Executive Officer all or a portion of the following in order to satisfy the Executive Officer's recoupment obligation:

Cash Incentive Plan: The Committee can recommend that the Non-Employee Board (i) cancel and forfeit the Executive Officer's annual or other cash incentive opportunity for the then current plan year, and/or (ii) require repayment of any annual or other cash incentive awards previously paid for prior years within the period described in Section 5.

Stock Plan: The Committee can recommend that the Non-Employee Board (i) cancel and forfeit any outstanding equity awards under its stock-based plans, (ii) require the Executive Officer to return a number of shares of Company stock received upon vesting and settlement of any restricted stock and restricted stock unit awards during the period described in Section 5 (or pay the cash value of such shares), and (iii) require the Executive Officer to return a number of shares received upon the exercise of any stock options during the period described in Section 5 (or pay the cash value of such shares). The cash value shall be determined as of the date of the Committee's demand for recoupment.

The Committee can also recommend that the Non-Employee Board recoup similar compensation under any subsequently adopted plans, arrangements or agreements, or compensation under any severance arrangements or any non-qualified deferred compensation arrangements.

5. Limitation on Period for Recoupment

In the event that the Company is required to prepare a Restatement, the Company must recover Erroneously Awarded Compensation received by Executive Officers during the three completed fiscal years immediately preceding the date that the Company is required to prepare a Restatement, and any transition period (that results from a change in the Company's fiscal year) of less than nine months within or immediately following those three completed fiscal years.

6. No Impairment of Other Remedies

This Policy shall not preclude the Committee from recommending that the Non-Employee Board take any other action to enforce an Executive Officer's obligation to the Company, including termination of employment, institution of civil proceedings, or action to effect criminal proceedings.

7. Miscellaneous

Notwithstanding the foregoing, to the extent any provision of applicable law, including the Recoupment Rules, requires non-discretionary recoupment or would result in a larger recoupment than permitted under this Policy, the provision of such applicable law shall supersede the relevant provisions of this Policy.

8. Effective Date

This Policy shall apply to all Incentive Compensation paid, awarded or granted on or after October 2, 2023.

Policy Acknowledgment and Consent

I hereby acknowledge that I have been designated an Executive Officer, I acknowledge and agree to the terms of this Policy, I agree to fully cooperate with the Company in connection with the enforcement of the Policy, including the repayment by or recovery from me of Erroneously Awarded Compensation, and I agree that the Company may enforce its rights under the Policy through any and all reasonable means permitted under applicable law as the Company deems necessary or appropriate under the Policy.

_____

Printed Name:_____ Date:_____